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Efficacy of a Preparation Intervention for the Management of Children's Pain and Fear during Needle Procedures: Help from a Robot Named MEDi®

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Efficacy of a Preparation Intervention for the Management of Children's Pain and Fear during Needle Procedures: Help from a Robot Named MEDi®

by

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Abstract

An intravenous (IV) line is required for most children receiving anesthetics prior to undergoing surgery. An IV may be established while a patient is awake or following induction of anesthesia using volatile anesthetics. IV inductions are often well-tolerated; however, despite the existing strategies that can provide evidence-based comfort for needle pain, many children still experience discomfort when an IV line is placed in the operating room (OR). In particular, IV inductions can be a distressing experience for a considerable number of children who require general anesthesia in the OR. Thus, given the wide acceptance of technology with children, a prospective study explored the effectiveness of a humanoid robot (MEDi®) programmed to deliver cognitive-behavioral strategies and teach deep breathing techniques that can be used during IV induction.

In this randomized, controlled, two-armed trial, children were randomly assigned to obtain induction according to standard protocol, or with preparation from MEDi® prior to induction. Surgical patients (n = 137) ages 4-12 years were recruited from a major Western pediatric hospital. Needle pain and fear ratings were collected from children, parents, pediatric anesthesiologists, and researchers. Follow-up interviews were conducted to assess the recall of pain-related memories.

Results indicate that pain and fear scores during IV placement were not significantly different between the robot intervention and standard care, and scores did not change over time both within and between study groups (*p*s > 0.05). However, several children did find the robot-facilitated preparation to be an enjoyable experience. After interacting with MEDi®, patients did show increased use of preparation strategies in the OR (Fisher's exact test (1) = 4.66, $p < 0.05$, Cramer's *phi* = 0.21). Children who received MEDi® were also more likely to complete the IV

induction procedure (thus not require the inhalation anesthesia to have the IV line secured), compared to standard care, Fisher's exact test (1) = 4.85, $p < 0.05$, Cramer's *phi* = 0.22). Of those who received pre-operative coaching, some children remembered the IV induction positively and one-third of participants were able to recall meeting MEDi® at the follow-up. This study was the first to examine how a robot can assist patients in learning strategies to cope with IV induction and suggests that it may help them tolerate IV procedures.

(350 words)

Preface

Chapter Five: Manuscript #1

Title: Efficacy of MEDi® preparation to manage children's pain and fear during IV induction: a randomized-controlled trial

Authors: Rachelle C.W. Lee, Jacqueline R. Pearson, Adam Spencer, Melanie Noel, Lisa Bell-Graham, Tanya N. Beran

All authors contributed in research design, manuscript reviewing, and ensuring the integrity of this work. Rachelle C.W. Lee was involved with data collection, analysis, and interpretation of findings, and drafted this manuscript.

Contribution of Authors

Dr. Tanya Beran – Academic supervisor, primary investigator, coauthor on written manuscript, content expertise (medical education, psychology, and statistics), project conceptualization, overall project quality, data analysis, and review and editing of thesis and manuscript.

Jacqueline Pearson – Supervisory committee member, coauthor on written manuscript, project conceptualization, content expertise (child life), methods implementation, research administration and training, results interpretation, review and editing of thesis and manuscript.

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Dr. Melanie Noel – Coauthor on written manuscript, project conceptualization, content expert (child psychology and pain memory), review and editing of manuscript.

Lisa Bell-Graham – Coauthor on written manuscript, project conceptualization, methods implementation, research administration and training, review and editing of manuscript.

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and always being there when I need to chat. Especially to my fiancé, your unconditional love always keeps me grounded to be my true self – as we continue to walk our journeys together.

Dedication

I would like to dedicate this thesis to those families, who have volunteered their time and help for supporting this study. I would also like to dedicate this thesis to the Alberta Health Services providers, their investment with the resources have been critical in making this clinical trial possible. Their generosity for research has allowed us to pilot and implement this coaching intervention in a new clinical setting at the Alberta Children's Hospital. I hope findings from this study will provide insights for novel pain management strategies for future surgery patients and help children cope with distressing medical procedures using the MEDi® robot.

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CHAPTER ONE: INTRODUCTION

This opening chapter introduces the relevance of a clinical study in pediatric pain management. The purpose for examining a novel teaching preparation for managing distress during IV induction is summarized here, followed by the research questions that guide the organization of this thesis.

1.1 Relevance of Needle Procedures in Pediatric Pain

Needle procedures continue to be a frequent source of pain and distress for children [10,22]. Children experience pain for multiple reasons in the healthcare setting; short painful procedures to help with diagnosis and treatment are one of the most prevalent [137]. In 2014, the World Health Organization recommended that by the age of six years, children receive up to 30 vaccinations against 12-20 diseases. In addition, healthy children may receive finger pricks and venous access as part of regular healthcare, and children with medical conditions may receive other painful diagnostic or therapeutic procedures [33]. A study conducted in eight Canadian pediatric hospitals revealed that 78.2% of patients had undergone at least one painful procedure within a 24-hour period, with only 28.3% having received one or more pain management interventions [137]. Pain in children is stressful for the child, family and caregivers; and consequently, the effects of under-treatment can be negative and long-lasting [22,33,40,121]. Increased hospital stay, longer recovery times, and endurance of preventable suffering are undesirable patient outcomes associated with pain and may be perceived as worse than the original injury or illness [146].

Among needle procedures, peripheral intravenous (IV) cannulation is performed to allow for the safe infusion of medications, hydration fluids, blood products, and nutritional supplements. Pediatric patients presenting for surgery require an IV line for many purposes: 1) to

maintain general anesthesia and sedation, 2) to provide analgesic, antiemetic and antibiotic medications, 3) to offer the means of resuscitation in the event of anesthetic or surgical complications, and 4) for their postoperative care [29,61]. Prior to surgery, the pediatric anesthesiologist can choose to insert an IV line following these approaches: 1) general anesthesia is induced with the use of a volatile anesthetic delivered by mask and an IV line is inserted (inhalational induction), or 2) an IV line is placed when patients are still awake and it is then used to administer parenteral anesthetics for general anesthesia (IV induction). Unless considered to be unsafe, pediatric anesthesiologists have traditionally used an inhalational induction technique prior to IV insertion. Although the inhalation route is a safe method to induce anesthesia, the use of a breathing mask may not be well-tolerated by many children regardless of flavor, parental presence, or distractions [79,102,154]. Prolongation of induction time may occur for children with difficulties following breathing instructions, who push the mask away or become combative, and breath hold due to the pungent odor of volatile anesthetics [138]. With such considerations, pediatric anesthesiologists may choose to conduct the IV insertion while the child is awake rather than under sedation. In some occasions when there are medical advantages, it is also now preferential for pediatric anesthesiologists to follow the IV induction approach. That is, for patients who fear an inhalational mask induction or those at high risk of complications associated with the use of volatile anesthetics (e.g., patient or family history of malignant hyperthermia, emergence delirium/agitation, diagnosis of muscular dystrophy), IV induction is the recommended option to induce anesthesia. [38,57,103]. Although emergence delirium/agitation appear as brief and self-limited events during recovery, a significant proportion of these children suffer negative postoperative behaviors (e.g., thrashing behaviors, night terrors) that may influence their responses to future medical procedures [123]. However,

establishing IV access in an awake pediatric patient in the operating room (OR) can be challenging especially in toddlers and young children, in children who are not adequately prepared, or in those with a fear of needle or painful medical procedures [145].

Needle procedures are frequently painful and distressing for both children and parents. Since pain is a subjective expression of an unpleasant sensation or emotional experience, it is difficult for parents to know the extent of pain their children are enduring. That is, "pain is what the patient says it is, and exists when [one] says it does" [95]. While parents and patients may make a similar assessment about the degree of pain, adult caregivers also play a crucial role in how children react to medical procedures. Parental factors (i.e., pain catastrophizing, self-efficacy) can influence the individual traits or states that dictate how a child's pain behavior is expressed [119]. Considerable research has studied the factor of parental presence during procedures, with mixed results in children's responses to pain and fear [18]. Perhaps parents' level of anxiety or specific child-parent interactions are relevant [41]. For instance, parent's distress-promoting behaviors or emotions are likely to increase the child's anxiety towards venipunctures [122]. Thus, a combination of parent factors can predispose or perpetuate children's distressful feelings during needle procedures.

The influence of cognitive and social developmental factors on pain perception can also drive the formation and expression of pain memories. The encounter of a stressful medical event, such as needle procedures, can form lasting impressions on how children and parents deal with future procedures. Pain memories are related to how somatosensory events are perceived by an individual, either at the time of the painful event or as a consequence of ongoing pain [131]. Similar to memories of non-distressing events, the process of remembering pain-related memories is an interpretative process that can be distorted over time [118]. In other words, the

recollection of episodic memories is not an exact reproduction of past experience; rather, it is an imperfect, adaptive process that is error-prone due to imagination inflation or post-event misinformation [128]. Emerging research has suggested that children's pain memories are a possible predictor of subsequent pain experiences in acute procedural settings [108,109]. Hence, the interplay of these attributes should be considered when implementing strategies to manage pediatric pain. As research in needle pain management is improving, our understanding about the complexity of the experience of pediatric pain continues to advance. Much work is still needed to translate this knowledge into practical applications that can help children tolerate painful needle procedures.

1.2 Robotics in Healthcare

Social robots in healthcare have become increasingly prevalent [74]. In 2012, the U.S. Food and Drug Administration approved the first robot to be navigated in a hospital environment for doctors to communicate with a patient through a tablet (*Remote Presence System, Model RP-VTATM 870.2910*). Other innovations of artificial intelligence have been developed to dispense medication, or deliver food and supplies in hospitals (e.g., ScriptPro, AZO Robotics). Outside of the hospital setting, social robots can serve as a therapeutic tool to provide comfort and assistance for seniors living in residential homes [49]. Given the wide acceptance of technology with children, the use of robotic applications in pain management has become an emerging field of study. Prior to the development of MEDi®, the application of robotics had not been explored in terms of pediatric pain management. Beran et al. (2011) launched the initial study on the use of humanoid robotics to help children learn coping strategies in mitigating needle-related distress [73,117]. To date, the efficacy of MEDi® in delivering a preparation to children receiving IV inductions prior to surgery has yet to be tested. This is the first randomized-controlled trial

conducted to evaluate the efficacy of MEDi® preparation for IV induction in the OR. This brief intervention facilitated by MEDi® is a form of technology-enhanced pre-operative education that was implemented just before surgery.

Despite the abundance of evidence-based pain management strategies (e.g., pharmacological, psychological) currently available to comfort distressed patients, many still encounter challenges with managing needle pain or fear during the IV induction. Thus, this study investigated the impact of a pre-operative educational intervention delivered by the MEDi® robot, which was introduced to patients on the day of their surgery. It was developed to engage children and their parents in a series of coaching activities to help them relax and cope with stressful needle procedures in the OR. Delivered alongside with standard care, the goal of using MEDi® was to provide families the opportunity to learn cognitive-behavioral strategies that patients can utilize at the time of induction.

1.3 Study Aims

The primary aim of this study was to understand children's pain and fear of an IV insertion after interacting with a humanoid robot (MEDi®) in comparison to children's experiences without this interaction. Secondary outcomes examined were use of breathing strategies during the needle procedure, overall completion of IV induction, and the formation of pain-related memories.

1.4 Research Questions

In this randomized controlled, two-armed clinical trial, the following research questions were addressed:

1. Do children who interact with MEDi® report lower levels of needle pain and fear, compared to patients in the standard care group? Are observers also likely to report lower levels of needle pain and fear?
2. Are IV inductions more likely to be completed (without the need of the mask) with children who interact with MEDi®, compared to patients who receive standard care? Is the former group likely to use the techniques taught by MEDi® during the IV needle procedure?
3. Do parents who interact with MEDi® along with their children report higher self-efficacy to manage patients' pain and fear, compared to standard care? Is there also an observable difference or change in parental self-efficacy before and after this interaction?
4. Do parents and their children consider that education from MEDi® prevents the development of negative pain memories about the surgical experience?

1.5 Thesis Outline

This thesis is organized in a sequential manner to reflect the process undertaken to implement the MEDi® robot preparation before surgery, followed by the reporting of study results to determine its effectiveness. Chapter Two presents a literature review of pediatric pain and current management strategies available to mitigate needle-related distress. In this chapter, information regarding the complexity of pediatric pain and factors that can influence the perception of procedural pain are presented. Additionally, this review describes how altered memories of needles can be influenced by children's perceptions of procedural-related distress. This chapter also highlights the current research gap and the intent of using MEDi® as a novel intervention to manage needle pain during IV inductions. Chapter Three provides an overview of the research design, including patient recruitment, study protocol, data collection, and data

analysis methods undertaken. Chapter Four describes the results of this clinical study in detail (including supplementary results not included in the manuscript). Chapter Five consists of the primary manuscript for this thesis, presenting the evidence for using the MEDi® robot to help children manage needle pain and fear. Finally, Chapter Six concludes with a discussion on the implications of these research findings, strengths and limitations relevant to this study, and concluding remarks.

CHAPTER TWO: LITERATURE REVIEW

This chapter provides an overview of selected research on pediatric pain and factors associated with pain management. Current strategies utilized to mitigate needle pain, and studies regarding robotic technology for pain management are also presented. This chapter will provide the context for exploring the use of MEDi® to help children cope with IV induction, and examine whether this intervention affects children's and parents' pain-related memories about needle procedures. Finally, the chapter concludes with the overarching aim and research questions addressed in this thesis.

2.1 Definition of Pain

Pediatric pain is a multidimensional experience. According to the International Association for the Study of Pain, pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage" [70]. Every individual learns the application of words to express discomfort through their experiences related to injury in early life [70]. In addition to patients' exposure to needle procedures or painful events, other factors may also contribute to the subjective experience of pain. Over the last few decades, our understanding of pediatric pain has increased. The experience of pain for a child is complex and is usually accompanied by anxiety, fear and behavioural changes. As physiological explanations cannot fully account for the impact of pain on children's behavior, researchers have taken a biopsychosocial approach to understand its complexities.

2.2 Biopsychosocial Perspective on Pain

In understanding the complexity of procedural pain in children, the Young model presents a combination of biological, cognitive, and psychological factors that may contribute to the experience of pain [156]. These characteristics may also explain why the perception of pain

is specific to the individual, and its quality, intensity, duration can vary along with the ability to control it [23,132]. Unique from other biopsychosocial models for pediatric pain, this theoretical model contextualizes procedural-related pain as occurring within three main phases: 1) pre-procedure, 2) procedure, and 3) post-procedure [156].

While acute pain occurs within a distinct timeframe, the perception of pain is substantially influenced by pre-procedure factors, including biological predispositions to pain receptor density and endogenous opioids. Pain channelopathies associated with mutations in SCN9A have been reported with individuals that lack the ability to sense pain [37]. Conversely, other pain channelopathies that result in hypersensitivity to nociceptive triggers (e.g., erythromelalgia, paroxysmal extreme pain disorder, familial episodic pain disorder) are linked to mutations in Na_v 1.7 and TRPA1 channel proteins [152]. Based on the gate control theory, the Young model illustrates the role of patient and system-specific factors in nociceptive pain processing and how our responses can be altered at the sensory, affective, and physiological levels [156].

During the procedural stage, the Young model posits that an individual's pain attitudes and coping skills determine the level of cognitive control and descending inhibition exerted on the substantia gelatinosa pain “gate”. Consequently, post-gate impulses can activate the pain action system, resulting in pain sensation. Several psychological factors have been considered ‘reactions to pain’ and are integral to the processing of pain-related information [98]. For example, the mindset that children bring to the procedure can be attributable to their memories of past pain, anticipatory fear or anxiety, and temperament. The experience of pain for children is often apparent in behavioral changes, fear, or anxiety associated with medical procedures [127]. Accordingly, children who retain overwhelming and frightening thoughts of past pain events

may expect to re-experience negative emotions, and have low frustration tolerance. They are at risk for experiencing high levels of pain. As the manifestation of anxiety can be closely connected to pain, accurate assessments and effective management of pediatric pain can be challenging [39].

Although pain may not be psychological in origin, how we respond to a pain stimulus is always psychological. The Young model postulates that a specific feedback mechanism can be developed in response to procedural pain; thereby, the long-term effects of pain and distress can affect the individual's cognitive and coping abilities in subsequent pain experiences. Indeed, recent studies suggest that patient and parent memories of medical procedures can influence their responses to future procedures [100,109,111]. As a result, pain is often associated with heightened levels of distress and anxiety during needle procedures, which can result in negative health outcomes if left untreated [14].

A major criticism of the Young model is that it does not acknowledge the role that parents have in their children's procedural pain experience [124]. Recent studies have shown that the interactions of parents and healthcare providers with children can influence their behavior in response to needle pain [24,113]. During the procedure stage, adult providers can facilitate encouraging statements or distractions to help children manage needle pain. Furthermore, the effect of social modelling suggests that adults act as models for children's behavior. In particular, parents' self-efficacy or sense of self-competence to cope with challenging circumstances may affect how their children react to adversities [5]. Those parents who report high levels of self-efficacy also tend to display reduced anxiety or self-doubt, and consequently, exhibit greater ability to cope with their child's pain [44]. Conversely, if parents exhibit overly distressing expressions toward pain, children can display a response with heightened pain or anxiety [17].

Likewise, distress-promoting behaviors exhibited by health professionals were also related to both children's and parents' distress behaviors [88]. As shown in Mahoney et al. (2010), non-procedural reassurance and humour are frequent verbal behaviors that parents and health professionals tend to utilize. In addition, health professionals are able to provide coping strategies and control to children during venipunctures. In the following section, a detailed review further explains the current research regarding the engagement of adult caregivers in pediatric pain management. This understanding suggests that regimens should consist of medical treatments to manage pain, along with strategies that can help children deal with their negative beliefs and thoughts about pain [45].

2.3 Factors Related to Pediatric Pain Management

The interaction of child, parent, health professional, and environmental factors can lead to the onset and maintenance of distress [122]. Racine et al. (2016) have proposed a framework outlining factors that can influence children's anticipatory distress for medical procedures; among them, predisposing, precipitating, perpetuating, and present factors.

Previous research has suggested that children's age, sex, and temperament are possible predisposing contributors to their perceived pain [122]. The role of children's age and their developmental level has been shown in many studies to be associated with pain experiences [55,69,92,136]. Between the ages of 2 to 7 years, children perceive their world concretely in terms of what they are able to touch, see or manipulate. That is, children at this prelogical age will find it difficult to believe that a needle will help them feel better. The ability for children to recognize the influence of pain and rate the intensity of pain usually begins around the preschool age [136]. By the age of 7 to 9 years, their concrete logical thinking allows them to understand the relationship between pain and disease symptoms [136]. However, children at this stage have

yet to develop the ability to clearly understand the cause of pain. As children progress into adolescence (i.e., 11 years or older), they acquire the capacity to formulate logical explanations about the physiological mechanisms of health and disease. Contrary to young children, adolescents tend to minimize or deny pain when their peers or parents are present during pain assessments [135]. Although the understanding of pain is parallel to their cognitive development, children's level of thinking may regress to an earlier stage when under stress [92]. Hence, concerns with overestimating or underestimating children's ability to cope with pain are common.

Precipitating factors are also implicated whereby past needle or pain events can lead to the onset of anticipatory distress to future medical procedures [75,93]. In terms of perpetuating factors, parent distress behaviors, anticipation of distress, and anxious predisposition can heighten children's perceived pain [38,109,154,155]. Collectively, these suggestions show that parental self-efficacy to manage children's distress is key to help them cope with pain; thereby, influencing their ability to carry out needle procedures even when in pain. Hence, these perpetuating factors are likely to maintain the child's distress both before and during the needle procedure. At the time of the medical procedure, present factors (i.e., healthcare provider's behaviors, induction location) are contextual variables that may positively or negatively affect children's distress and reaction to procedural pain [88]. For example, children induced in a low sensory stimulating environment appear less anxious during post-operative recovery than brightly-lit OR settings [76]. In sum, factors such as children's age, parent's anxiety, and previous pain experiences must be considered when testing the efficacy of targeted interventions.

2.3.1 Parental Pain Catastrophizing

Parents of hospitalized children can report feelings of anxiety, fear, guilt, a sense of lack of control, and distress [83]. Furthermore, high levels of parental anxiety prior to children's surgery are likely to be associated with high levels of children's anxiety [75]. Parent distress-promoting behaviors, such as reassurance, have been shown to be predictors of less optimal coping outcomes in children [24]. According to retrospective studies, modeling and information sharing of negative hospital experiences are modes of fear acquisition [107,118]; thereby, heightened pain perception can contribute to anticipatory distress and the formation of negative pain memories [108]. In addition, one multi-site longitudinal study indicates that parent pain catastrophizing scores may predict children's pain at 12 months after surgery [113]. Thus, this risk factor may be critical for the development of chronic postsurgical pain. As suggested in Rabbitts et al. (2013), there is a significant subgroup of children who followed a trajectory pattern characterized with late recovery from pain, which was already distinct at two weeks after surgery and with parent pain catastrophizing as a predictor for pain recovery. Furthermore, those children were likely to experience poorer patient-reported health and functional outcomes at 12 months, compared to the early recovery group with progressively reduced pain shortly post-surgery [121]. Hence, such individual cognitive factors may be implicated in the development of exaggerated negative memories about pain. Together, these results suggest that parents are affected by their children's pain experience; and, at the same time, parents may also influence their children's response to needle pain. However, another study from Birnie et al. (2017) suggested that baseline child and parent pain catastrophizing did not predict children's pain during a 24-hour follow-up period after surgery [11]. These mixed findings may be due to discrepancies in research methodologies (i.e., different procedures examined, varied timing of

assessment for pain and distress), or differences in children's age and their clinical diagnosis [10,91,135]. Thus, it is important to continue to study this factor.

2.3.1 Health Professional Interactions

Health professionals who administer venipunctures are also implicated in children's perception of pain. In addition, parents' satisfaction towards the care that children received stems from their expectations that healthcare providers should manage patients' pain. Given their crucial role during painful medical procedures, negative or distress-promoting behaviors exhibited by health professionals are associated with high child anticipatory distress [88]. On the contrary, positive behaviors may include strategies that reduce distress and worry for parents and children, and these are associated with reductions in children's self-reported pain and fear. Furthermore, the demeanour of healthcare providers as calm adults and their ability to deliver clear, confident instructions may increase the effectiveness of pain management [34]. In what can be an overwhelming context, they can also encourage anxious parents and help them feel empowered to engage in coping-promoting behaviors, along with ways to avoid distress-promoting behaviors. That is, parents can assist or coordinate with healthcare professionals, when circumstances permit, to facilitate pain management interventions. For example, excessive restraint when administering a needle may increase the child's distress. Hence, attempts to place children in a comfortable position can positively influence how they perceive procedural experiences (i.e., ensuring children are held by the parent in the sitting position) [142]. Additionally, reassuring children that the needle procedure will not be painful may increase their feelings of fear. Rather, healthcare providers can consider providing tactile stimulation, such as gently rubbing or stroking the skin near the site of venipuncture [142]. Depending on the needs

of the patient and clinical setting, healthcare providers are strongly recommended to plan and provide comfort management before, during, and after a medical procedure [40,141].

To address the complexity of pediatric pain, several pain management interventions for needle procedures have been investigated. Seeking ways to decrease pediatric pain is an ongoing challenge that healthcare professionals encounter in the delivery of safe medical care. However, current research suggests that there are limited pain management strategies shown to be consistently effective in helping patients reduce pain during venipunctures [39].

2.4 Evaluation of Current Pain Management Strategies

Several pharmacological and non-pharmacological approaches can be used in the clinical setting to help minimize pain experienced during needle procedures [39,102]. In 2015, the Canadian Medical Association Journal published an update regarding the clinical practice guideline on recommendations to reduce pain in children during needle injections using the 5P approach [141]. It categorizes interventions for pain mitigation during venipunctures into five domains: procedural, physical, pharmacological, psychological, and process. According to clinical guidelines for pediatric pain management, the adoption of appropriate and effective interventions when performing skin-breaking procedures are strongly recommended [141]. Relevant to the present study are the pharmacological and psychological domains discussed next.

2.4.1 Pharmacological Interventions

Ongoing efforts have been dedicated to system-wide protocols to ensure the access and administration of local topical anesthetics for needle pain management [81]. Studies have shown that amethocaine applied for IV cannulations is more effective with a quicker effect than eutectic mixtures of local anesthesia (EMLA) [78]. Other topical applications such as vapocoolant sprays have been evaluated, and results are shown to be less effective than topical numbing cream

during IV cannulations [36,42]. The use of a sedative premedication prior to induction of anesthesia is another form of pharmacological intervention in pediatric pain care. Sedative premedications (e.g., midazolam, clonidine, ketamine) can help prepare pediatric patients for a smooth induction of anesthesia and allow for easier parent-child separation before the surgery [21]. In addition, premedications can also serve as anxiolytic agents, which may decrease children's anxiety that is associated with adverse events from various medical problems such as congenital heart disease and developmental conditions [21]. However, disadvantages with using sedative premedications include the risk of respiratory depression, the need for increased perioperative monitoring, and delayed hospital discharge due to persistent post-operative sedation [4].

Notwithstanding these efforts, evidence for a pharmacological strategy to consistently reduce pain during IV procedures is lacking because children continue to report procedural-related distress due to limited effectiveness of topical anesthetics [36,78,81,103]. As a result, this suffering of avoidable pain is mandated by the Children's Rights Charters of several countries – that is, those who experience persisting pain or acute pain from elective procedures should adhere to improved analgesic treatments [31,32]. With multimodal approaches, topical anesthetics are recommended for administration in combination with non-pharmacological strategies for reducing pain and distress [13,47,153]. Best practices in multimodal or "opioid-sparing" analgesia can utilize a combination of polypharmacy, procedural interventions, rehabilitation, and psychological therapies that act in a synergistic manner to provide more effective pediatric pain control, compared to one modality of analgesia [54]. Thus, the gold standard of care for pain management should consider the use of different evidence-based safe treatments appropriate for the patient.

2.4.2 Nonpharmacological Interventions

In the recent decade, much attention has been devoted to the education around non-pharmacological interventions (i.e., psychological, physical) in conjunction to pharmacological aids [25,84,142]. Given that isolated use of pharmacological interventions is often inadequate in pain reduction, the use of psychological therapies has gained acceptance in practice. They are, moreover, considered noninvasive and easy to deliver. Evidence for distractions, breathing techniques, and cognitive behavioral strategies have been found to help reduce needle-related procedural pain and distress in children [10]. Certified child life specialists, who facilitate hospital-wide support for families to use non-pharmacological techniques, have improved patients' experience with venous access procedures [81]. Through a combination of therapeutic play, preparation, and educational opportunities, they provide psychosocial supports to help children cope with medical procedures and reduce the stress that families may encounter with hospital experiences. Research has also shown that the combined use of pharmacological and psychological strategies may buffer children from developing negative memories of distress regarding the procedure [33]. Hence, non-pharmacological treatments are emerging as a favored adjunct to pharmacotherapy. There is some evidence that distraction and cognitive-behavioral therapy (CBT) can be efficacious in situations when pharmacotherapy might not be possible (i.e., time restraints, drug allergies) [10].

Cognitive-Behavioral Therapy (CBT)

Several non-pharmacological interventions draw from both cognitive and behavioral schools of thought; thus, both approaches are often used in combination to target thoughts and behaviors. One form of psychological therapy is cognitive-behavioral therapy (CBT), which is a problem-oriented strategy that focuses on identifying and changing current distressing thought

and behavioral patterns [56]. The goal of CBT is to help individuals develop skills to improve their self-efficacy and sense of control to cope with external stressors.

CBT is a widely-used approach for treating clinical conditions such as chronic pain and fatigue, anxiety disorders, and somatoform disorders [68]. Referring to a class of interventions that target maladaptive cognitions that contribute to the maintenance of emotional distress and behavioral problems, CBT is an established treatment that demonstrates pain reduction in children undergoing IV cannulation for diagnostic testing or chemotherapy [63,151]. The goal of these techniques is to help children learn coping skills to overcome distress [120]. Among non-pharmacological approaches that can be facilitated by a trained health professional, cognitive-behavioral strategies that involve imagery, relaxation or self-regulation can also provide pain relief independently or in combination with other pain management modalities [129]. Previously observed to be effective in other clinical settings, it is possible that CBT may work with patients in the OR. While research into the best management of children's pain is improving, the evidence to support an intervention that is consistently effective in reducing pain is lacking. For this reason, children, families, and medical providers continue to seek interventions that are effective and can be utilized by healthcare personnel in a variety of situations. In particular, IV inductions can be a distressing experience for a considerable number of children who require general anesthesia in the OR. In the following sections, a new application that can provide additional support to these patients is described.

MEDi® - A Technology-Enhanced Teaching Preparation

The use of technology-enhanced modalities to deliver psychological therapy is an emerging field in pediatric pain management. Conventionally, children are coached by parents or healthcare providers to use CBT-based strategies that can help them cope with a medical

procedure. With children's growing interest in and propensity for electronic devices, different forms of advanced technology have been explored for procedural-related support during a needle procedure. Alongside with pharmacological treatments, internet-based programs for delivering CBT to assist children in developing coping behaviors for different chronic pain conditions have also been studied [115]. In 2015, a clinical trial was conducted in the emergency department to examine the use of iPad distraction to manage the pain and fear of IV cannulation [1]. A recent study conducted by Rodriguez et al. (2019) also revealed that the screen size of electronic video devices did not reduce children's fear or improve their compliance with induction procedures. However, no significant reductions in child-reported pain or behavioral distress were observed with the use of technology-enhanced distraction therapy. Previously, research has also evaluated the effectiveness of virtual reality (VR) in acute pain management (i.e., burn care, cancer pain, routine medical procedures) [84]. Therapies with VR fully immerse the patient into a 'virtual world' using a combination of technology, including a head-mounted display with an integrated head tracking system, headphones with sound and noise reduction, and/or devices for users to manipulate within the virtual setting [85]. In clinical settings, children immersed in VR experience reduced levels of pain and request its use during other medical procedures [58]. Additionally, in the 2018 Cochrane review, evidence for VR devices were considered a novel form of effective distraction to consider when managing pediatric acute pain from needle procedures. For IV procedures (e.g., subcutaneous venous port devices), previous studies have investigated the use of VR as a distraction for pediatric patients when the needle was administered, and few have reported reliable findings in reduced self-reported needle pain despite having a VR experience during the procedure [12,106]. Gold et al. (2009) indicated that children in the control group experienced a four-fold increase in pain before and after the IV

placement, whereas no significant change in scores was found in the VR group. Of major concern is that nausea, headache, drowsiness, and postural instability symptoms have also been reported with this intervention [6]. Thus, other methods of technology-enhanced psychological therapies should also aim to be highly engaging while ensuring they do not elicit physical discomfort.

In terms of acute procedural pain, MEDi® is another technology-enhanced aid that has been evaluated for pediatric pain management. MEDi® is the first humanoid robot developed to deliver coaching preparations that are tailored to the medical procedure pediatric patients are receiving [7,117]. This 2-foot tall humanoid robot (NAO® robot produced by Softbank Robotics) has two hands with self-adaptive gripping abilities, force sensitive sensors on its arms and feet to perceive contact with objects, light emission diodes in its eyes and body, four microphones to identify sounds, and two loud speakers for communication. Using a computer tablet to initiate its actions, this function enables MEDi® to execute a series of commands for all participants in various situations such as before, during, and after procedures. Hence, MEDi® is able to provide children with both procedural-specific programmes and patient-specific interactions based on children's reaction to the robot. Programmed with CBT strategies to use evidence-based distraction and teach coping behaviors, MEDi® can deliver relaxation training with a combination of deep breathing exercises, distractions, preparation, and coaching to learn these adaptive strategies [15,20]. Recent studies have shown that this innovation can effectively help children cope with venipunctures [8]. Children who interacted with MEDi® were found to experience significantly less pain and distress during flu vaccinations, compared to those who had not interacted with the robot [7]. Other positive outcomes were that children with the robot

and their parents reacted more positively during the needle procedure than children and their parents in standard care [8].

Currently, efforts are devoted to implement the use of MEDi® in several pediatric hospital clinics in Canada, United States, and Australia. Recent studies have further suggested that the MEDi® robot was acceptable to pediatric cancer patients, who reported reduced levels of distress during subcutaneous port needle insertions [73]. Novel implementation of MEDi® in the blood clinic waiting room was also found to be acceptable and appropriate with parents and patients [26]. Reasons including the need for intervention and comparison to other distraction techniques were identified as facilitators for introducing MEDi® into clinical care. Beyond the clinical environment, public engagement initiatives via social media have increased awareness and interest towards the novel use of social robots in pediatric care [26]. Due to its ease of operation and versatility for children of all ages, MEDi® offers a promising intervention for pain management, and education for patients about health during wait times [8]. To our knowledge, this thesis describes the first study to investigate its use in helping children learn to cope specifically with IV induction, a procedure frequently performed in the OR.

2.5 Technologically Enhanced Devices for Pediatric Pain

Given the increasing demand for integrated use of technology in healthcare, "techno-psychological" approaches may potentially support pediatric patients receiving elective surgery who require invasive needle procedures. In the first study conducted with MEDi®, observations revealed that children smiled more often when encountering venipunctures with, as compared to without, MEDi® [8]. Parents have also commented on a faster recovery from the vaccination and the sense of strength in children's comments when reflecting on the needle experience [7]. Children and parents have, furthermore, expressed interest to have MEDi® involved with future

needle procedures [7]. Parents indicated that their children developed stronger memories for MEDi® than for the needle and felt more empowered to cope with vaccines [8]. As a pain coach, humanoid robots can be designed to use cognitive-behavioral, distraction, and coaching strategies that can be used to support children during needle procedures. Hence, we propose that this intervention may also be efficacious with pediatric patients undergoing IV induction. Findings from such research may provide clinicians and parents with useful information about effective coping strategies that may help pediatric patients manage pain when receiving IV inductions. A preparation delivered by MEDi® is also expected to inform parents about how they can support their children, leading to parental self-efficacy, low anxiety, and positive pain memories [109]. Thus, this clinical study sought to explore the effectiveness of MEDi®, a humanoid robot programmed to deliver cognitive-behavioral strategies and teach breathing techniques that can be used during IV procedures. Specifically, it examines whether children who receive preparation with MEDi® exhibit more effective pain management during IV induction than children with standard care.

2.6 Research Aim

As stated in the previous review, extensive research has been conducted to understand the complexity of pediatric pain and how we currently manage procedural-related discomfort. However, there continues to be a lack of supporting evidence for an effective intervention that can help children manage needle pain and fear in the OR. Hence, the aim of this research is to examine the efficacy of MEDi®, a novel robot-facilitated intervention for pediatric surgery patients receiving IV inductions. To achieve this goal, the research questions addressed are as follows:

Question #1: Do children who interact with MEDi® report lower levels of needle pain and fear compared to patients in the standard care group? Are observers also likely to report lower levels of needle pain and fear?

Pediatric patients who interact with MEDi® are expected to experience lower levels of pain and fear, compared to children in standard care. If children report high levels of pain, observers may also report high levels of procedural pain and fear.

Question #2: Are IV inductions more likely to be completed (without the need of the mask) with children who interact with MEDi®, compared to patients who receive standard care? Is the former group likely to use the techniques taught by MEDi® during the IV needle procedure?

Pediatric patients who interact with MEDi® are expected to be more cooperative with IV insertion and IV induction, and less likely to convert to a mask inhalational induction, compared to standard care. Furthermore, children who receive standard care are likely to require more attempts to secure the IV placement and more likely to convert to mask induction using volatile anesthetic due to the failed attempt(s) of IV line placement. Children who learned cognitive-behavioral techniques from MEDi® may use those strategies (i.e., deep breathing skills, encouragement) more frequently during the needle procedure, compared to those in standard care.

Question #3: Do parents who interact with MEDi® along with their children report higher self-efficacy to manage patients' pain and fear, compared to standard care? Is there also an observable difference in parental self-efficacy before and after this interaction?

Parents in the MEDi® intervention are expected to express greater self-efficacy to manage their children's pain and fear in future IV procedures, compared to those in the standard care group.

Question #4: Do parents and their children perceive that preparation from MEDi® prevents the development of negative pain memories about the surgical experience?

Compared to children in standard care, patients in the MEDi® group may recall fewer negative pain memories about the IV induction, and express lower levels of recall and anticipatory pain or fear about IV procedures.

CHAPTER THREE: METHODS

This chapter provides an overview of the study design and methodological steps taken to investigate the use of the MEDi® robot for IV induction preparation. It also includes a summary regarding the methods followed for data acquisition and analyses performed to evaluate intervention outcomes.

3.1 Study Design

This study was a collaborative effort between Alberta Children's Hospital and the University of Calgary Cumming School of Medicine. The study team consisted of research leads from the Department of Community Health Sciences, child life, pediatric anesthesiology, and short stay surgery. The study adhered to methodological standards for reporting randomized controlled trials (RCTs) according to the Consolidated Standard of Reporting Trials (CONSORT) guidelines [19]. Conducted as an RCT with two groups, study recruitment occurred from 2016-2018. All consented participants were randomized to receive either the preparation intervention delivered by MEDi® or standard care in receiving IV induction. Patients were not randomly selected; rather, eligible participants were recruited when patients arrived at their scheduled date for surgery. Enrolled patients were then randomized to receive either the preparation delivered by MEDi® or standard care. Two-weeks after the surgery, follow-up interviews were conducted with children and their parents to assess the recall of pain-related memories.

3.2 Study Participants

An *a priori* sample size calculation was performed using G*Power Version 3.1 [51]. A total of 110 children was determined to be sufficient to detect a clinically and statistically significant difference with a small to moderate effect (difference of 2.0, which is equivalent to

the difference of one face on the Faces Pain Scale-Revised (FPS-R)). This sample size calculation is based on power of 0.80 and alpha-level of 0.05 for a two-tailed test [50].

The inclusion criteria for eligible participants included pediatric patients between the ages of 4-12 years with a legal guardian or parent who has the ability to both understand and communicate in English. Patients must have been scheduled for elective surgery, required general anesthesia, and met expectations for physical fitness according to the American Society of Anesthesiology class I and II criteria. The exclusion criteria were the following: 1) patients receiving IV placement outside the OR, 2) patients who were cognitively unable to self-report pain, 3) patients with a hearing/visual impairment or developmental disability that impedes self-reporting ability, 4) families or patients with a language barrier, 5) patients with medication allergies to propofol or lidocaine, 6) families that requested inhalational anesthesia or this method was selected by the pediatric anesthesiologist, and 7) patients receiving a sedative premedication before the surgery. According to the protocol for IV induction, the listed medications were administered by pediatric anesthesiologists to induce general anesthesia. Thus, patients who were at risk of adverse side effects to these medications were excluded from the study. In cases when children were found to have one or more of the exclusion criteria after enrolment, data from these patients were not included in subsequent analyses and they did/did not participate in all of the research activities.

An overview for the flow of participants through different stages of the study is depicted in a CONSORT diagram (see **Figure 1**). During the pre-procedural phase, 137 patients were assessed for eligibility and enrolled into the study. A total of 103 children, who were randomly assigned to either the robot (22 male, 23 female) or standard care condition (35 male, 23 female), had completed their allocated condition. In the procedural phase, all children would attempt to

receive an IV induction in the OR; and in cases when this procedure was not completed, patients would be put under sedation via breathing mask for inhalational induction. A response rate of 47% was calculated for the follow-up interviews (i.e., proportion of patients who received their allocated treatment and completed the memory recall interview). A detailed breakdown of patients that could not be reached during this post-procedural phase is also indicated in the flow diagram. Although not all patients completed the two-week memory interview, data collected from all patients in the intervention or standard care groups were reported in the results.

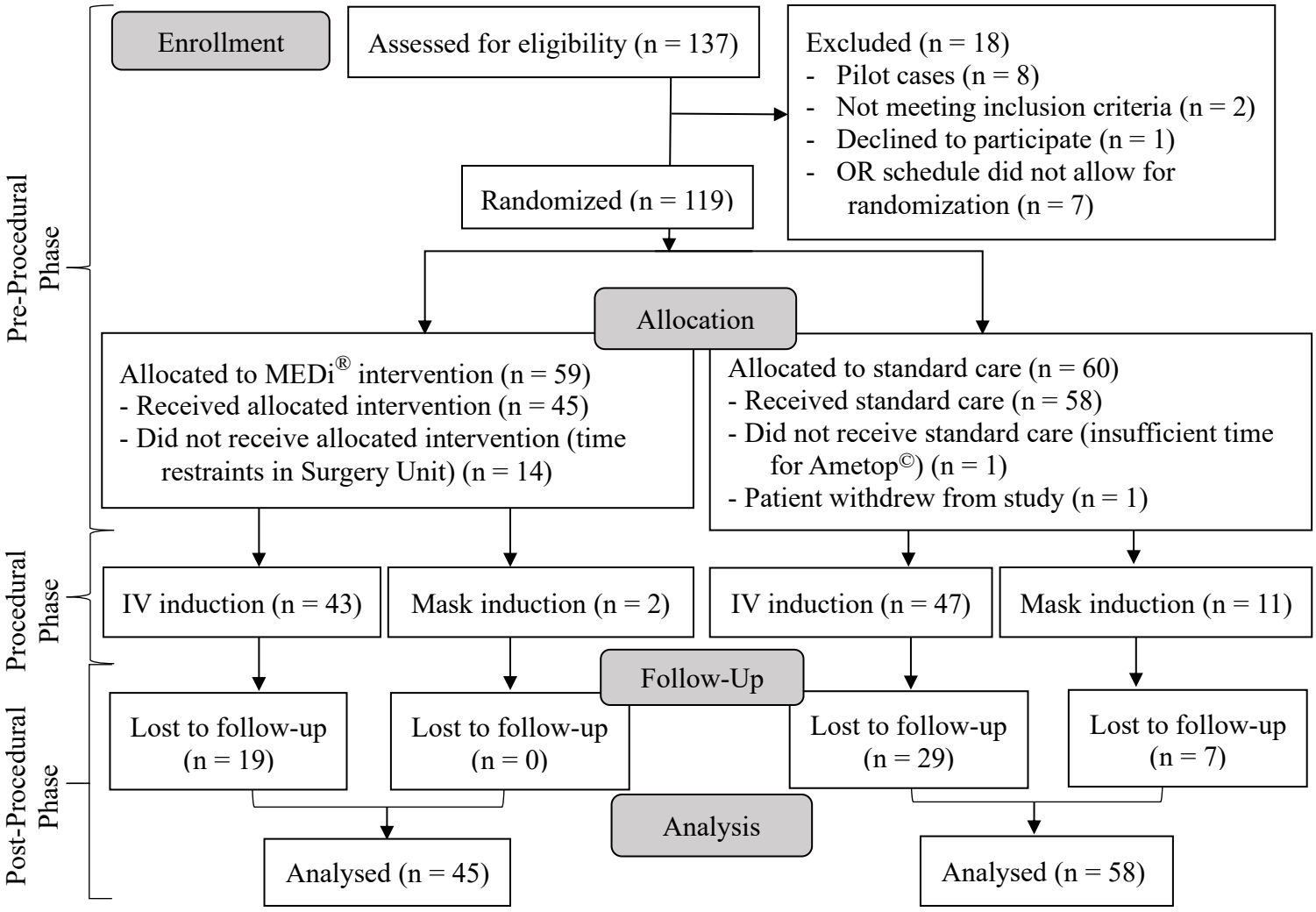

Figure 1. CONSORT flow diagram.

3.3 Study Procedures

3.3.1 Pilot Study

The study procedures were piloted with eight patients to test feasibility in the Surgical Short Stay Unit (SSSU). Feedback from the medical staff and research team informed the study adjustments to 1) prevent interference with daily operations in the SSSU, 2) optimize the research process to efficiently collect patient information and self-reported ratings, and 3) establish an approach to securely store research data. Prior to launching the study, information about the finalized protocol was provided to clinical staff in the SSSU, including nurses and attending pediatric anesthesiologists. Specific teaching was provided to research assistants (RAs) regarding how to introduce the study to families, and how to obtain informed consent and assent from eligible participants.

3.3.2 Pre-Procedural Phase

Enrollment

Children receiving surgical procedures with an IV placement were approached by nurses and RAs in the SSSU, and recruited as study participants. The initial screening process was performed by short stay surgery nurses. That is, they reviewed the patients' clinical information to verify that the inclusion criteria were met, and no exclusion criteria were present. Once eligible families provided permission to the nurse to be contacted, the research team approached them to introduce the study and seek informed consent (see Appendix B). Families or patients not interested in participating were not approached by the RAs. Eligible patients could also decline to give consent in the SSSU or withdraw consent to continue the enrolment at any point of the study. However, the number of patients not approached for consent were not tallied. To reduce selection bias inherent in non-random sampling, we attempted to enroll subjects

consecutively during hours when RAs were available. However, eligible patients may not have been approached by the RAs who were involved with the enrolment of another patient. The mean time required to complete the recruitment phase was 105 minutes (minimum = 40 minutes, maximum = 314 minutes), beginning with the time when RAs approached families for informed consent and ending with the time when RAs left families after data collection in the OR.

Several steps were followed next upon obtaining consent. Once notified about the patient's participation in the study, the pediatric anesthesiologist then prepared the instruments and weight-based anesthetic agents required for the IV induction. Once informed consent was obtained, all patients received the topical local anesthetic Ametop©, which was applied to the dorsum of the hands by nurses at least 30-45 minutes prior to the scheduled OR time. The scheduled surgery time was also documented to estimate when Ametop© should be applied in the SSSU. RAs also assisted in completing the data collection questionnaire in the SSSU for each participant. Information on patient demographics was collected, including age, ethnicity, sex, duration of study intervention, pre-operative pain management strategies used, or support resources accessed (see Appendix C). Baseline ratings for patients' anticipatory fear were collected from both parents and children in the SSSU. Additionally, levels of parental self-efficacy and anxiety were recorded. At this time, families were also asked to schedule a follow-up telephone interview. Families were given a take-home package and asked to open it during this later interview. It consisted of the rating scales that would be used when answering interview questions. Upon completion of these steps, RAs then proceeded to the study's randomization phase.

The randomization to study arm was determined by a random sequence allocation for each patient using Research Randomizer©. The alpha-numeric code for randomization was

secured in an opaque envelope, opened by one RA after consent and pre-intervention measures were completed. The RA then administered the intervention or standard care procedure. To minimize observer effects, the other RA remained blinded from the randomization so as not to bias pain and fear ratings in the OR. Pediatric anesthesiologists and surgical staff involved with performing IV induction also remained blinded to the allocated treatment. All RAs were unblinded after induction and data collection in the OR were completed.

MEDi® Intervention and Standard Care

MEDi® delivered the preparation in a separate and private room with the child and parent, prior to receiving the IV induction and surgery. MEDi® was seated on a cart at the child's eye level in a sitting position (see **Figure 2**). It was pre-programmed to first greet participants and introduce itself. Then, the robot provided some instructions about the breathing 'game' (e.g., "You can tell everyone this secret if you want… It's called tissue breathing. It's something you can do to relax when you go to the operating room."). MEDi® then invited the child to practice deep breathing with role modeling, and imitated breathing sounds while holding a tissue in its hand. With the tissue as an aid to help children practice abdominal breathing skills, the child and parent were asked to repeat the exercise, and MEDi® encouraged participants to use these breathing techniques in the OR. After the blowing exercises were completed, MEDi® thanked the participants and finished by entertaining them with a dance. The mean duration of the interaction was 9.91 minutes (SD = 2.98, minimum = 5 minutes, maximum = 20 minutes). Children's and their parents' behaviors during the intervention were noted by the RAs who operated the MEDi® robot. In contrast to the MEDi® intervention group, participants in the standard care group did not receive this teaching preparation, and instead continued to wait unaccompanied by the RAs in the SSSU until transferred to the OR.

All children were monitored in the SSSU, and once called to the OR, were transferred along with their family with the assistance of a porter, to the holding area as the OR staff prepared for surgery. This space was the last waiting area that patients and their families stayed prior to being transferred to the OR. The pediatric anesthesiologist, a member of the perioperative nursing team and pediatric surgeon formally greeted the children and their parents within the holding area. The pediatric anesthesiologist assessed and examined the patient, and discussed the anesthetic plan with families (i.e., details of establishment of IV and IV induction, airway management, minor and major risks of the anesthetic). The surgical team also explained the surgical plan, and any questions or concerns raised by the family were addressed. A formalized surgical checklist with all perioperative stakeholders was then completed, and the patient and one family member were then led to the OR. Children's behavior and use of other pain management strategies in the holding area and OR were documented by the RAs blinded from randomization.

Figure 2. Technology-enhanced pre-operative education intervention with MEDi®.

3.3.3 Procedural Phase

After the child was in the OR and positioned (sitting or supine, with parent by his/her side) onto the surgical bed, an IV line was inserted by the pediatric anesthesiologist caring for the patient. In addition to patients themselves, children's pain and fear during IV insertion were rated by parents, RAs, and pediatric anesthesiologists. The RA collected these scores from raters prior to the administration of propofol (i.e., IV established but prior to injection of IV medications and induction of anesthesia). If a pediatric anesthesiologist attempted but failed to secure an IV line, pain and fear ratings were gathered prior to conversion to a mask-based inhalational induction using the sevoflurane volatile anesthetic. Of note, RAs responsible for gathering pain and fear scores in the OR were blinded to the patient's assigned study arm.

Following IV cannulation, an admixture of 1% propofol emulsion (4 – 6mg/kg) and lidocaine (2 mg/mL) was administered to induce anesthesia. At this point, the blinded RA also rated the patient's pain and fear during the administration of the propofol IV bolus. In cases where children appeared too distressed to attempt IV insertion, the pediatric anesthesiologist would communicate his/her plan to convert to a mask-based inhalational induction using sevoflurane with other members of the clinical team. Information regarding the total duration and number of needle attempts required to establish and complete the IV induction procedure was documented.

Concurrently with the collection of pain and fear ratings, additional information about the IV procedure and patient behaviors in the OR were recorded by the unblinded RA. That is, any comfort measures used by parents and medical professionals were documented. Details regarding the duration of IV cannulation (from the moment the needle contacted the dorsum of hand to securing the IV with tape), and the number of needle attempts to obtain IV access were also

documented. The RAs indicated whether patients were able to complete the IV induction or whether the pediatric anesthesiologist used the breathing mask to administer inhalational anesthetics for induction. In cases when IV induction was incomplete, reasons for why the mask was used were noted. Once the patients were under sedation, the RAs escorted the parents out of the OR.

3.3.4 Post-Procedural Phase

Two weeks after the hospital visit, at the scheduled time, RAs contacted families to conduct the telephone interview. Guided by an interview script, study participants answered questions related to their experience with the hospital visit and IV needle procedure. Their responses were recorded and documented on an interview form for analyses. The duration of the interview was approximately 15 minutes, and the response rate was 47% of all enrolled study participants. It is noted that the difference between completed follow-up interviews between groups was statistically significant ($X^2(1) = 4.01$, $p = 0.045$). Compared to standard care, the odds of completing a follow-up interview was 2.25 times greater for study participants who had interacted with MEDi® at the hospital.

3.4 Measures

Several ratings for children's pain and fear in the OR were gathered across various time points in specific locations by several raters (see **Table 1**). During the pre-procedural phase, RAs introduced the rating scales to families and explained when they would be administered in the OR. With the exception of the pain catastrophizing questionnaire, study participants verbally responded to the questions for all measures and responses were documented by the RAs.

Table 1. Measures reported in the pre-procedural, procedural, and post-procedural phases.

Time/Location	Measures	Raters
Pre-procedural phase		
In SSSU	Children's fear (anticipated)	Child, parent
	Parents' self-efficacy	Parent
	Parents' pain catastrophizing*	Parent
	Parents' anxiety*	Parent
Procedural phase		
Before IV insertion	Children's fear (anticipated)	Child, parent
After IV insertion (before propofol was given)	Children's fear and pain	Child, parent, anesthesiologist (blinded), RA (blinded)
During propofol bolus	Children's fear and pain	RA (blinded)
Post-procedural phase		
Two-week follow-up	Children's fear before IV insertion (recalled)	Child, parent
	Children's fear and pain during IV insertion (recalled)	Child, parent
	Children's fear and pain (anticipated)	Child, parent
	Parents' self-efficacy (anticipated)	Parent

*Note: These items were measured in SSSU only (before the allocated intervention was given), along with other demographic and clinical data.

In the SSSU, children's level of fear about the upcoming surgery was rated by children themselves and their parents; and parents were also asked about their feelings of self-efficacy and concern about their children's pain. Once in the OR, children rated their fear as did their parents, moments before the IV procedure was conducted. After an attempted IV insertion, children's perceived needle fear was rated by all raters (i.e., patients, parents, RAs, pediatric anesthesiologists). Following the establishment of an IV line, children would then proceed to the step of administering a bolus of propofol for IV induction. Moments prior to the injection of a propofol-lidocaine admixture, the RAs reassessed the level of fear that children experienced at this time of the procedure. Of note, pain was also rated at all these time points, with the

exception of pre-procedural time points because only children's fear for the upcoming needle procedure could be assessed.

In the two week-follow up interview, children and their parents were interviewed about patients' experiences of pain and fear. A total of 18 open and closed questions were asked to children and their parents separately by the RAs (see Appendix D). First, the parent who completed the measures at the hospital was interviewed, followed by the child. Thus, interviews were conducted independently with each participant. To evaluate the formation of distressing memories since the hospital visit, parents were first asked two open-ended questions regarding their experiences during the IV procedure and overall hospital visit (e.g., "I would like you to tell me everything that you [your child] can remember about the IV insertion in the hand just before the surgery"). When participants were no longer able to recall any details about the event freely, they were prompted (maximum three times) with statements such as, "What else happened?", "Tell me more," "uh huh," or "What else?". Then, they were asked to rate their child's levels of fear before and after the IV needle was inserted. Parents were also asked to recall the level of needle pain that children experienced during the IV needle insertion. After recalling the induction experience, parents provided reports of anticipatory pain and fear, when asked how much pain and fear their children would expect to have if they were to undergo another IV procedure in the future. Similar to the pre-intervention questionnaire completed in the SSSU, parents' level of self-efficacy to manage their children's pain and fear was also re-assessed in the follow-up interview. These questions were then repeated with the child over the phone, except for the items about parents' level of self-efficacy. Here, additional information was noted to understand the occurrence of post-operative painful events and how often the sedation procedure

was discussed with children since hospital discharge. Any mention of the MEDi® robot or use of breathing skills during the surgery visit as coping strategies were also documented by the RA.

In summary, **Figure 3** provides an outline for the order of administration of measures during the pre-procedural, procedural, and post-procedural phases. Specifically, this diagram further illustrates the different locations where data collection occurred before, during, and after IV induction.

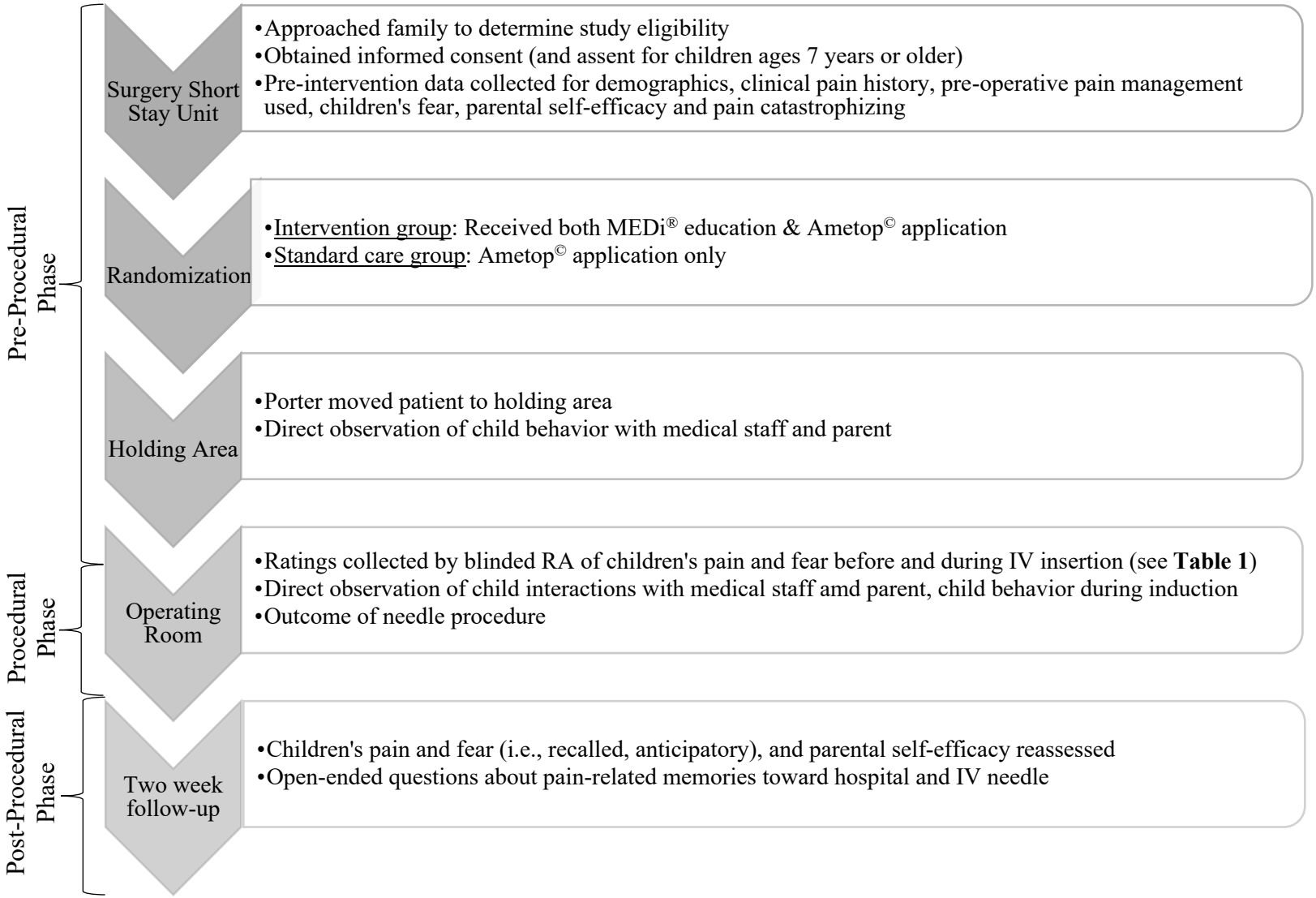

Figure 3. Flow diagram for the data collection process in each location.

3.4.1 Intensity of Pain

Pain was measured using an adapted version of the FPS-R, a six-item scale depicting faces with gradually increasing expressions of pain. Each face is labelled numerically from 0 (no pain) to 10 (most pain) for participants to express the level of pain experienced [65]. Several studies have shown high concurrent validity and test-retest reliability of FPS-R scores, and it is an age-appropriate measure for children's pain [43,52,144]. In this study, inter-rater reliability of FPS-R scores for needle pain provided by patients, parents, pediatric anesthesiologists, and researchers were high (r = 0.53-0.72, $p < 0.01$).

However, research has suggested that young children may provide unreliable responses on numerical rating scales. Although most young children are able to count, they may have yet to develop an understanding for the quantitative significance of numbers [129,147]. Some children may have sequence bias by selecting the leftmost or rightmost face for the first question and then score responses in an ascending or descending series, respectively, with each successive question (e.g., 0-2-4-6-8-10) [3]. To address these concerns in our study, letters were used to label items on the FPS-R scale for children to select the face that is closely aligned with their pain (see **Figure 4**). Furthermore, given that patients may not be able to physically point to the faces in front of the researcher due to potential mobility or environmental constraints, the letter labels allowed children to effectively communicate the selected facial expression that represented their response.

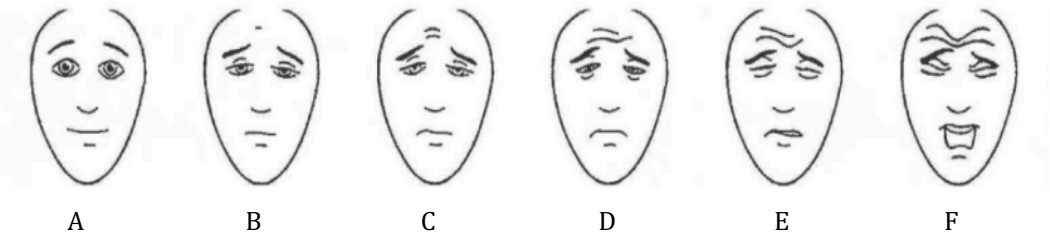

Figure 4. Measure of pain adapted from the Faces Pain Scale-Revised [65].

3.4.2 Intensity of Fear

Fear was measured using the Children's Fear Scale (CFS) [93], a five-item scale depicting faces with gradually increasing expressions of fear and that is labelled numerically from 0 (no fear) to 4 (most fear). This tool has been used in studies to measure needle-related fear in various pediatric clinical settings [25,93]. Evidence of interrater and test-retest reliability, as well as concurrent and discriminant validity have supported the use of CFS to measure children's fear [93]. Similar to the pain scale, letters were used to label the faces instead of a numerical scale to obtain an accurate representation of children's fear level (see **Figure 5**).

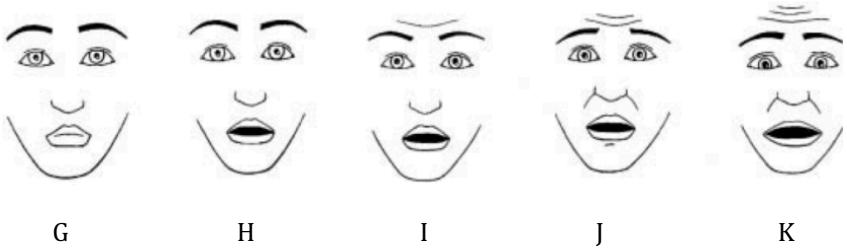

Figure 5. Measure of fear adapted from the Children's Fear Scale [93].

3.4.3 Level of Parental Catastrophizing of Child's Pain

The Pain Catastrophizing Scale – Parent Version (PCS-P) was used to assess concerning and catastrophic thoughts and feelings that parents may have when their children experience pain [65]. A total of 13 items were rated on a 5-point Likert scale, yielding a total score and three subscale scores: rumination (i.e., perseveration of thoughts pertaining to suffering and avoidance), magnification (i.e., exaggerating negative consequences of pain), and helplessness (i.e., tendency to perceive oneself as being helpless in the face of pain) [139]. All PSC-P items were assessed using a 5-point Likert scale (0 = not at all, 1 = mildly, 2 = moderately, 3 = severely, 4 = extremely). The maximum score is 52. Several studies have shown that it has good internal consistency and validity scores as an indicator of parental catastrophizing [93,108,139].

Low baseline scores indicate low feelings of rumination, magnification, or helplessness in regard to their children's pain. A total score of 30 or higher is considered a clinically relevant level of pain catastrophizing.

3.4.4 Parental Self-Efficacy and Anxiety

The Pain Self-Efficacy Questionnaire has been shown to be a reliable and valid indicator of coping with pain for a number of clinical populations [35,101,105]. Its items informed the development of three closed-ended questions used in the present study. The first two questions evaluated parents' perceived ability to manage their child's distress using an 11-point rating scale (i.e., **"**How much do you think that you will be able to help [child's name] feel less pain (or 'fear') at his/her needle procedure? A score of 0 means that you think you will have no ability to reduce [child's name]'s pain (or fear) and 10 means that you think that you will have complete and total ability to reduce his/her pain (or 'fear')".) [104]. A separate question asked parents about their level of anxiety in helping their children while receiving the IV procedure. This third item was administered using the following question: "How anxious do you think you will feel during the needle procedure on a scale from 0 ('not at all nervous or anxious') to 10 ('most nervous or anxious')". Parental measures for the first two questions were positively correlated ($r = 0.55$, $p < 0.05$). However, they were not significantly correlated with the third question about anxiety ($ps > 0.05$). Hence, the mean scores for the first two questions were used as an indicator of self-efficacy, and the scores for the third question were used to measure anxiety.

3.4.5 Demographic and Clinical Data

Demographic data were obtained regarding the patient's age, sex, previous pain experiences and parent education. Information about the use of pain management interventions prior to surgery and observations of patient interactions during the IV induction procedure were

also recorded. Clinical data related to the IV induction include the date and time of surgery, number of needle attempts, duration of procedure, and utilization of breathing mask for sedation.

3.5 Analyses

3.5.1 Quantitative Analyses

All quantitative data were analyzed using SPSS® (Statistical Package for the Social Sciences) version 24.0. Data entered into a spreadsheet were verified by two RAs prior to analysis. All pre- and procedural data were analyzed, including those participants who did not participate at follow-up. For patients who received an IV cannulation attempt, self-reported ratings of procedural-related pain and fear collected in the OR were included in the analyses. For some children, CFS or FPS-R were missing if they were induced with inhalation anesthesia and did not receive at least one IV needle insertion attempt. Descriptive statistics of all of the demographic and clinical data were reported.

To evaluate whether the teaching preparation administered by MEDi® was related to the level of pain and fear experienced during needle insertion, one-way analyses of variance (ANOVAs) were conducted for all of the pain and fear ratings shown in **Table 1**. Significant *p*-values indicated differences in self-reported pain or fear between patients receiving MEDi® versus standard care, and effect sizes were reported with partial eta squared. Levels of significance for children's pain and fear were adjusted with Bonferroni correction to reduce the risk of Type 1 errors when performing multiple comparisons. Possible violations in the assumptions of normal distribution, independent observations, and equal variances were examined.

To assess whether MEDi® reduced the formation of pain-related memories, self-reported pain and fear ratings were analyzed using four one-way repeated-measures ANOVAs. That is,

fear ratings reported at six time points were examined to determine if children's and parent's perceptions of fear were reduced more in patients who received MEDi® preparation compared to those who did not: in the pre-procedural (in the SSSU and OR), procedural (after IV start), and post-procedural phases (recalled fear before and after the IV insertion, and anticipatory fear at follow-up). In addition, child- and parent-reported pain scores were examined at three time points during the procedural (after IV start) and post-procedural phases (recalled and anticipatory pain at follow-up). For cases where the assumption of sphericity was not met, the Greenhouse-Geisser correction was used.

A one-way repeated-measures ANOVA was conducted to determine if between-group differences in parental self-efficacy were found after their children received the allocated treatment. Significant findings in parent self-efficacy would indicate changes in how well parents think they can manage their children's pain or fear during future needle procedures.

To understand whether receiving MEDi® preparation may be associated with the completion rate of IV inductions, a chi-square test was conducted. In the case of small cell sizes, the Fisher's exact test was performed. Significant results would suggest differences in the frequency of completed IV inductions between the MEDi® intervention and standard care groups.

To examine the similarity in ratings among children, parents, pediatric anesthesiologists and RAs, Pearson's product moment correlations were calculated. These analyses were also performed to assess potential associations among the sociodemographic factors, duration of MEDi® intervention or IV procedure, and number of needle attempts with pediatric pain ratings. The absolute value, sign of the coefficient, and its *p* value were indicative of the magnitude, directionality, and significance of the correlation, respectively.

3.5.2 Qualitative Analyses

All qualitative data collected during the hospital stay and follow-up interviews were documented. Common themes in pain management strategies and specific types of support accessed to prepare for surgery were identified. These responses were categorized based on the different interventions utilized: distractions, heat/ice application, medication, physical comfort, information documents, or expert advice. Observations made in the surgical unit about children's behavior during IV procedure and their interactions with parents and medical staff were also analyzed (e.g., conversations related to procedural or non-procedural topics, coping strategies, physical comfort, parental positioning). If children received inhalational anesthesia in the OR, reasons for why the IV induction procedure was not attempted or completed were examined.

To determine the types of expectations patients held about future pain and subsequent pain reporting, children's and parents' responses to questions about the hospital and IV induction experiences were categorized according to a revised content coding scheme developed by Noel et al. (see Appendix A; Table A.1) [107]. Two independent researchers (RL and CK) coded the interview transcripts following an iterative approach. That is, each researcher independently coded the responses in batches of 10 cases and then discussed any discrepancies in the codes prior to continuing with the next set. Free recall interviews were coded for the presence of emotions (positive/negative/neutral), coping behaviors, and details related to the child's body or medical procedures. For emotions and coping behaviors, other secondary codes were assigned to specify the type of emotion and coping strategy recalled by study participants. Multiple codes could be identified per response; however, if the same code appeared more than once, it was counted only once. In addition, any mention of the MEDi® robot or use of breathing techniques

in the hospital was coded. Frequency statistics were calculated for each code identified per utterance. Inter-rater agreement between coders was determined using Cohen's *kappa* statistic.

3.6 Ethical Considerations

This clinical trial obtained research ethics from the University of Calgary Conjoint Health Research Ethics Board (CHREB). There is a conflict of interest disclosed for this study. Dr. Tanya Beran, primary investigator of this study, is commercializing the MEDi® robot. This relationship is disclosed at all research presentations and documented on the consent form, including this thesis. Dr. Beran advised on data analysis, but did not collect, manage, or store the data.

CHAPTER FOUR: RESULTS

This chapter provides a detailed description of the results presented within the manuscript in Chapter 5, along with supplementary findings about children's and their parent's experiences with MEDi®. The results are presented in two main sections based on the quantitative and qualitative analyses performed.

4.1 Quantitative Analyses

4.1.1 Description of Study Participants

As shown in **Table 2**, the sample consisted of 57 male and 46 female children ages 4-12 years (mean = 7.56, SD = 2.60), and Caucasian was the predominant race. The highest education level for most parents was a university or college degree. At the pre-procedure stage (in the SSSU), parents reported moderate levels of self-efficacy in managing children's pain and fear, as well as low anxiety and pain catastrophizing towards the IV procedure. The majority of children had not previously experienced any IV procedures. A total of 34 patients had received at least one surgery prior to this visit (20 in MEDi® group, 14 in standard care group). Many children (n = 25, 24.3%) had experienced a medical and/or pain-related condition (e.g., pneumonia, rheumatoid arthritis, cellulitis, acute lymphoid leukemia). There were no significant differences in participant characteristics, hospital experiences, or pain catastrophizing scores between the two study groups (ps > 0.05). During the hospital visit, most children had used a combination of distractions and conversations with their family or medical staff to help manage pain or fear (see **Table 2**). Distractions that were most frequently used include portable entertainment devices and comfort items (e.g., toys, stuffed animals, blankets).

Table 2. Means and standard deviations of child and parent characteristics (pre-procedure phase).

Correlates	Total (n = 103)	MEDi® (n = 45)	Standard care (n = 58)	Statistic(df)	p
Child characteristics					
Sex (%)				$X^2(1) = 1.35$	0.25
Male	57 (55.34)	22 (48.89)	35 (60.34)		
Female	46 (44.66)	23 (51.11)	23 (39.66)		
Race (%)				-	-
Caucasian	66 (64.08)	27 (60.00)	39 (67.24)		
Metis	3 (2.91)	1 (2.22)	2 (3.45)		
Asian	12 (11.65)	6 (13.33)	6 (10.34)		
East Indian	6 (5.83)	3 (6.67)	3 (5.17)		
Aboriginal	2 (1.94)	1 (2.22)	1 (1.72)		
Black	3 (2.91)	-	3 (5.17)		
Hispanic	2 (1.94)	-	2 (3.45)		
Other	9 (8.74)	7 (15.56)	2 (3.45)		
Age in years	7.56 (2.60)	7.47 (2.67)	7.63 (2.56)	$F(1,100) = 0.10$	0.75
Past admissions	1.07 (3.00)	1.40 (3.84)	0.81 (2.15)	$F(1,101) = 0.97$	0.33
Past surgeries	0.88 (2.24)	0.78 (2.23)	0.97 (2.27)	$F(1,101) = 0.18$	0.68
Pain after last surgery*	4.62 (2.91)	4.36 (3.12)	4.80 (2.82)	$F(1,32) = 0.19$	0.67
Past IV starts	3.91 (15.71)	3.18 (14.80)	4.48 (16.48)	$F(1,101) = 0.17$	0.68
Pain conditions (%)	8 (7.76)	4 (8.89)	4 (6.90)	$X^2(1) = 0.14$	0.73
Previously diagnosed illnesses (%)	19 (18.45)	9 (20.00)	10 (17.24)	$X^2(1) = 0.13$	0.72
Parent characteristics					
Mother's education (%)				$X^2(1) = 2.27$	0.13
High school or under	20 (19.42)	12 (26.67)	8 (13.79)		
University/College	80 (77.67)	33 (73.33)	47 (81.03)		
Not applicable/missing	3 (2.91)	-	3 (5.17)		
Father's education (%)				$X^2(1) = 0.90$	0.34
High school or under	24 (23.30)	13 (28.89)	11 (18.97)		
University/College	72 (69.90)	31 (68.89)	41 (70.69)		
Not applicable/missing	7 (6.80)	1 (2.22)	6 (10.34)		

Table 2 (continued). Mean and standard deviations of child and parent characteristics (pre-procedure phase).

Correlates	Total (n = 103)	MEDi® (n = 45)	Standard care (n = 58)	Statistic(df)	p
Parents' self-efficacy	6.62 (2.20)	6.78 (1.92)	6.49 (2.39)	$F(1,101) = 0.43$	0.51
Parents' anxiety	3.60 (3.15)	3.00 (2.86)	4.07 (3.29)	$F(1,101) = 2.99$	0.09
Pain catastrophizing	16.80 (8.03)	17.56 (9.32)	16.21 (6.90)	$F(1,101) = 0.71$	0.40
Helplessness	5.47 (3.75)	5.89 (4.28)	5.14 (3.28)	$F(1,101) = 1.02$	0.32
Magnification	2.67 (1.82)	3.00 (2.23)	2.41 (1.38)	$X^2(1) = 1.06$ †	0.30
Rumination	8.66 (3.64)	8.67 (3.68)	8.66 (3.65)	$F(1,101) = 0.00$	0.99
Pre-operative pain management (%)					
Pharmacological pain management strategies					
Oral analgesics (i.e., Tylenol, Advil)	93 (90.29)	44 (97.78)	49 (84.48)	$X^2(1) = 5.11$	0.04
Non-pharmacological strategies **				-	-
Ice/Heat compress	3 (2.91)	2 (4.44)	1 (1.72)		
Comfort items (e.g., stuffed animals, blankets)	13 (12.62)	9 (20.00)	4 (6.90)		
Distraction activities (e.g., books, toys, electronics)	58 (56.31)	30 (66.67)	28 (48.28)		
Breathing exercises	4 (3.88)	-	4 (6.90)		
Parental presence	6 (5.83)	2 (4.44)	4 (6.90)		
Parent-child conversations	98 (95.15)	41 (91.11)	57 (98.28)	$X^2(1) = 1.72$	0.31
Support accessed (e.g., doctors, pamphlets)	35 (33.98)	18 (40.00)	17 (29.31)	$X^2(1) = 1.49$	0.29
Information sessions attended (i.e., Surgery 101)	4 (3.88)	1 (2.22)	3 (5.17)	$X^2(1) = 0.59$	0.63

† Kruskal-Wallis *H* Tests performed for data that violated assumptions of homogeneity.
* Pain assessed on an 11-point numerical rating scale.
** One or more strategy may have been coded per patient.

4.1.2 Children's Pain

To address the first research question about whether lower procedural pain was found during IV induction, the differences between the MEDi® and standard care groups were analyzed. As shown in **Table 3**, low levels of needle pain were reported by all raters in both groups (i.e., most scores were at the low end of the continuum on the FPS-R). Additionally, there were no significant differences between treatment groups at the time of IV insertion, IV bolus of propofol, recalled level of pain two-weeks after hospital discharge, or expected level of pain for future IV procedures (ps > 0.05). Parent, RA, and pediatric anesthesiologist ratings for child's pain during IV insertion were also found to be similar between study arms. Likewise, when the propofol admixture was administered, results did not suggest a significant difference in RA-reported ratings for children's pain when the bolus of propofol was given.

Similarly, there were no significant group differences in pain scores at the post-procedural phase (at two-week follow-up). That is, the mean pain scores reported by parents in the MEDi® and standard care group were similar when they were asked to recall their children's level of perceived pain in the OR. When asked if their children were to receive another IV needle procedure, parents from both treatment conditions anticipated their children to experience similar pain levels in the future.

Analyses from between-group repeated-measures ANOVA further confirmed no interaction effect between study arm and for children's ($F(2,84) = 0.56$, $p = 0.57$) and parents' ($F(2,88) = 0.16$, $p = 0.85$) reports of needle pain over time. This finding indicates that when needle pain was assessed during the procedural and post-procedural phases, no difference was found between treatment groups across different time points.

Table 3. Self- and observer-reported ratings for children's pain and fear by treatment condition.

Pain/Fear	MEDi® Mean (SD)	Standard care Mean (SD)	Statistic(df)	p*
Pre-procedural phase				
Fear before IV				
Child	0.98 (1.18)	0.91 (0.92)	$F(1,101) = 0.10$	0.76
Parent	1.02 (1.06)	1.09 (0.94)	$F(1,101) = 0.11$	0.75
Procedural phase				
Fear before IV				
Child	1.16 (1.26)	1.13 (1.02)	$F(1,97) = 0.02$	0.89
Parent	1.41 (1.19)	1.38 (1.05)	$F(1,98) = 0.02$	0.88
Pain during IV insertion				
Child	2.74 (2.96)	2.76 (2.97)	$F(1,91) = 0.00$	0.98
Parent	2.86 (2.46)	2.70 (2.78)	$F(1,96) = 0.09$	0.77
Researcher	2.76 (2.70)	2.67 (2.57)	$F(1,97) = 0.03$	0.87
Anesthesiologist	2.55 (2.74)	2.27 (2.69)	$F(1,94) = 0.25$	0.62
Fear during IV insertion				
Child	1.39 (1.34)	1.14 (1.13)	$F(1,90) = 0.96$	0.33
Parent	1.59 (1.06)	1.31 (1.08)	$F(1,96) = 1.61$	0.21
Researcher	1.56 (1.08)	1.19 (0.97)	$F(1,97) = 3.23$	0.08
Anesthesiologist	1.20 (1.16)	1.12 (1.22)	$F(1,95) = 0.12$	0.73
Pain during propofol bolus				
Researcher	0.93 (2.02)	1.46 (2.60)	$F(1,89) = 1.15$	0.29
Fear during propofol bolus				
Researcher	0.67 (0.99)	0.65 (0.81)	$F(1,89) = 0.02$	0.88
Post-procedural phase				
Recalled fear in OR				
Child	1.42 (1.17)	1.49 (1.05)	$F(1,44) = 0.01$	0.95
Parent	1.23 (0.95)	1.35 (0.99)	$F(1,44) = 0.17$	0.68
Recalled pain during IV				
Child	3.23 (3.58)	2.67 (2.48)	$F(1,45) = 0.38$	0.54
Parent	2.69 (2.65)	2.76 (2.72)	$F(1,45) = 0.01$	0.93
Recalled fear during IV				
Child	1.12 (1.33)	1.05 (0.89)	$F(1,43) = 0.04$	0.84
Parent	1.46 (1.24)	1.25 (0.97)	$F(1,44) = 0.40$	0.53
Anticipated pain for next IV				
Child	3.12 (3.22)	3.82 (3.14)	$F(1,45) = 0.56$	0.46
Parent	3.08 (2.28)	3.00 (2.20)	$F(1,46) = 0.01$	0.91
Anticipated fear for next IV				
Child	1.28 (1.46)	1.20 (0.95)	$F(1,43) = 0.05$	0.83
Parent	1.15 (1.29)	1.35 (1.09)	$F(1,44) = 0.30$	0.59

*Adjusted alpha-levels with Bonferroni correction are 0.006 for 9 group comparisons performed with FPS scores and 0.003 for 15 group comparisons performed with CFS scores. A significant difference is suggested if *p*-value is less than this adjusted value.

To understand the association between children's pain during the time of needle insertion and at follow-up, pain scores were examined using correlational analyses (see **Table 4**). With the exception of RA reported pain during propofol bolus not related with any other pain scores, positive and significant correlations were shown among all ratings in the OR and during follow-up for needle pain. Thus, raters reporting high pain scores in the OR were also likely to recall high levels of needle pain, as well as anticipate high pain in the future. However, RA-reported pain ratings during the propofol bolus were not related to any other pain ratings.

Table 4. Correlations between self- and observer-reported pain ratings.

Time/Rater	Procedural phase				Post-procedural phase			
	Pain during IV insertion			Propofol bolus	Recalled pain during IV		Anticipated pain for next IV	
	Parent	RA	Anes	RA	Child	Parent	Child	Parent
Procedural phase								
Pain during IV insertion								
Child	0.57**	0.53**	0.59**	-0.05	0.61**	0.59**	0.45**	0.58**
Parent		0.69**	0.61**	-0.03	0.55**	0.74**	0.38*	0.64**
RA			0.72**	-0.01	0.46**	0.64**	0.44**	0.40**
Anesthesiologist				0.19	0.39**	0.65**	0.36*	0.36*
Post-procedural phase								
Recalled pain during IV								
Child				-0.10		0.43**	0.68**	0.59**
Parent				-0.20			0.40**	0.59**
Anticipated pain for next IV								
Child				0.05				0.57**
Parent				0.09				

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).
Note: Anes = anesthesiologist

4.1.3 Children's Fear

To address the latter part of the first research question about changes in children's fear over time, differences in fear scores between treatment groups were analyzed. As shown in **Table 3**, low levels of children's fear were reported by all raters. There are no significant differences in fear ratings between patients who received MEDi® or standard care at each time point for any raters (ps > 0.05).

Results from repeated-measures ANOVA neither suggest interaction effects between study arm and reports of fear provided by children ($F(5,205) = 0.86$, $p = 0.51$) and parents ($F(4,161) = 1.88$, $p = 0.12$) among different time points. Of note, due to violation of sphericity, analyses for parent ratings were reported with the Greenhouse-Geisser correction. This finding indicates that, similar to needle pain, no difference was found with fear ratings across the pre-procedural, procedural, and post-procedural phases.

The relationships between fear scores provided by children and observers are examined next. As shown in **Table 5**, results indicated that observers' rated needle fear during IV placement similarly to children's ratings, with parents' scores most alike. Thus, if children reported high needle fear during IV cannulation, their parents, pediatric anesthesiologists, and RAs were likely to agree. Furthermore, if children expressed high needle fear during the IV start, these patients and their parents were likely to recall high levels of fear and expectations for high levels of fear in the next IV procedure. However, there were also several fear ratings that were not significantly correlated across all time points. In particular, researcher-reported ratings for children's fear during propofol bolus was least correlated with other fear ratings. In addition, pre-procedural fear ratings were also not consistently correlated with child- or observed-reported fear during the procedural or post-procedural stages. That is, children who experienced high level of

needle fear before the IV start did not suggest that they would experience similar levels of needle fear during induction procedure or after hospital discharge.

Table 5. Correlation between self- and observer-reported fear ratings.

Location/Rater	Pre-procedural phase	Procedural phase							Post-procedural phase					
	Fear before IV insertion	Fear before IV insertion		Fear during IV insertion				Propofol bolus	Recalled fear before IV		Recalled fear during IV		Anticipated fear for next IV	
	Parent	Child	Parent	Child	Parent	RA	Anes	RA	Child	Parent	Child	Parent	Child	Parent
Pre-procedural phase														
Fear before IV insertion														
Children	0.52**	0.54**	0.46**	0.22*	0.14	0.21*	0.24*	0.14	0.47**	0.32*	0.37*	0.28	0.12	0.40**
Parent		0.50**	0.58**	0.17	0.14	0.14	0.07	-0.06	0.25	0.32*	0.17	0.17	-0.09	0.06
Procedural phase														
Fear before IV insertion														
Child			0.56**	0.31*	0.16	0.43**	0.24*	0.16	0.38**	0.56**	0.24	0.15	0.11	0.19
Parent				0.20	0.19	0.21*	0.09	-0.05	0.50**	0.56**	0.10	0.09	-0.09	0.31*
Fear during IV insertion														
Child					0.46**	0.43**	0.26*	0.20	0.44**	0.42**	0.47**	0.48**	0.43**	0.37*
Parent						0.47**	0.47**	0.30**	0.36*	0.39**	0.58**	0.64**	0.39**	0.60**
RA							0.63**	0.40**	0.24	0.29	0.42**	0.38**	0.39**	0.28
Anesthesiologist								0.45**	0.06	0.22	0.35*	0.47**	0.26	0.44**
Post-procedural phase														
Recalled fear before IV														
Child								0.07		0.28	0.29*	0.19	0.37*	0.40**
Parent								0.15			0.52**	0.44**	0.09	0.32*
Recalled fear during IV														
Child								0.23				0.72**	0.49**	0.49**
Parent								0.35*					0.40**	0.50**
Anticipated fear for next IV														
Child								0.11						0.48**
Parent								0.16						

* Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).

Note: Anes = anesthesiologist

The relationship between children's pain and fear in the OR is shown in **Table 6**. Overall, children, parents, RAs, and pediatric anesthesiologists who reported high pain scores during IV placement were also likely to report high fear scores. With one exception, pediatric anesthesiologists' reports of needle pain were not significantly correlated with their patients' rating of needle fear. That is, if children reported high levels of fear during IV placement, the pediatric anesthesiologists were not likely to have rated their patients' needle pain as high. Analyses also indicated that pain and fear during needle insertion were not consistently related to needle-related discomfort when a propofol bolus was given subsequently.

Table 6. Correlation between pain and fear ratings during the procedural phase.

Raters	Fear during IV insertion				Fear during propofol bolus
	Child	Parent	RA	Anes	RA
Pain during IV insertion					
Child	0.41**	0.52**	0.39**	0.52**	0.10
Parent	0.27*	0.66**	0.33**	0.42**	0.12
RA	0.28**	0.45**	0.42**	0.51**	0.18
Anesthesiologist	0.16	0.38**	0.42**	0.56**	0.33**
Pain during propofol bolus					
RA	0.05	0.09	0.22	0.22*	0.60**

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).
Note: Anes = anesthesiologist

Demographic Factors Related to Pain

To further understand whether specific children or parent factors were related to children's pain and fear, correlational analyses were conducted with study participants' demographic data (see **Table 7**). Many child and parent factors were not significantly correlated with any pain scores. Age was not related to self- or observer-reports of needle pain, with the exception of children's ratings of future anticipated pain, which were significantly and negatively correlated with age. That is, older children were likely to expect low levels of needle-

related pain for their next IV procedure. Also indicated in this table is the positive correlation between parents' anxiety and their ratings of needle pain during the IV start. This result suggests that parents with high pre-procedural anxiety were likely to also rate their children's needle pain as high. When this anxiety, along with children's age were included as covariates in univariate and repeated-measures ANOVAs, no significant results were found (*ps* > 0.05).

Demographic Factors Related to Fear

Similar to their pain ratings in the OR, children's age was also identified as related with their self- and parent-reports of pre-procedural fear (see **Table 7)**. However, during the post-procedural phase, children's age was found to be negatively correlated with children's anticipatory fear for future IV needles. That is, older children were likely to expect little fear for their next IV needle procedure. Also shown in this table are other factors that were associated with needle fear, which include the number of previous hospital admissions and father's highest education level. Interestingly, father's education was negatively correlated with children's fear during IV start and level of fear recalled two-weeks after the surgery. When these factors were added as covariates, no significant results were found in the repeated measures ANOVA analyses (*ps* > 0.05).

However, children's fear was not related to the following demographic factors: previous number of IV starts, mother's highest level of education, and mean parental self-efficacy. Additionally, there were specific fear measures during the procedural and post-procedural phases that did not correlate with any child or parent factors (i.e., reports of needle fear from pediatric anesthesiologists, fear during propofol bolus, and children's recall of needle fear).

Table 7. Demographic factors related to children's pain and fear.

Location/Rater	Child factors					Parent factors				
	Age	Previous admissions	Previous surgeries	Pain from last surgery	Previous IVs	Mother's education	Father's education	Self-efficacy	Anxiety	Pain catastrophizing
Pre-procedural phase										
Fear before IV (SSSU)										
Children	0.13	0.13	0.05	0.27	0.00	-0.41	0.00	-0.07	0.09	0.10
Parent	0.39**	0.22*	0.09	0.24	0.06	-0.04	0.01	-0.06	0.24*	0.22*
Procedural phase										
Fear before IV										
Child	0.31**	0.20	0.03	0.43*	0.15	-0.01	-0.04	0.03	0.08	0.06
Parent	0.22**	0.26**	0.18	0.10	0.06	0.07	0.06	-0.03	0.17	0.22*
Pain during IV										
Child	0.00	0.03	-0.09	-0.03	0.07	-0.10	-0.20	0.04	0.02	0.09
Parent	0.11	0.06	0.01	0.15	0.04	-0.09	-0.17	0.09	0.20*	0.10
RA	0.03	0.14	0.17	0.05	0.05	-0.06	-0.11	0.01	-0.05	-0.03
Anesthesiologist	0.03	-0.42	-0.06	0.16	0.08	0.07	-0.10	0.03	-0.05	-0.05
Fear during IV										
Child	0.19	0.16	0.22*	0.14	-0.07	0.01	-0.25*	0.07	0.00	0.11
Parent	0.16	0.25*	0.07	0.24	-0.11	-0.13	-0.26*	0.07	0.11	0.26**
RA	0.02	0.25*	0.07	0.40*	0.07	-0.08	-0.11	0.19	-0.02	-0.01
Anesthesiologist	0.04	0.16	0.04	0.22	0.03	0.06	-0.13	0.06	-0.13	0.04
Pain during propofol bolus										
RA	-0.04	0.04	0.10	0.09	-0.05	-0.01	-0.07	0.08	-0.13	-0.12
Fear during propofol bolus										
RA	-0.07	0.16	0.12	0.26	0.01	0.03	-0.18	0.12	-0.17	-0.10

Table 7 (continued). Demographic factors related to children's pain and fear.

Location/Rater	Child factors					Parent factors				
	Age	Previous admissions	Previous surgeries	Pain from last surgery	Previous IVs	Mother's education	Father's education	Self-efficacy	Anxiety	Pain catastrophizing
Post-procedural phase										
Recalled fear in OR										
Child	-0.05	0.06	0.03	-0.06	0.08	0.07	0.13	-0.08	0.24	0.10
Parent	0.04	-0.16	0.02	-0.05	-0.18	0.09	-0.24	0.05	0.18	0.03
Recalled pain during IV										
Child	-0.28	-0.17	0.08	-0.23	0.03	0.22	0.04	-0.14	0.00	0.01
Parent	0.01	0.00	0.17	0.24	-0.07	0.11	-0.09	0.03	0.04	0.07
Recalled fear during IV										
Child	-0.10	0.01	0.37*	-0.14	-0.12	0.05	-0.33*	-0.10	0.18	0.20
Parent	-0.12	-0.02	0.20	0.01	-0.18	0.19	-0.26	-0.13	0.12	0.14
Anticipated pain for next IV										
Child	-0.29*	-0.01	0.28	-0.11	-0.12	0.17	0.11	-0.17	0.01	-0.01
Parent	-0.21	0.00	0.02	0.34	-0.12	0.19	-0.09	-0.21	0.19	0.25
Anticipated fear for next IV										
Child	-0.31*	0.18	0.22	0.23	0.17	0.16	-0.08	-0.08	0.02	-0.03
Parent	-0.14	-0.09	0.15	0.11	-0.13	0.24	-0.02	-0.22	0.10	0.10

* Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).

4.1.4 Completion of IV Induction

This section addresses the research question about whether children who received the MEDi® preparation were more likely to successfully complete IV inductions compared to children in standard care. As shown in **Table 8**, this result is significant, indicating that the former group required conversion to inhalation induction less often than the latter group. Specifically, the odds ratio indicates that children with the robot intervention were 5.04 times more likely to complete the IV induction, compared to those who did not. Most children (n = 90, 87%) were able to complete the IV induction procedure. For patients who did not undergo IV induction, specific reasons stated by the pediatric anesthesiologists on converting to mask-based inhalational induction were also collated. In many cases, they chose to use the mask for induction if a vein could not be located on either dorsum of both hands in which Ametop© had been applied. Other patient considerations, such as needle distress or inadequate analgesic effects with Ametop©, were also assessed by the pediatric anesthesiologist in the OR. If these factors suggested that the IV procedure was not an appropriate induction procedure, the attending anesthesiologist would switch to using breathing mask to deliver volatile gases for inducing anesthesia.

Table 8. Outcome of induction attempts.

Method	**Total** (%) **(n = 103)**	**MEDi®** (%) **(n = 45)**	**Standard care** (%) **(n = 58)**	**Statistic**(df)	**p,** φ_c
IV	90 (87.38)	43 (95.56)	47 (81.03)	$X^2(1) = 4.85$	0.04, 0.22
Inhalational Reasons for use	13 (12.62)	2 (4.44) • IV cannulation was not completed after one attempt on each hand. (n = 1) • Child preferred receiving inhalation anesthetics in the OR prior to IV start. (n = 1)	11 (18.97) • After the anesthesia resident had two attempts with IV insertion, the attending anesthesiologist suggested to use the breathing mask for induction. (n = 1) • When needle was presented to child, patient pulled hand away. Pediatric anesthesiologist proceeded with the mask instead of attempting an IV start. (n = 1) • Patient showed signs of phobia towards both the needle and mask. (n = 1) • Difficult IV start (i.e., pediatric anesthesiologist could not locate a vein on the child's hand for IV insertion) (n = 4) • The topical numbing cream was not applied long enough (i.e., 25 minutes), and child showed signs of discomfort after the first needle attempt was incomplete. (n = 1) • IV start was completed, but pediatric anesthesiologist decided the breathing mask would be a better approach for induction (e.g., Child could not tolerate propofol due to pain/anxiety during infusion.). (n = 1) • No reason provided. (n = 2)		

4.1.5 Parental Self-Efficacy

To address the third research question about parents' ability to manage their children's distress towards needle procedures, the difference in self-efficacy between the MEDi® and standard care groups was analyzed. Parental self-efficacy to manage their children's pain and fear for standard care (mean = 7.05, SD = 1.97) and MEDi® (mean = 7.01, SD = 2.27) were not significantly different ($F(1,44) = 0.00$, $p = 0.96$). When measured in the SSSU and two-weeks post-surgery, results from repeated measures ANOVA analyses with between-subjects effects showed that parental self-efficacy did not improve over time for the MEDi® group compared to standard care ($F(1,43) = 0.02$, $p = 0.88$).[3]

For the remainder of this chapter, findings from the qualitative analyses with MEDi® are presented. In particular, observations made in the SSSU and OR regarding the use of pain management interventions before and during the IV induction procedure are described. Additional results pertinent to children's behavior with parents and healthcare providers are examined. Subsequently, participants' perceptions of their hospital experience collected at the follow-up interviews are also analyzed and presented.

4.2 Content Analyses

4.2.1 Use of Preparation Strategies during Hospital Visit

To address the research question about differences in the use of pain management techniques after receiving preparation with MEDi®, children's coping behavior between groups were analyzed. Common themes in their behavior during pre-induction phases of the IV procedure were coded according to the coping categories in Appendix A (see Table A.1). In

[3] Self-efficacy was also assessed in the SSSU, at the pre-procedural phase. The difference between MEDi® and standard care treatments is reported in **Table 2**.

particular, any mention of breathing exercises that were self-initiated or encouraged by an adult caregiver for relaxation were considered as a coping behavior related to deep breathing. When children were engaged in conversations with surrounding adult caregivers, they were most frequently involved with non-procedural topics to introduce humor into the clinical environment or divert their attention from the needle procedure. Additionally, children from both study groups exhibited deep breathing behaviors as a form of coping during the IV procedure. Between-group analyses further revealed that more children, who received additional preparation with MEDi®, performed breathing exercises in the OR compared to standard care (Fisher's exact test (1) = 4.66, $p < 0.05$, Cramer's *phi* = 0.21). In both groups, the surgical staff encouraged participants to use other coping strategies, such as telling patients to focus on wiggling their toes or ask the parent to assist in keeping the child in a comfortable position during the IV start.

4.2.2 Patient Interactions with MEDi®

Observations regarding the robot and use of breathing strategies were documented with a total of 12 children (27% of 45 patients who completed the MEDi® intervention). Overall, RAs noted that many children were "engaged", "interactive", or enjoyed their experience with the robot. Observations further showed that several children and their parents continued to talk about the experience with MEDi® after they proceeded to the holding area or OR (n = 6, 12.5%). While some patients and their families waited in the holding area, they were engaged in conversations about meeting the robot and sharing of positive experiences at the hospital. In other instances (i.e., in the OR), their discussion about MEDi® were encouragements made by parents and nurses to help children practice breathing exercises during the time of needle procedures. For instance, tissue breathing may have been expressed as: "…[child] talking about tissue breathing with mom in the holding area…, asking patient to do breathing", "encouraging breathing in through nose,

out through mouth", or "told [child] to breathe like MEDi® taught, and talking about [the] robot". For one patient, the child had kept the tissue used during the MEDi® intervention and was later prompted by her mother to complete breathing exercises with it in the OR. Although breathing techniques were not the only strategy utilized for pain management, the parent commented that "deep breathing is a very good coping mechanism… She [Child] was very scared, but the tissue breathing made her 'calm down perfectly'". As for standard care, observations about breathing-related behaviors in the OR were noted in only two patients (3% of 58 children who completed standard care). For these cases, one patient was encouraged by his mother to practice deep breathing in the OR (i.e., described as "rollercoaster breathing"). Another patient was noted to exhibit increased breathing while the child watched a pediatric anesthesiologist perform the IV procedure. However, given that no additional details were provided to describe the child's initial reaction to seeing the needle, increased breathing may have been a physiological response to heightened distress, rather than a positive coping behavior.

4.2.3 Hospital Experiences with MEDi® and IV Induction

At follow-up, children and their parents were prompted to freely recall their memories of the IV procedure and hospital visit (n = 26 in MEDi® group, n = 22 in standard care group). Using the Noel et al. revised scheme, moderate to strong interrater agreement was achieved throughout the coding process (see **Table 9**). In both groups, a combination of positive, negative, and neutral emotions was mentioned when study participants were asked to recall their overall experience with the hospital visit and IV induction procedure. Within the different types of negative emotions expressed, children and their parents did not relate their hospital experience with any memory of an angry emotional state.

Table 9. Interrater reliability for qualitative coding scheme.

Codes	Child		Parent	
	SSSU and OR	**IV procedure**	**SSSU and OR**	**IV procedure**
Positive emotion	1.00	0.91	0.96	0.87
Negative emotion				
Mad	-*	-*	-*	-*
Sad	1.00	1.00	0.79	0.90
Pain	1.00	0.87	1.00	0.93
Anxiety/Fear	1.00	1.00	0.91	0.70
Bad	0.88	1.00	0.91	1.00
Unspecified	-*	-*	0.78	0.66
Neutral emotion				
Present	0.63	1.00	1.00	-*
No emotions	0.96	0.96	1.00	1.00
Coping				
Breathing only	-*	-*	1.00	0.66
Robot only	1.00	1.00	1.00	1.00
Robot and breathing	1.00	-*	1.00	1.00
Ametop©	1.00	1.00	1.00	1.00
Distractions	0.95	1.00	0.82	0.73
Talk	1.00	1.00	0.96	0.86
Other	0.92	1.00	0.87	0.91
None	1.00	1.00	1.00	0.88
Body	0.94	0.95	0.90	0.90
Medical/Procedural	0.75	0.75	0.76	0.78

* No kappa statistic is provided because these codes were not assigned.

Note: Initial calibration of the revised coding scheme was completed with two coders reviewing five randomly selected interviews. Their codes were then evaluated to ensure that the coding scheme could appropriately capture the content in interview responses. Once calibration was achieved, coding was completed with all interviews following an iterative approach.

Then, the interview question about the effect of MEDi® preparation on the formation of pain-related memories, compared to standard care, was examined. Responses from a majority of participants included medical or procedural related details when asked to recall their overall hospital experience with the IV needle procedure. Some children and their parents also had memories of using Ametop© and other distractions at the hospital or during the IV procedure. Similarly, many parents considered conversing with their children or medical staff as a way to help children cope with procedural-related distress. Despite the existing strategies facilitated by nurses and medical staff, results suggested that children and their parents were also able to remember using deep breathing techniques that were taught or reinforced during the preparation with MEDi®. Uniquely, unlike parents who remembered their children performing breathing exercises during the hospital visit or in the OR, children did not recall any details about using this type of coping strategy alone. Rather, the only situation in which children remembered practicing breathing exercises in the hospital was when they also recalled receiving pre-operative teachings with the MEDi® robot. In other cases, some children solely recalled their interactions with MEDi® and did not include the use of deep breathing as a coping behavior during their hospital visit.

To address the final research question about the development of pain memories after IV induction, further examination of the children's and their parents' hospital experience between intervention groups was undertaken. Frequency statistics from both coders are presented in **Table 10 and 11**. The majority (n = 73, 76.0%) of study participants could recall details regarding the hospital environment or medical procedures. Approximately, one-third of children (n = 14, 29.2%) and their parents (n = 16, 33.3%) referred to a body part or sensation during the interview. Overall, parents mentioned more emotions than their children; however, most children

recalled the needle procedure as a neutral experience (i.e., without any emotion expressed in their interview). Although more children (Fisher's exact test (1) = 0.98, *p*s > 0.05) and their parents (Fisher's exact test (1) = 1.82, *p*s > 0.05) who interacted with MEDi® had recalled positive emotions about the IV procedure than those without the robot intervention, the difference was not statistically significant. Similar observations were also found with parent responses regarding their children's hospital visit (Fisher's exact test (1) = 3.78, *p*s > 0.05). When participants were asked about their hospital experience, several children (n = 12, 46.2%) and their parents (n = 12, 46.1%) remembered interacting with the MEDi® robot at the hospital. Some parents also perceived the interaction with MEDi® as providing good distraction to divert their children's attention from the upcoming medical procedures. Several children and their parents described the impact of this experience:

> "Little nervous and scared, went in and realized it wasn't so bad … During waiting, saw MEDi, [and] taught her tissue breathing… Once IV was in, she [child] didn't feel anything, lightheaded and dizzy during propofol, blinked eyes and fell asleep." (patient #47)

> "… She [Child] became distressed when she was told about the gas as she didn't like the smell. She was excited about the IV and numbing cream so she wouldn't have to get the gas. Loved meeting MEDi, still talks about meeting him." (parent #63)

> "… I remember your robot, that was cool I remember tissue breathing and going into the room where they do the surgery and going to sleep and they put the thing in my hand… they tried once to put it [the needle] in and I guess it missed cause they had to do it a couple more times. Then when they got it in the doctor told me that it would only take a

second then I was out. It was big, not the needle but the amount of sleeping stuff, the syringe...” (child #99)

“… The longer we waited he [child] got a little bit more nervous as time went on. What I think helped to be honest is when we got up to see the robot. It took his mind off of that for a bit. When he came back I noticed he was calmer than before…” (parent #99)

Although several children and their parents remembered meeting MEDi® as a positive event, 54% of the study participants (n = 14, total of 26 families in MEDi® group interviewed), who received a coaching preparation did not recall the robot at follow-up. Some children and their parents also recalled the IV procedure or surgery as a negative memory with untreated needle pain. That is, study participants who were initially prepared to receive inhalation anesthesia (i.e., patient was notified prior to hospital visit and expected to receive the breathing mask for induction) may also recall the IV needle insertion as being painful. The following quote describes the impact of both these aspects on pain perception:

“… we had discussed it prior, I had originally told her that she wouldn’t have to have a needle, I was expecting a mask induction. She was quite upset by it, she said that it hurt. She cried. Luckily they were pretty quick about it and induced her quickly. I don’t think she was very pleased, but everything went pretty smooth.” (parent #97)

This 4 year-old child had no documented history of hospital admissions or surgery events, and her discomfort received a wide range of scores across raters. She rated her pain and fear during the IV procedure to be the highest possible score (FPS = 10/10, CFS = 4/4), and yet the lowest possible scores were provided by the pediatric anesthesiologist (FPS = 2/10) and RA (CFS =

2/4). Two-weeks following the surgery, the patient and her parent continued to recall her initial self-reported levels of pain and fear about the IV procedure.

At the follow-up interview, many study participants recalled different types of coping strategies that were facilitated throughout their surgery stay. Additionally, results revealed that all children, who recalled doing deep breathing exercises, remembered meeting MEDi® at the hospital. That is, patients in the standard care group did not recall using breathing strategies during the IV procedure.

Table 10. Frequency of content codes in memory interviews (1st coder – RL).

Codes present*	Child (%)				Parent (%)			
	SSSU and OR		IV Procedure		SSSU and OR		IV Procedure	
	MEDi®	SC	MEDi®	SC	MEDi®	SC	MEDi®	SC
Positive emotion	5 (19.23)	4 (18.18)	5 (19.23)	2 (9.09)	20 (76.92)	11 (50.00)	22 (84.62)	15 (68.18)
Negative emotion								
Mad	-	-	-	-	-	-	-	-
Sad	-	1 (4.55)	-	1 (4.55)	-	2 (9.09)	4 (15.38)	2 (9.09)
Pain	1 (3.85)	3 (13.64)	5 (19.23)	5 (22.73)	1 (3.85)	2 (9.09)	5 (19.23)	4 (18.18)
Anxiety/Fear	6 (23.08)	2 (9.09)	1 (3.85)	3 (13.64)	8 (30.77)	8 (36.36)	6 (23.08)	2 (9.09)
Bad	1 (3.85)	4 (18.18)	1 (3.85)	1 (4.55)	4 (15.38)	2 (9.09)	2 (7.69)	2 (9.09)
Unspecified	-	-	-	-	4 (15.38)	2 (9.09)	1 (3.85)	1 (4.55)
Neutral emotion								
Present	3 (11.54)	1 (4.55)	-	3 (13.64)	1 (3.85)	4 (18.18)	1 (3.85)	-
No emotions	15 (57.69)	13 (59.09)	17 (65.38)	12 (54.55)	3 (11.54)	6 (27.27)	2 (7.69)	3 (13.64)
Coping								
Breathing only	-	-	-	-	1 (3.85)	-	2 (7.69)	-
Robot only	8 (30.77)	-	2 (7.69)	-	11 (42.31)	-	1 (3.85)	-
Robot and breathing	4 (15.38)	-	-	-	1 (3.85)	-	1 (3.85)	-
Ametop©	7 (26.92)	6 (27.27)	2 (7.69)	2 (9.09)	5 (19.23)	7 (31.81)	5 (19.23)	4 (18.18)
Distractions	6 (23.08)	7 (31.81)	3 (11.54)	3 (13.64)	6 (23.08)	5 (22.73)	7 (26.92)	9 (40.91)
Talk	1 (3.85)	3 (13.64)	1 (3.85)	3 (13.64)	10 (38.46)	9 (40.91)	10 (38.46)	8 (36.36)
Other	4 (15.38)	3 (13.64)	5 (19.23)	3 (13.64)	8 (30.77)	11 (50.00)	9 (34.62)	7 (31.81)
None	5 (19.23)	10 (45.45)	15 (57.69)	11 (50.00)	4 (15.38)	7 (31.81)	6 (23.08)	4 (18.18)
Body	5 (19.23)	6 (27.27)	7 (26.92)	7 (31.81)	6 (23.08)	8 (36.36)	8 (30.77)	5 (22.73)
Medical/Procedural	20 (76.92)	17 (77.27)	15 (57.69)	11 (50.00)	20 (76.92)	20 (90.91)	18 (69.23)	16 (72.73)

Note: Standard care (SC)

Table 11. Frequency of content codes in memory interviews (2nd coder – CK).

Codes present	Child (%)				Parent (%)			
	SSSU and OR		IV procedure		SSSU and OR		IV procedure	
	MEDi®	SC	MEDi®	SC	MEDi®	SC	MEDi®	SC
Positive emotion	5 (19.23)	4 (18.18)	5 (19.23)	1 (4.55)	20 (76.92)	10 (45.45)	22 (84.62)	16 (72.73)
Negative emotion								
Mad	-	-	-	-	-	-	-	-
Sad	-	1 (4.55)	-	1 (4.55)	1 (3.85)	2 (9.09)	4 (15.38)	1 (4.55)
Pain	1 (3.85)	3 (13.64)	5 (19.23)	5 (22.73)	1 (3.85)	2 (9.09)	4 (15.38)	4 (18.18)
Anxiety/Fear	6 (23.08)	2 (9.09)	1 (3.85)	3 (13.64)	9 (34.62)	7 (31.81)	4 (15.38)	4 (18.18)
Bad	-	4 (18.18)	1 (3.85)	1 (4.55)	4 (15.38)	3 (13.64)	2 (7.69)	2 (9.09)
Unspecified	-	-	-	-	3 (11.54)	1 (4.55)	1 (3.85)	1 (4.55)
Neutral emotion								
Present	4 (15.38)	1 (4.55)	-	3 (13.64)	1 (3.85)	4 (18.18)	-	-
No emotions	14 (53.85)	13 (59.09)	17 (65.38)	11 (50.00)	3 (11.54)	6 (27.27)	2 (7.69)	3 (13.64)
Coping								
Breathing only	-	-	-	-	1 (3.85)	-	1 (3.85)	-
Robot only	8 (30.77)	-	2 (7.69)	-	11 (42.31)	-	1 (3.85)	-
Robot and breathing	4 (15.38)	-	-	-	1 (3.85)	-	1 (3.85)	-
Ametop©	7 (26.92)	6 (27.27)	2 (7.69)	2 (9.09)	5 (19.23)	7 (31.81)	5 (19.23)	4 (18.18)
Distractions	7 (26.92)	7 (31.81)	3 (11.54)	3 (13.64)	4 (15.38)	6 (27.27)	8 (30.77)	10 (45.45)
Talk	1 (3.85)	3 (13.64)	1 (3.85)	3 (13.64)	11 (42.31)	9 (40.91)	8 (30.77)	7 (31.81)
Other	5 (19.23)	3 (13.64)	5 (19.23)	3 (13.64)	10 (38.46)	10 (45.45)	10 (38.46)	6 (27.27)
None	5 (19.23)	10 (45.45)	15 (57.69)	11 (50.00)	4 (15.38)	7 (31.81)	7 (26.92)	5 (22.73)
Body	6 (23.08)	6 (27.27)	8 (30.77)	7 (31.81)	7 (26.92)	7 (31.81)	7 (26.92)	6 (27.27)
Medical/Procedural	19 (73.07)	20 (90.91)	15 (57.69)	9 (40.91)	20 (76.92)	21 (95.45)	21 (80.77)	17 (77.27)

Note: Standard care (SC)

4.3 Summary of Findings

In summary, the results reported in this chapter provide several insights to understanding the efficacy of MEDi® on how pediatric patients and their parents tolerate stressful procedures performed in the OR. Demographics and pre-intervention measures were similar for study participants in both groups.

In receiving additional preparation with MEDi® prior to the IV induction, children did not experience significant differences or changes over time in pain, compared to those without MEDi®. Likewise, no mean differences in children's fear were found during the pre-procedural, procedural, or post-procedural phases. Overall, agreement was found between patient and observer reports of pain and fear during IV insertion. There is also supporting evidence that children's perceived pain and fear in the OR is positively linked to their recall and anticipatory levels of pain and fear at two-week follow-up. A number of demographic factors were related to the level of pain or fear that children experienced: children's age, previous number of hospital admissions and surgeries, children's recall of pain after last surgery, father's level of education, and parental pain catastrophizing and anxiety. However, patients who received MEDi® preparation to cope with needles were more likely to complete the IV induction, compared to standard care.

At the post-procedural phase, parental self-efficacy measures did not suggest any change in their perceived ability to manage children's pain and fear during future needle procedures. When asked to recall their hospital experiences, memories of children and their parents were expressed with a collection of positive, neutral, and negative emotions. Although the emotions used to describe their surgical visit were not statistically significant between groups, most parents with children, who received support from MEDi®, described the IV procedure as a

positive experience (n = 22, 84.6%). One-third of study participants were able to recall meeting the robot and the positive experiences of MEDi® in their hospital care, including the opportunity to use deep breathing as a coping skill. RAs also noted that, in both groups, some parents provided assistance to help children practice deep breathing exercises during the procedural phase. Evidence from frequency analyses further indicated that many participants from both groups could recall one or more forms of pain management strategies used to cope with needles in the OR (e.g., topical numbing cream, distractions, engaging in conversations).

Following this chapter, the manuscript summarizes the research methods and main findings of this study. The manuscript concludes with a discussion about the impact of MEDi® on patients' ability to complete IV inductions, including relevant limitations to the clinical study and suggested areas of future investigation regarding robotic applications in family-centered care.

CHAPTER FIVE: MANUSCRIPT

Title: Impact of MEDi® preparation on children's ability to tolerate IV induction: a randomized-controlled trial

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Abstract

Intravenous (IV) lines are routinely administered to pediatric patients prior to the delivery of anesthesia for elective surgery. Aside from using volatile anesthetics to aid with needle insertion, IV lines are often placed while children are awake in the operating room (OR). Although IV inductions are safe and usually well-tolerated, many still express needle-related discomfort despite the current strategies that can minimize procedural pain. This randomized-controlled, two-armed trial examined the impact of a humanoid robot (MEDi®) programmed to teach breathing strategies, on children's ability to tolerate IV procedures. A total of 137 children (4-12 years) were recruited in Short Stay Surgery at a tertiary pediatric hospital. Patients were randomly assigned to standard care or a robot-facilitated intervention that taught breathing strategies before the IV procedure. Children's pain and fear before, during, and after induction were rated by patients, parents, pediatric anesthesiologists, and researchers. Follow-up interviews were conducted with children and their parents to assess pain-related memories. No significant differences or changes in fear and pain were found between study groups (ps > 0.05). However, it is evident that children enjoyed interacting with MEDi® and exhibited higher use of breathing-based strategies in the OR (Fisher's exact: $X^2(1) = 4.66$, $p < 0.05$, $\varphi_c = 0.21$). They were also 5.04 times more likely to complete IV induction (without inhalational anesthetics), compared to standard care (Fisher's exact: $X^2(1) = 4.85$, $p < 0.05$, $\varphi_c = 0.22$). This study was the first to examine children's experience of IV induction when provided support from MEDi®.

(250/250 words)

Summary

This is the first clinical study that evaluates the use of MEDi®, a humanoid robot, to teach breathing strategies that help children tolerate IV inductions.

(25/25 words)

Keywords

pain management, pediatric pain, psychology, robotics, human-robot interaction, intravenous induction

1. Introduction

Venous cannulation is a source of pediatric procedural pain [22,39], particularly for most surgical patients who require an intravenous (IV) line for anesthetic delivery. Pediatric anesthesiologists can choose to either conduct the needle insertion while patients are awake or asleep using inhalational induction in the operating room (OR). Although both approaches are safe, the breathing mask may not be well-tolerated by children regardless of use of flavors, parental presence, or distractions [79,102,154]. There are clinical circumstances when an IV induction is selected over inhalational induction (e.g., malignant hyperthermia, congenital heart defect) [30,38,112]. However, despite the delivery of various evidence-based pain management strategies, some children still express feelings of discomfort during needle insertions [145]. If untreated, there are short- and long-term consequences with needle pain, including prolonged recovery times and avoidance of medical care [146]. Thus, novel approaches must be considered.

Several factors are implicated in the onset and maintenance of needle-related pain or fear [122]. Research indicates that children's previous hospital or pain events could increase procedural pain [75,93]. Parental factors may also be relevant predictors of suboptimal outcomes

in their children (i.e., distress-promoting behaviors, low self-efficacy, and anxious predispositions) [24,90,122]. Emerging evidence further suggests that pain-related memories from previous procedures can negatively influence children's ability to tolerate future needles [108,109]. Thus, research suggests that various factors may be related to procedural outcomes and children's ability to tolerate needle pain.

Although ongoing efforts seek to investigate effective pharmacological treatments, children continue to report procedural-related pain [42,103,141]. Their isolated use is often inadequate for acute pain reduction; therefore, the addition of noninvasive psychological therapies has gained acceptance [10,54,140]. As an established psychological therapy to change maladaptive thought and behavioral patterns, cognitive-behavioral strategies (e.g., deep breathing exercises) aim to help children manage distress and are shown to be effective for needle procedures [68,120,151]. Given children's enjoyment of technology-enhanced devices, pre-programmed cognitive-behavioral strategies that are facilitated by a humanoid robot may help them tolerate discomfort during IV inductions. Studies have shown that MEDi® (NAO® robot produced by Softbank Robotics) reduces children's pain and fear during medical procedures [8,48]. Its ease of operation and versatility for children may offer a promising intervention for patients receiving IV inductions.

We hypothesized that patients who were taught breathing strategies by MEDi® would be more tolerant to IV induction compared to the standard care. Specifically, we expected that they would experience less pain and fear, require fewer needle attempts to secure IV lines, and be less likely to require inhalational anesthetics to aid with induction. We also expected that they would develop reduced pain-related memories about IV procedures. Since parents were also invited into the MEDi® preparation, we predicted that they would develop self-efficacy to manage needle

discomfort. Finally, several child (e.g., past pain events) and parent factors (e.g., education, self-efficacy, anxiety, pain-catastrophizing) were measured to determine their role in children's experiences of IV induction.

(494/500 words)

2. Methods

2.1 Participants and Settings

A total of 137 children undergoing surgical procedures requiring IV placement in the OR at a mid-Western children's hospital were recruited between July 2016 and May 2018. This clinical trial was registered and the full protocol is available (ClinicalTrials.gov Identifier ID: NCT02859051). Ethics approval was obtained from the Conjoint Health Research Ethics Board at the University of Calgary.

2.2 Inclusion/Exclusion Criteria

Eligible participants included pediatric patients between the ages of 4-12 years presenting at the Surgery Short Stay Unit (SSSU) for elective surgery with a parent or legal guardian and fulfilled the American Society of Anesthesiology class I or II criteria of physical fitness [99]. Participants were excluded from study involvement based on the following criteria: 1) an IV line was already in place, 2) developmental disability or hearing/visual impairment that would preclude completion of self-report measures, 3) language barrier that compromised English comprehension, 4) contraindication to receiving IV anesthetics (i.e., propofol, lidocaine), 5) received anxiolytic premedication to facilitate IV insertion, or 6) preference for inhalation anesthesia by family or pediatric anesthesiologist prior to entering the OR.

2.3 Trial Design and Randomization

This randomized-controlled, two-armed trial in the pediatric surgical unit adhered to methodological standards set out by the Consolidated Standard of Reporting Trials guidelines for randomized clinical trials [19]. A pilot study was conducted to refine and evaluate the feasibility of the *a priori* study protocol in the clinical setting. The randomization of participants to either the standard care or robot intervention (a pre-operative preparation offered in addition to standard care) arm was determined by random sequence allocation using Research Randomizer©. The numeric code for randomization was secured in an opaque envelope until the time of intervention allocation, at which point it was opened. All physical research data were stored securely in a locked cabinet with access only granted to pertinent research personnel, and patient identifiers were removed prior to conducting analyses.

2.4 Flow of Participants

Figure 1 depicts the flow of participants through each study phase: pre-procedural, procedural, post-procedural. A total of 137 participants were screened for eligibility, with 119 who provided consent and were randomly assigned to receive MEDi® intervention (n = 59) or standard care (n = 60). Of those, 103 children received the assigned study intervention or standard care with anesthetic induction, while the remaining 16 had insufficient time for completion of the MEDi® intervention (n = 14) or the standard care treatment (n = 1). Only one child in the standard care group withdrew from the study at this stage. The follow-up response rate in the post-procedural phase was 47% (n = 26 in MEDi® group, and n = 22 in standard care group). The mean number of days to complete follow-up interviews with families was 17 days (SD = 5.3, minimum = 13 days, maximum = 37 days). The final sample size included in data analyses is 103 participants (n = 45 in MEDi® group, n = 58 in standard care group).

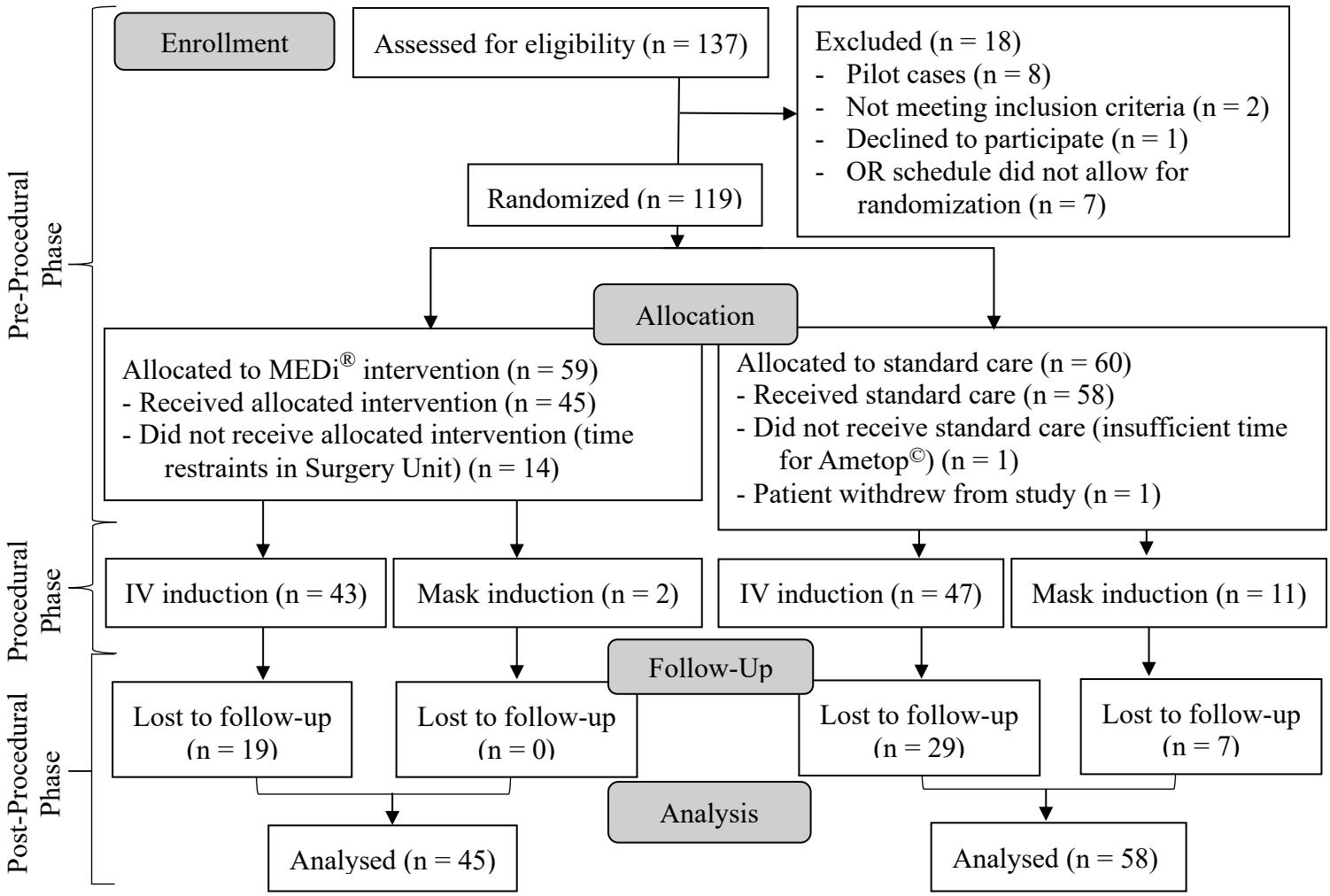

Figure 1. CONSORT flow diagram.

2.5 Study Procedures

2.5.1 Pre-Procedural Phase

Once the initial screening to determine patient eligibility was completed by a SSSU nurse, written informed consent was obtained by two research assistants (RAs) with child assent also obtained for ages seven years or older. Families were then asked to schedule a telephone interview and were provided with a take-home package containing rating scales, which were to

be opened at follow-up. Demographic and clinical information was collected from children and their parents, who then completed the pre-procedural measures shown in **Table 1**.

Table 1. Measures reported in the pre-procedural, procedural, and post-procedural phases.

Time/Location	Measures	Raters
Pre-procedural phase		
In SSSU	Children's fear (anticipated)	Child, parent
	Parents' self-efficacy	Parent
	Parents' pain catastrophizing	Parent
	Parents' anxiety	Parent
Procedural phase		
Before IV insertion	Children's fear (anticipated)	Child, parent
After IV insertion	Children's fear and pain	Child, parent, anesthesiologist (blinded), RA (blinded)
During propofol bolus	Children's fear and pain	RA (blinded)
Post-procedural phase		
Two-week follow-up	Children's fear before IV insertion (recalled)	Child, parent
	Children's fear and pain during IV insertion (recalled)	Child, parent
	Children's fear and pain (anticipated)	Child, parent
	Parents' self-efficacy (anticipated)	Parent

Next, participants were randomized to receive either the MEDi® robot intervention or standard care before undergoing IV insertion. Randomization was conducted by one RA who opened a randomization envelop. The pediatric anesthesiologists, surgical staff, and second RA were blinded from the group allocation to minimize observer bias when rating procedural discomfort. All patients received Ametop©, a local anesthetic applied on the dorsum of their hands by a nurse 30-45 minutes prior to the IV procedure. For standard care, patients received only Ametop© and continued waiting until the OR was ready. Healthcare providers were able to provide comfort and psychosocial support for distressed patients using various methods of pre-operative pain management available (e.g., oral analgesics, distractions, non-procedural conversations). For the MEDi® robot group, a preparation described below was given in addition

to the standard care provided by the pediatric anesthesiologist and surgical team. After the application of Ametop©, MEDi® was introduced to children as a non-pharmacological strategy to help them cope with the upcoming IV induction procedure. The robot coaching session was administered an average of 42.50 minutes before the scheduled surgery (SD = 17.88, minimum = 6 minutes, maximum = 88 minutes).

MEDi® Intervention

Pre-operative coaching of children and their parents with MEDi® was delivered in a private room while they waited for surgery. MEDi®, a two-foot tall humanoid robot, was situated on a cart at the child's eye level (see **Figure 2**). The robot's actions were controlled with a tablet operated by the RA who was not blinded from randomization. Pre-programmed to demonstrate deep breathing techniques, MEDi® encouraged children to practice this skill with the aid of its lights and sound effects. Specifically, MEDi® held a tissue in its hand and invited children and their parents to participate by blowing on the tissue as a means of practicing deep breathing. MEDi® would also engage with study participants using a combination of dialogue and dance moves throughout the preparation. The mean duration of the intervention was 10 minutes (n = 45, minimum = 5 minutes, maximum = 20 minutes).

Figure 2. Technology-enhanced pre-operative education with MEDi®.

2.5.2 Procedural Phase

Using an IV set and Y-piece tubing attachment primed with 2% lidocaine pre-prepared by the pediatric anesthesiologist, the IV needle was inserted into a hand vein within the region that the Ametop© had been applied and secured with an adhesive tape. To induce general anesthesia, syringes of propofol-lidocaine admixtures (1 mL of 2% lidocaine per 9 mL of propofol emulsion) were given through the IV cannula by pediatric anesthesiologists. As indicated in **Table 1**, children's pain and fear were assessed by multiple raters at several time points. Parents and medical staff were permitted to employ different pain management strategies during IV insertion to maintain the natural interactions that usually take place in the OR (e.g., distractions, child/parent positioning, emotional support, use of tourniquet). Observations of patients' behavior were documented by RAs (those blinded from the randomization) in the surgical holding area and OR.

2.5.3 Post-Procedural Phase

Two weeks following surgery, study participants were contacted to evaluate memories of pain pertaining to their hospital and IV induction experiences. Telephone interviews were conducted by RAs with the parent and then separately with their child to avoid bias in memory recall.

2.6 Primary Outcome Measures

2.6.1 Pain

Children, their parents, RAs, and pediatric anesthesiologists rated pain using an adapted version of the Faces Pain Scale-Revised (FPS-R), a six-item face scale that depicts gradual expressions of increased pain (0 = no pain, 10 = most pain) [65]. Studies have shown high concurrent validity and test-retest reliability with FPS-R scores, suggesting that the FPS-R to be an age-appropriate measure of children's pain [52,144]. Alphabet letters were used to label items on the FPS-R scale so children could easily select and communicate the face that aligned with their pain experiences.

2.6.2 Fear

All raters assessed needle-related fear using the Child Fear Scale (CFS) adapted from McMurtry et al., a five-item face scale depicting incremental expressions of increased fear (0 = no fear, 4 = most fear) [25,93]. Evidence of interrater and test-retest reliability, as well as concurrent and discriminant validity in different clinical settings, have supported its use to measure children's fear [81]. Similar to the pain measurement scale, letters were used to label the CFS faces.

2.7 Secondary Outcome Measures

2.7.1 Parental Catastrophizing

Parents completed the Pain Catastrophizing Scale – Parent Version (PCS-P) in the SSSU, to assess catastrophic thoughts and feelings when their children experienced pain. The 13 items were rated with a 5-point Likert scale, resulting in a total score (maximum of 52) and 3 subscale scores in the areas of rumination, magnification, and helplessness were assigned [139]. Good internal consistency and validity have shown that the PCS-P is a suitable indicator of parental catastrophizing [59,108]. A total score of 30 or higher is considered a clinically relevant level of parental pain catastrophizing when their children were admitted to the hospital for surgery.

2.7.2 Parental Self-Efficacy

Parents were asked to rate three closed-ended questions adapted from the Pain Self-Efficacy Questionnaire [35,101,105]: “How much do you think that you will be able to help [child’s name] feel less pain (or fear) at his/her needle procedure?” (0 = no ability to reduce child’s pain/fear, 10 = total ability to reduce child’s pain/fear’), “How anxious do you think you will feel during the needle procedure” (0 = not at all nervous or anxious, 10 most nervous or anxious). Parental measures for the first two questions were found to be correlated with each other (r = 0.55, $p < 0.05$), but not with the third question about anxiety ($ps > 0.05$). Thus, the mean score of the first two questions was used to measure parents’ self-efficacy to manage their children’s discomfort, while the score for the third question was used to assess parent’s pre-procedural anxiety.

2.7.3 Pain Related Memories

Participants were first asked two open-ended questions regarding how they felt on the day of the surgical visit (i.e., “I would like you to tell me everything that you can remember about when you and [child’s name] came to the hospital for his/her surgery”, “I would like you to tell me everything that you can remember about when [child’s name] was getting their IV in just before their surgery”). Additional information was gathered about the occurrence of post-operative painful events and how often the IV induction procedure had been discussed with the child since discharge. Any mention of the MEDi® robot or use of breathing techniques as a coping strategy during the surgical visit was documented.

2.7.4 Additional Behaviors

Child and parent behaviors during the robot interventions, waiting times, and IV procedures were recorded. In addition to pain management strategies used to comfort patients, interactions between patients, their parents, and medical staff in the OR were further noted.

Information about the IV induction experience was also gathered. First, we recorded the amount of time required to secure IV access in the child’s hand (from the moment the needle first contacted the skin to the time when an adhesive tape was applied to secure the IV on the dorsum of hand). Also recorded were the number of needle attempts made by the pediatric anesthesiologist, and whether the breathing mask was used prior to sedation as a means of helping calm children.

2.8 Data Analysis Plan

The sample size was determined to be 110 children *a priori*; based on a power size of 0.80 and alpha level of 0.05 for a moderate effect using two-tailed tests. This sample size would detect a minimum clinically significant difference of 2.0 or one face on the FPS-R.

All quantitative data collected from patients who attempted IV induction, including participants with incomplete follow-up interviews, were analyzed using IBM SPSS (Statistical Package for the Social Sciences) v.24. Between-group comparisons of children's pain and fear, and parental self-efficacy were performed using one-way analysis of variance (ANOVA) and repeated measures ANOVA. Chi squared tests of association were used to compare the allocated treatments with respect to categorical data. Possible violations in the assumptions of normal distribution, independent observations, and equal variances were examined. For data violating these assumptions, the equivalent non-parametric analyses were performed using the Fisher's exact test. Significant *p*-values were adjusted with Bonferroni correction to reduce the risk of Type 1 errors when performing multiple comparisons. Bivariate Pearson's product-moment correlation coefficient analyses were also performed to evaluate the associations between children's pain and fear with demographic variables.

Behaviors recorded during the hospital visit were coded to identify common themes regarding the use of breathing skills and other pain management strategies to help children complete IV inductions. Responses from the follow-up interviews were coded by two independent researchers, using a coding scheme adapted from Noel et al. [107]. Of note, only observations collected during the hospital visit are discussed in this paper.

3. Results

3.1 Sociodemographics and Clinical Data

Demographic characteristics for children and their parents are presented in **Table 2**. There were no significant differences in participant characteristics between the two allocated treatments. Children were primarily Caucasian and most of their parents had completed education at the college-level or higher. The mean wait time in the SSSU was 69 minutes (n = 101, SD = 26

minutes) and total time that researchers spent with families was 105 minutes (n = 95, SD = 42 minutes). Some children (8%) reported experiencing pain-related conditions prior to this hospital visit (i.e., arthritis or joint -related pain, abdominal pain, shoulder pain, leg and ankle pain). Previous illnesses experienced by 18% of children included achondroplasia, acute lymphoid leukemia, celiac disease, hernia, Bell's palsy, kidney infection, asthma, respiratory syncytial viral infection, pneumonia, rheumatoid arthritis, cellulitis, large cell hepatitis, patent ductus arteriosus, and eye-related conditions. Known allergies reported in 22% of children were amoxicillin, pet dander, pollen, perfumes, mold, nuts, grass, and hay fever.

3.2 Group Equivalence on Pre-Procedural Measures

As shown in **Table 2**, fear scores provided by patients and their parents were low at the time of hospital admission. Also, parental self-efficacy to manage their children's discomfort was moderate. Parents' level of pre-procedural anxiety towards their children's IV procedure was low, as was their pain catastrophizing scores. No significant differences were found between groups.

3.3 Use of Pain Management and Support Resources

Table 2 also describes the different pain management strategies, in addition to MEDi® and Ametop©, used prior to entering the OR. Most patients who received MEDi® (98%) and standard care (84%) used at least one strategy while waiting for surgery, with distractions found to be most frequently utilized. Some families (38%) had accessed support resources to prepare for surgery. Most parents (95%) had spoken with their children in advance about surgical details, benefits to undergoing surgery, or potential blood loss as a result of medical procedures.

Table 2. Means and standard deviations of child and parent characteristics (pre-procedure phase).

Correlates	Total (n = 103)	MEDi® (n = 45)	Standard care (n = 58)	Statistic(df)	p
Child characteristics					
Sex (%)				$X^2(1) = 1.35$	0.25
Male	57 (55.34)	22 (48.89)	35 (60.34)		
Female	46 (44.66)	23 (51.11)	23 (39.66)		
Race (%)				-	-
Caucasian	66 (64.08)	27 (60.00)	39 (67.24)		
Metis	3 (2.91)	1 (2.22)	2 (3.45)		
Asian	12 (11.65)	6 (13.33)	6 (10.34)		
East Indian	6 (5.83)	3 (6.67)	3 (5.17)		
Aboriginal	2 (1.94)	1 (2.22)	1 (1.72)		
Black	3 (2.91)	-	3 (5.17)		
Hispanic	2 (1.94)	-	2 (3.45)		
Other	9 (8.74)	7 (15.56)	2 (3.45)		
Age in years	7.56 (2.60)	7.47 (2.67)	7.63 (2.56)	$F(1,100) = 0.10$	0.75
Past admissions	1.07 (3.00)	1.40 (3.84)	0.81 (2.15)	$F(1,101) = 0.97$	0.33
Past surgeries	0.88 (2.24)	0.78 (2.23)	0.97 (2.27)	$F(1,101) = 0.18$	0.68
Pain after last surgery*	4.62 (2.91)	4.36 (3.12)	4.80 (2.82)	$F(1,32) = 0.19$	0.67
Past IV starts	3.91 (15.71)	3.18 (14.80)	4.48 (16.48)	$F(1,101) = 0.17$	0.68
Pain conditions (%)	8 (7.76)	4 (8.89)	4 (6.90)	$X^2(1) = 0.14$	0.73
Previously diagnosed illnesses (%)	19 (18.45)	9 (20.00)	10 (17.24)	$X^2(1) = 0.13$	0.72
Parent characteristics					
Mother's education (%)				$X^2(1) = 2.27$	0.13
High school or under	20 (19.42)	12 (26.67)	8 (13.79)		
University/College	80 (77.67)	33 (73.33)	47 (81.03)		
Not applicable/missing	3 (2.91)	-	3 (5.17)		
Father's education (%)				$X^2(1) = 0.90$	0.34
High school or under	24 (23.30)	13 (28.89)	11 (18.97)		
University/College	72 (69.90)	31 (68.89)	41 (70.69)		
Not applicable/missing	7 (6.80)	1 (2.22)	6 (10.34)		

Table 2 (continued). Mean and standard deviations of child and parent characteristics (pre-procedure phase).

Correlates	Total (n = 103)	MEDi® (n = 45)	Standard care (n = 58)	Statistic(df)	p
Parents' self-efficacy	6.62 (2.20)	6.78 (1.92)	6.49 (2.39)	$F(1,101) = 0.43$	0.51
Parents' anxiety	3.60 (3.15)	3.00 (2.86)	4.07 (3.29)	$F(1,101) = 2.99$	0.09
Pain catastrophizing	16.80 (8.03)	17.56 (9.32)	16.21 (6.90)	$F(1,101) = 0.71$	0.40
Helplessness	5.47 (3.75)	5.89 (4.28)	5.14 (3.28)	$F(1,101) = 1.02$	0.32
Magnification	2.67 (1.82)	3.00 (2.23)	2.41 (1.38)	$X^2(1) = 1.06$ ǂ	0.30
Rumination	8.66 (3.64)	8.67 (3.68)	8.66 (3.65)	$F(1,101) = 0.00$	0.99
Pre-operative pain management (%)					
Pharmacological pain management strategies					
Oral analgesics (i.e., Tylenol, Advil)	93 (90.29)	44 (97.78)	49 (84.48)	$X^2(1) = 5.11$	0.04
Non-pharmacological strategies **				-	-
Ice/Heat compress	3 (2.91)	2 (4.44)	1 (1.72)		
Comfort items (e.g., stuffed animals, blankets)	13 (12.62)	9 (20.00)	4 (6.90)		
Distraction activities (e.g., books, toys, electronics)	58 (56.31)	30 (66.67)	28 (48.28)		
Breathing exercises	4 (3.88)	-	4 (6.90)		
Parental presence	6 (5.83)	2 (4.44)	4 (6.90)		
Parent-child conversations	98 (95.15)	41 (91.11)	57 (98.28)	$X^2(1) = 1.72$	0.31
Support accessed (e.g., doctors, pamphlets)	35 (33.98)	18 (40.00)	17 (29.31)	$X^2(1) = 1.49$	0.29
Information sessions attended (i.e., Surgery 101)	4 (3.88)	1 (2.22)	3 (5.17)	$X^2(1) = 0.59$	0.63

ǂ Kruskal-Wallis *H* Tests performed for data that violated assumptions of homogeneity.
* Pain assessed on an 11-point numerical rating scale.
** One or more strategies may have been coded per patient.

3.4 Primary Outcome Results

3.4.1 Children's Pain

As shown in **Table 3**, no significant between group differences were found. Children, their parents, RAs, and pediatric anesthesiologists reported needle pain and fear at all phases to be at the lower end of severity. In addition, pain scores did not significantly change between the procedural and post-procedural phases, and there were no between-subject effects, for child ($F(2,84) = 0.56$, $p = 0.57$) or parent ($F(2,88) = 0.16$, $p = 0.85$) reports between the MEDi® and standard care groups.

3.4.2 Children's Fear

Similar results were found for fear (see **Table 3**). Scores were also in the low range and did not significantly differ between the MEDi® and standard care groups. Fear did not significantly change across the three phases according to children ($F(5,195) = 1.76$, $p = 0.12$) and parents ($F(2,210) = 1.75$, $p = 0.15$). No interaction effects were found between the two groups.

Table 3. Self- and observer-reported ratings for children's pain and fear by treatment condition.

Pain/Fear	MEDi® Mean (SD)	Standard care Mean (SD)	Statistic(df)	p*
Pre-procedural phase				
Fear before IV				
Child	0.98 (1.18)	0.91 (0.92)	$F(1,101) = 0.10$	0.76
Parent	1.02 (1.06)	1.09 (0.94)	$F(1,101) = 0.11$	0.75
Procedural phase				
Fear before IV				
Child	1.16 (1.26)	1.13 (1.02)	$F(1,97) = 0.02$	0.89
Parent	1.41 (1.19)	1.38 (1.05)	$F(1,98) = 0.02$	0.88
Pain during IV insertion				
Child	2.74 (2.96)	2.76 (2.97)	$F(1,91) = 0.00$	0.98
Parent	2.86 (2.46)	2.70 (2.78)	$F(1,96) = 0.09$	0.77
RA	2.76 (2.70)	2.67 (2.57)	$F(1,97) = 0.03$	0.87
Anesthesiologist	2.55 (2.74)	2.27 (2.69)	$F(1,94) = 0.25$	0.62
Fear during IV insertion				
Child	1.39 (1.34)	1.14 (1.13)	$F(1,90) = 0.96$	0.33
Parent	1.59 (1.06)	1.31 (1.08)	$F(1,96) = 1.61$	0.21
RA	1.56 (1.08)	1.19 (0.97)	$F(1,97) = 3.23$	0.08
Anesthesiologist	1.20 (1.16)	1.12 (1.22)	$F(1,95) = 0.12$	0.73
Pain during propofol bolus				
Researcher	0.93 (2.02)	1.46 (2.60)	$F(1,89) = 1.15$	0.29
Fear during propofol bolus				
Researcher	0.67 (0.99)	0.65 (0.81)	$F(1,89) = 0.02$	0.88
Post-procedural phase				
Recalled fear in OR				
Child	1.42 (1.17)	1.49 (1.05)	$F(1,44) = 0.01$	0.95
Parent	1.23 (0.95)	1.35 (0.99)	$F(1,44) = 0.17$	0.68
Recalled pain during IV				
Child	3.23 (3.58)	2.67 (2.48)	$F(1,45) = 0.38$	0.54
Parent	2.69 (2.65)	2.76 (2.72)	$F(1,45) = 0.01$	0.93
Recalled fear during IV				
Child	1.12 (1.33)	1.05 (0.89)	$F(1,43) = 0.04$	0.84
Parent	1.46 (1.24)	1.25 (0.97)	$F(1,44) = 0.40$	0.53
Anticipated pain for next IV				
Child	3.12 (3.22)	3.82 (3.14)	$F(1,45) = 0.56$	0.46
Parent	3.08 (2.28)	3.00 (2.20)	$F(1,46) = 0.01$	0.91
Anticipated fear for next IV				
Child	1.28 (1.46)	1.20 (0.95)	$F(1,43) = 0.05$	0.83
Parent	1.15 (1.29)	1.35 (1.09)	$F(1,44) = 0.30$	0.59

*Adjusted alpha-levels with Bonferroni correction are 0.006 for 9 group comparisons performed with FPS scores and 0.003 for 15 group comparisons performed with CFS scores. A significant difference is suggested if the *p*-value is less than this adjusted value.

3.4.3 Demographic Factors Related to Pain and Fear

To understand the role of child and parent factors in patients' experience of the IV procedure, correlational analyses examined the relationship of these variables and pain scores (see **Table 4**). Pain was not significantly correlated with the demographic variables, with the exception of child age and parental anxiety. That is, younger children were likely to expect high needle pain during their next IV procedure. The positive correlation between parents' anxiety and their pain ratings indicated that anxious parents were likely to rate that their children experienced more pain during needle procedures. When child age and parental anxiety were added as covariates in the previous analyses of pain scores, there was no change in the results (*ps* > 0.05).

Also described in **Table 4** is the relationship of demographic factors with pre-procedural, procedural, and post-procedural fear. Similar to pain, patient's age was also significantly correlated with child and parent reports of needle fear. In addition, a number of factors were found to be correlated with fear scores, including children's history of pain events, father's level of education, and parents' pain catastrophizing. When these pre-procedural measures were examined as covariates, there remained no significant group differences or changes over time for fear (*ps* > 0.05).

Table 4. Demographic factors related to children's pain and fear.

Location/Rater	Child factors					Parent factors				
	Age	Previous admissions	Previous surgeries	Pain from last surgery	Previous IVs	Mother's education	Father's education	Self-efficacy	Anxiety	Pain catastrophizing
Pre-procedural phase										
Fear before IV										
Children	0.13	0.13	0.05	0.27	0.00	-0.41	0.00	-0.07	0.09	0.10
Parent	0.39**	0.22*	0.09	0.24	0.06	-0.04	0.01	-0.06	0.24*	0.22*
Procedural phase										
Fear before IV										
Child	0.31**	0.20	0.03	0.43*	0.15	-0.01	-0.04	0.03	0.08	0.06
Parent	0.22**	0.26**	0.18	0.10	0.06	0.07	0.06	-0.03	0.17	0.22*
Pain during IV										
Child	0.00	0.03	-0.09	-0.03	0.07	-0.10	-0.20	0.04	0.02	0.09
Parent	0.11	0.06	0.01	0.15	0.04	-0.09	-0.17	0.09	0.20*	0.10
RA	0.03	0.14	0.17	0.05	0.05	-0.06	-0.11	0.01	-0.05	-0.03
Anesthesiologist	0.03	-0.42	-0.06	0.16	0.08	0.07	-0.10	0.03	-0.05	-0.05
Fear during IV										
Child	0.19	0.16	0.22*	0.14	-0.07	0.01	-0.25*	0.07	0.00	0.11
Parent	0.16	0.25*	0.07	0.24	-0.11	-0.13	-0.26*	0.07	0.11	0.26**
RA	0.02	0.25*	0.07	0.40*	0.07	-0.08	-0.11	0.19	-0.02	-0.01
Anesthesiologist	0.04	0.16	0.04	0.22	0.03	0.06	-0.13	0.06	-0.13	0.04
Pain during propofol bolus										
RA	-0.04	0.04	0.10	0.09	-0.05	-0.01	-0.07	0.08	-0.13	-0.12
Fear during propofol bolus										
RA	-0.07	0.16	0.12	0.26	0.01	0.03	-0.18	0.12	-0.17	-0.10

Table 4 (continued). Demographic factors related to children's pain and fear.

Location/Rater	Child factors					Parent factors				
	Age	Previous admissions	Previous surgeries	Pain from last surgery	Previous IVs	Mother's education	Father's education	Self-efficacy	Anxiety	Pain catastrophizing
Post-procedural phase										
Recalled fear in OR										
Child	-0.05	0.06	0.03	-0.06	0.08	0.07	0.13	-0.08	0.24	0.10
Parent	0.04	-0.16	0.02	-0.05	-0.18	0.09	-0.24	0.05	0.18	0.03
Recalled pain during IV										
Child	-0.28	-0.17	0.08	-0.23	0.03	0.22	0.04	-0.14	0.00	0.01
Parent	0.01	0.00	0.17	0.24	-0.07	0.11	-0.09	0.03	0.04	0.07
Recalled fear during IV										
Child	-0.10	0.01	0.37*	-0.14	-0.12	0.05	-0.33*	-0.10	0.18	0.20
Parent	-0.12	-0.02	0.20	0.01	-0.18	0.19	-0.26	-0.13	0.12	0.14
Anticipated pain for next IV										
Child	-0.29*	-0.01	0.28	-0.11	-0.12	0.17	0.11	-0.17	0.01	-0.01
Parent	-0.21	0.00	0.02	0.34	-0.12	0.19	-0.09	-0.21	0.19	0.25
Anticipated fear for next IV										
Child	-0.31*	0.18	0.22	0.23	0.17	0.16	-0.08	-0.08	0.02	-0.03
Parent	-0.14	-0.09	0.15	0.11	-0.13	0.24	-0.02	-0.22	0.10	0.10

* Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).

3.5 Secondary Outcome Results

3.5.1 IV Induction Outcomes

To further understand how children may have experienced IV induction, completion rates of the procedure without the use of inhalational anesthetics were examined. The mean number of needle attempts that children received was 1.25 (n = 102, SD = 0.61). From the moment the needle contacted the skin to the time when the needle was secured on the hand with an adhesive tape, the mean time required to insert an IV line was 61 seconds (n = 99, minimum = 6 seconds, maximum = 283 seconds), and did not significantly differ between the MEDi® and standard care groups. A majority of children (n = 90) completed the IV induction without the aid of sedative gas, while the remaining 13 children received inhalational induction for reasons listed in **Table 5**. Children who received MEDi® coaching were 5.04 times more likely to complete their IV induction procedure, compared to standard care. Correlational analyses showed that the number of needle attempts was not correlated with reports of needle pain or fear during the procedure or at follow-up (ps > 0.05).

3.5.2 Parental Self-Efficacy

Given that parents were invited to participate in the robot intervention with their children, between-group analyses were performed to see if they differed between the standard care (mean = 7.05, SD = 1.97) and MEDi® (mean = 7.01, SD = 2.27) groups, with no significance found at post-procedure ($F(1,44) = 0.00$, $p = 0.96$). Also, self-efficacy scores did not change significantly over time and no interaction effect were found between groups ($F(1,43) = 0.02$, $p = 0.88$).

Table 5. Outcome of induction attempts.

Method	**Total** (%) **(n = 103)**	**MEDi®** (%) **(n = 45)**	**Standard care** (%) **(n = 58)**	**Statistic**(df)	**p,** φ_c
Intravenous	90 (87.38)	43 (95.56)	47 (81.03)	$X^2(1) = 4.85$	0.04, 0.22
Inhalational Reasons for use	13 (12.62)	2 (4.44) • IV cannulation was not completed after one attempt on each hand. (n = 1) • Child preferred receiving inhalation anesthetics in the OR prior to IV start. (n = 1)	11 (18.97) • After the anesthesia resident had two attempts with IV insertion, the attending anesthesiologist suggested to use the breathing mask for induction. (n = 1) • When needle was presented to child, patient pulled hand away. Pediatric anesthesiologist proceeded with the mask instead of attempting an IV start. (n = 1) • Patient showed signs of phobia towards both the needle and mask. (n = 1) • Difficult IV start (i.e., pediatric anesthesiologist could not locate a vein on the child's hand for IV insertion) (n = 4) • The topical numbing cream was not applied long enough (i.e., 25 minutes), and child showed signs of discomfort after the first needle attempt was incomplete. (n = 1) • IV start was completed, but pediatric anesthesiologist decided the breathing mask would be a better approach for induction (e.g., Child could not tolerate propofol due to pain/anxiety during infusion.). (n = 1) • No reason provided. (n = 2)		

3.5.3 MEDi® Interactions and Use of Breathing Skills

Some children (n = 12, 26.7%) who interacted with MEDi® appeared "engaged", "interactive", or enjoyed their experience with the humanoid robot. A subset of these children and their parents continued to talk about their MEDi® experience after they had moved from the SSSU into the surgical holding area (n = 6, 13.3%). When participants were brought into the OR, children (n = 7, 15.6%) were also found to perform deep breathing exercises, with the assistance of nurses (n = 2) or parents (n = 5). Examples of how this strategy was facilitated are described in the following observations noted by RAs:

> "… mom held child and talked to her about tissue breathing. Resident did the IV induction, some rubbing on the hand by nurse, after the IV [insertion] mom talked about the child's favorite TV show." (participant #63)

> "Child using MEDi breathing techniques in OR holding [area] with mom… [In the OR,] talking about Gangnam style dance and song… [mom] telling her to breathe like MEDi® taught, and talking about robot". (participant #103)

Although breathing techniques were not the only strategy utilized for pain management, a parent had commented that "deep breathing is a very good coping mechanism… [and] tissue breathing made her [child] 'calm down perfectly'".

Additional analyses revealed that study participants more readily applied coping strategies taught during MEDi® preparation than those who did not receive additional coaching. That is, more frequent use of deep breathing was observed with children in the robot group (n = 15, 33%), compared to those in the standard care group (n = 2, 3%) (Fisher's exact test (1) = 4.66, $p < 0.05$, $\varphi_c = 0.21$). Examples of children in the MEDi® group completing breathing

exercises at the time of IV procedures included: "…[child] talking about tissue breathing with mom in the holding area…, asking patient to do breathing", "encouraging breathing in through nose, out through mouth", or "told [child] to breathe like MEDi® taught, and talking about [the] robot". In particular, one child had kept the tissue provided in the robot intervention and used it as a memory aid when prompted by her mother to practice deep breathing in the OR. For standard care, observations of breathing-related behaviors were noted with only two patients: one patient was noted to exhibit increased breathing while the child watched a pediatric anesthesiologist perform the IV procedure, and the other patient was encouraged by mom to do deep breathing or "rollercoaster breathing" when the IV line was inserted. However, given that minimal context was provided about child's reaction to the needle in the first case, increased breathing could have been a physiological response to heightened anxiety rather than a positive coping behavior.

4. Discussion

This study was the first to examine children's experiences of IV induction after receiving support from a humanoid robot and its impact on children's pain, fear, and pain-related memories. Although there was no improvement across the study phases or differences between the study groups in pain or fear, all of these scores were low; thereby, limiting the ability of the MEDi® intervention to have an effect. This outcome might be due to the efficacious pharmacological effects of Ametop©. Similar results were found in the existing literature on children's pain during IV cannulations performed with topical anesthetic pre-treatments [64,96,102]. Most patients also accessed other distractions or support resources (self, parent or health professional initiated) to help them cope with the stress and pain of needle insertions. Thus, the combined use of effective pain management strategies (in addition to MEDi®) and the caring demeanor of the healthcare

professionals might have created a buffering effect on children's perceived pain and fear. Furthermore, the encounter of different post-operative events (e.g., complications, parent-child conversations about hospital experience) might have influenced how participants recalled needle pain or fear, along with their anticipation of discomfort towards future IV procedures.

Although our study did not show a measurable reduction in needle pain or fear after receiving the robot-facilitated preparation in the OR, several other studies with MEDi® have suggested a significant effect on children's discomfort during needle procedures conducted in other settings (e.g., pediatric emergency department, oncology unit, and phlebotomy and infectious disease clinics) [2,73,89]. Perhaps other explanations specific to the clinical context and how MEDi® was introduced may account for the nonsignificant results. For instance, children's movement into an OR environment that consists of bright lights and various pieces of surgical equipment after receiving the MEDi® intervention could have been overwhelming for them, which may have dulled the robot's effect. Also, the contextual cues associated with an IV induction can be unique to this type of procedure, compared to other needle procedures that are conducted on a routine basis (e.g. vaccination, phlebotomy). The observation of low needle pain and fear in both study groups also suggest that a MEDi® preparation may be most effective with children who express high procedural anxiety or fear. Moreover, the timing of introducing MEDi® to families before they entered the OR is different from other studies where it was used before and during the procedure. Hence, significant effects may have been found if the robot had remained with the child during IV induction.

Surprisingly, the secondary outcomes revealed several desirable effects on the completion of IV induction, suggesting that MEDi® may help children tolerate with this needle procedure conducted in a surgical setting. Children who had visited with MEDi® required fewer

IV insertion attempts and less use of inhalation anesthesia, compared to those in standard care. Thus, they may have been more cooperative. One possible explanation is that although parental self-efficacy and anxiety may not have been significantly affected, their behaviors did suggest an enhanced parental role when some of them coached their children to use breathing, and more children in the MEDi® group did use the breathing. These actions may have helped them relax enough to allow pediatric anesthesiologists to insert the needle. Also, about a dozen children were observed to be excited and happy about seeing the robot, which may have put them in a calmer state and increased their distress tolerance. In other words, the pain and fear may not have subsided, but their strength to endure those reactions may have been improved. Based on the comments and reactions of children and their parents, it was clear that most of them found enjoyment during the session with MEDi®.

Based on our results, we recommend that future research explore the timing, location, and duration of MEDi® implementation. Also, other negative experiences other than pain and fear (e.g., frustration, sadness, anger), in addition to positive experiences (e.g., happiness, satisfaction, coping ability) should be measured to gain a broader understanding of its potential effects. Other methods of implementation should be considered such as using MEDi® to facilitate discussions and provide procedural preparation in a chat forum or online session that allow for opportunities to remotely deliver the MEDi® intervention. Indeed, other web-based programs for pediatric pain management have been developed for such purposes [115]. Thus, the impact of a robot can extend to a more widespread audience that is not restricted to one hospital. Also, it is not yet known what physical features or actions/expressions of the robot are most likely to have a most desirable impact on children and their parents.

This study's results should be interpreted in light of several limitations. The recruitment rate could not be determined as it is not known how many families declined the initial invitation made by the nurses. Also, attrition during the study phases occurred due to the inclusion/exclusion criteria, inability to complete the MEDi® intervention and nonparticipation at follow-up. Thus, generalizability may be limited. In 11 cases, the Ametop© had not been applied early enough to induce skin-numbing effects. The call to surgery earlier than scheduled could not be controlled by the researchers. In particular, 14 patients in the robot group were called early to surgery and, thus, were unable to receive the MEDi® preparation. Procedural ratings had been collected from them, and when these scores were combined with those from children who had completed the MEDi® preparation, there was no difference in the comparisons with the standard care group on any of the dependent variables (pain, fear, self-efficacy, anxiety, pain catastrophizing). Also, observations from three cases indicated that the pediatric anesthesiologist chose to utilize vapocoolant sprays to assist with IV insertion. In cases of major delays before surgery (i.e., greater than two hours since application), the anesthetic effect of Ametop© on the site of needle insertion may have faded. Furthermore, being aware of their assignment to receive either the MEDi® intervention or standard care alone might have altered children's and their parents' perception of pain or fear. Although the RAs and pediatric anesthesiologists who completed the ratings in the OR were blinded to the randomization, these raters in two cases heard a child and parent talk about MEDi® before arriving to the OR.

With a commitment to managing procedural pain using a multimodal approach, this study offered patients and their parents the opportunity to experience IV induction in a calm, gentle manner. In addition to the "gold standard of care" offered to our pediatric surgical patients, we evaluated the impact of MEDi® coaching to help them undergo painful needle procedures with

deep breathing techniques. Healthcare providers engage with families in many ways to support them in stressful clinical environments and MEDi® played a unique role that enabled multidisciplinary care teams to help children complete the IV induction. In collaboration with pediatric anesthesiologists and child life specialists, this study presented initial evidence supporting the use of a humanoid robot with pediatric patients prior to general anesthesia. By offering an interactive activity with MEDi® during wait times, this brief coaching session was able to prepare pediatric patients for the upcoming induction procedure without disrupting the flow of their surgical care. Promising evidence suggests that the implementation of MEDi® in a triadic fashion (robot, child, parent) is feasible in pediatric surgical settings and public interest in the integrative use of humanoid robotics in clinical activities continues to grow. Hence, future studies should explore different avenues in which pediatric patients and their families can receive this novel form of procedural support.

(1246/1500 words)

5. Conflict of Interest

There is a conflict of interest to declare for this research study and ethics approval was obtained from Conjoint Health Research Ethics Board at the University of Calgary, Canada (Ethics ID: REB16-0148_MOD2). Dr. Tanya Beran, primary investigator of this study, is commercializing the MEDi® robot. This relationship is disclosed at all research presentations and documented on the consent form. Dr. Beran advised on data analysis, but did not collect, manage, or store the data.

6. Acknowledgements

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CHAPTER SIX: DISCUSSION

In this last chapter, interpretations of the results will be explained in depth and in relation to existing research. Then limitations are discussed in full, followed by recommendations for future research to inform the ongoing efforts of determining the effectiveness of MEDi® for children receiving IV induction.

6.1 Summary of Findings

Results of this study suggest that the implementation of MEDi® may help children tolerate IV needle procedures. Although children's pain and fear were not significantly different between the robot and standard care groups, and did not change across any phase of the study, children who completed a teaching preparation with MEDi® on breathing skills were more likely to complete the IV induction procedure. Moreover, they were also found to practice deep-breathing exercises more frequently in the OR. Finally, at follow-up, some of them recalled meeting MEDi® during the hospital visit and remembered the breathing techniques.

6.2 Interpretation of Findings

6.2.1 Differences in Pain and Fear

Results showed no significant differences in needle-related pain or fear between children in the MEDi® or standard care groups, or observable changes over time. Overall, patients, their parents, researchers and pediatric anesthesiologists rated children's pain and fear as low for both groups. This outcome may have been due to the high number of other pain management strategies in place for both groups. Firstly, the Ametop© that was administered to all children may have created a sufficient numbing effect that lowered pain and fear; thus, reducing the ability of other strategies to have a measurable impact. Similar observations have been noted by past studies with pediatric patients that received topical numbing cream prior to receiving an IV

poke [64,96,102]. However, previous studies have also shown that Ametop© was ineffective for some children; hence, the delivery of pain-related support via other modalities may still need to be considered for these children. A methodological explanation known as the 'floor effect' is also possible [66]. That is, the pain and fear rating scales may not have been able to distinguish small differences at the low end of the continuum. Thus, different experiences of low levels of pain and fear may not have been detected.

Another explanation for the nonsignificant effect of the robot on pain and fear could be that other strategies had been implemented before the administration of Ametop©, such as educational sessions, information pamphlets, online resources, and expert advice from various health professionals involved in the patients' care. Several child- or parent-initiated strategies were also used while waiting for surgery (i.e., comfort items, distractions, parent-child conversations, and heat or ice packs). As they were not used consistently or in any standardized way, it is difficult to know how they may have affected our results, but they may have contributed to the low scores.

Aside from the confounding effects of other support strategies used by study participants, the MEDi® intervention itself may not have been effective at reducing needle pain and fear. How breathing exercises were introduced to patients might be problematic in addressing our research aims. In the pre-programmed script, tissue breathing was described as a strategy to help children relax during their IV induction, but the desired outcomes for pain and fear reduction were not explicitly conveyed. If children and their parents did not believe that MEDi® could have a benefit for pain management, then they might have been hesitant to practice deep breathing during the IV procedure. In addition, the actual procedural setting could have posed challenges for participants to execute the step-by-step approach for tissue breathing. That is, there was not

always sufficient time for patients to repeat the entire breathing exercise, and other distractions in the environment might have interfered with their focus. There might have also been a dosage effect whereby MEDi® perhaps did have a calming effect on children's fear of IV procedures; however, it might not have lasted long enough to counter the competing factors that occurred within a busy OR (e.g., conversations between medical staff, uncertainty about the procedure, number of staff surrounding the patient).

Several recent studies in other clinical contexts (e.g., emergency department, infectious disease clinics) have reported promising results of MEDi® on children's procedural distress [2,48,73,89]. In particular, Jibb et al. (2018) found that pediatric oncology patients who received MEDi® coaching seemed to experience less distress when undergoing subcutaneous port needle insertions compared to standard care. A distinction that may account for the discrepancy in our primary outcomes is the different needle procedure examined in this study and other MEDi® related studies. Children in the present study might have found it more challenging to overcome the fear of IV induction, compared to medical procedures examined in other studies that are encountered more frequently in routine care (e.g., vaccinations, phlebotomy, dressing change). Relevant to this study, many patients did not have any prior experiences with IV induction or received a surgical procedure. That is, if children have experienced similar events in the past, they are likely to generate accurate mental representations of pain when they need to undergo the procedure again [71]. Conversely, if this event is their first encounter with IV induction, children may not be familiar with the visual, auditory, tactile, or olfactory cues associated with the procedure. As such, the context can influence how children construct their expectations of pain or fear towards a new procedural experience.

6.2.2 Changes in Pain, Fear and Self-Efficacy

Although the present study shows that children with MEDi® preparation did not have lower pain and fear than children without the intervention, it is also true that MEDi® did not exacerbate patients' pain and fear toward IV inductions or future IV procedures. Since no interaction effects in pain or fear over time were found, our results suggest that children's and their parents' recalled pain and fear did not change since the hospital visit, nor did they expect to experience more discomfort when undergoing subsequent IV procedures. These findings may be interpreted according to the 5P model that describes the bi-directional relationship of needle pain and fear [94]. While the acute pain from needles can dissipate within minutes or days after the procedure, the emotional consequence of unmanaged pain may have a lasting impact on children's pain or fear for future needles [93]. As such, unmitigated pain from IV inductions may increase fear, which in turn can perpetuate the pain or fear children expect in an escalating manner. Conversely, with well-managed needle pain, patients are less likely to develop fearful memories of pain over time or anticipate pain at future needle procedures. Hence, our primary outcomes further suggest that children who received MEDi® support did not seem to develop needle fear after their induction experience. It also appears that the impact of MEDi® did not supersede the effects of standard care, as similar findings were found with those who did not participate in the robot intervention. However, possible confounders may account for the lack of change in pain or fear trajectories. For instance, children with memories of seeing blood, the point of the needle, or needle being inserted when the procedure was performed can also influence their recollection or expectation of IV inductions.

Several interpretations can also be drawn from the lack of improved parental self-efficacy between the MEDi® and standard care groups. One explanation might be that parents did not

perceive themselves to be a group of targeted learners for the MEDi® preparation. Pre-programmed to deliver age-appropriate education for children, all parents in our study had agreed to accompany their children when completing the robot intervention. However, some parents appeared less engaged than others when the intervention was being administered. Thus, parents' attitude towards the robot might have influenced the impact of MEDi® on their confidence during and after the IV induction. Although parental self-efficacy did not significantly improve with coaching education that was delivered by a humanoid robot, other observations were suggestive of MEDi®'s impact on the parental role during the IV induction. A number of them proactively encouraged their children to try breathing exercises while the IV was being inserted. This action may also account for the increased cooperation seen with children completing IV inductions, given the preceding guidance with MEDi®. This interpretation is also consistent with previous research that suggests when parents were involved with the pain management interventions for hospitalized children, children's ability to cope with medical procedures is high [97,116].

6.2.3 Factors Influencing Pain and Fear

Several interpretations can be drawn regarding the relationship between specific demographic factors and the perceptions of needle discomfort. Findings from follow-up interviews also provided insights about study participants' memories of the IV induction, along with their expectations toward subsequent IV procedures.

This study identified several plausible factors that might have influenced the varied pain and fear scores among patients undergoing IV inductions: children's age, past pain events, parents' anxiety and pain catastrophizing, and fathers' educational level. In terms of age, our results suggested that older children reported low needle pain and fear, which is well

substantiated in other studies [71,150]. Age may be relevant because younger children likely have fewer pain experiences to draw on as reference points for scaling their current pain [28]. In addition to age, our study also found parents' pre-procedural anxiety to be related with their perception of needle pain – suggesting that parents who appear anxious were likely to perceive their children's needle procedure as painful. The notion that parents should be present during painful procedures is well-accepted, and researchers are examining how and why parents' behaviors during medical procedures relate to their children's experience. For example, worried parents tend to engage in pain-promoting behaviors, more so than parents who are not anxious [62]. Furthermore, parents who exhibit poor psychological functioning (i.e., high anxiety) may exacerbate their children's perceived pain [114].

Although there is evidence to support the influence of patient's age and parental anxiety on pain or fear perceptions, the complex interplay of demographic factors on needle fear remains unclear. In particular, minimal data are available about the paternal characteristics that impact their children's needle experience. Despite the existing evidence to suggest that parental education attenuates effective pediatric pain management, this research does not evaluate the influence of maternal and paternal education as independent factors [46]. Interestingly, findings from this study indicated that father's level of education may be a protective factor against needle-related fear. That is, with fathers who have high educational attainment, these children were likely to report low fear at the time of IV insertion and recall low fear at follow-up. Although similar findings were not found with mothers, perhaps educated fathers were likely to exhibit coping-promoting behaviors with their children [24]. Fathers with high education attainment might also feel enabled to communicate with patients and provide them with details about the forthcoming anesthesia or surgery[53]. In addition to level of education, parent pain

catastrophizing was also identified as a factor related to their children's pre-procedural and procedural fear. Similarly, parent pain catastrophizing is considered a predictive factor for post-surgical pain experiences and mixed results suggested its role on the persistence of children's pain at follow-up [11,77]. Recent studies also suggest that the catastrophic thinking of parents can serve as an underlying bias on their memories of sensory pain [110]. Thus, this finding in our study provides added insights about the influence of parental thoughts on the experience and memory of needle pain with children receiving IV inductions.

Our findings also revealed that children's past experiences with pain may influence their fear before, during, and after IV inductions. That is, patients who had more hospital admissions and surgeries, or experienced more pain during their last surgery were likely to report high needle fear. Research suggests that individuals who have experienced a significant painful event are likely to develop severe needle fear and perceive subsequent needles as unpleasant [93].They are also likely to selectively emphasize and encode threatening aspects of the needle procedure, which can lead to memories of the needle being more fear than patients initially reported [94]. Perhaps this explanation is why patients who appear hesitant or fearful of needles can trace their worries back to one poorly managed needle experience [108].

In regard to children's and parents' memories about the IV procedure, the qualitative findings from the follow-up interviews suggest that many participants remembered MEDi® as a positive hospital experience. Our results also reveal that some children would rely on the breathing strategies taught by the robot during the procedure or moments prior to needle insertion. Thus, opportunities for participants to apply these skills in the OR might have consolidated their memories about the preparations' benefits and altered their expectations for future procedures [72]. Interestingly, unlike their parents, no children who received the robot

intervention were able to solely recall facilitating breathing skills without the memory of meeting MEDi®. That is, at follow-up, some parents remembered the use of deep breathing as a separate event, without needing to recall their interactions with MEDi®. However, children had recalled memories of deep-breathing exercises, along with their memories of the humanoid robot. Children also tend to recall or have a greater impression of MEDi® when asked about their overall hospital visit, rather than remembering it as a part of the IV procedure. Perhaps the novel intervention with MEDi® may be interpreted by children differently compared to other well-documented pain management interventions (e.g., distractions, parental presence, Ametop©). Also, the friendliness and physical appearance of the robot are characteristics that may have visually helped the children to remember the MEDi® preparation.

Our study also revealed that there were children who received the MEDi® intervention but later recalled negative memories about the IV procedure at follow-up. Their responses included accurate details about the hospital experience, such as the number of needle attempts, the process of IV induction, and the surgical environment when the procedure was being performed. Similar to those who remembered the IV procedure positively, these participants were able to recall a number of pharmacological and psychological interventions besides MEDi® that were used to help them cope with needle pain and fear. Despite remembering the IV induction as a painful or fearful event, several participants also recalled practicing deep breathing strategies during the robot intervention. Although some parents did believe MEDi® was an effective distraction that helped their children to feel at ease, others did not find the robot to be as useful. It is possible that some children were more responsive to the behavioral distractions or cognitive techniques delivered by MEDi®, while others coped with pain better as social support

or information seekers [67,87,133]. Thus, these findings suggest that some children might not be responsive to or interested in MEDi® due to varied coping styles between individuals.

Interestingly, our findings showed that there was a higher completion rate of follow-up interviews with participants in the MEDi® group, than those in standard care. It is possible that families who spent time with MEDi® might have had an invested interest to complete the study due to their engagement in patient care. Furthermore, this evidence suggests that families who participated in a MEDi® preparation as part of their surgical care may attend to post-operative activities more proactively than those who did not interact with the robot.

Conversely, some children and their parents, who received coaching support with the robot, did not recall MEDi® or remember undergoing deep breathing exercises at the hospital visit. Without additional prompting, these participants might have forgotten to mention their MEDi® experience at the time of follow-up. Lack of interest or not considering the preparation as a memorable event of the hospital experience might be potential reasons for why study participants did not recall their meeting with MEDi®. Another plausible reason is that children or their parents, at post-procedural phase, may have continued to feel overwhelmed from the hospital experience. Hence, they would have recalled details about the medical procedure or distressing memories of the event predominately, as opposed to behaviors that they perceived as helpful [118]. Given the dynamic environment with many opportunities to provide comfort for a child in pain, families might have memories of specific events in patient's care (i.e., presence of caring, professional medical staff) that seemed more helpful than the MEDi® preparation. Hence, several reasons might account for why some children did not remember the robot intervention better than other children.

6.2.4 Outcomes of IV Induction

Despite finding no significant differences or changes in children's pain or fear in our study, it was surprising that children in the MEDi® group were more likely to complete the IV induction. This evidence suggests that a brief MEDi® preparation while they waited helped children tolerate the needles and cooperate as the medical team completed the induction process. In addition, most children only required one needle insertion attempt to secure an IV line with low pain or fear. However, results from other MEDi® related studies revealed that, while children had robot accompaniment, they completed medical procedures with apparent reductions in procedural pain or distress [7,48,73]. Unlike previous research studied the presence of MEDi® at the time when a medical procedure was performed, the robot intervention in this study was not delivered in the setting where IV inductions were typically performed. As a result, the robot may have had a milder impact on children and their parents, given that they met MEDi® in a pre-operative preparation rather than having the robot distractions physically present as the procedure was being conducted. Even though children experienced needle pain and fear during the IV induction, an increased number of patients were able to endure the unpleasantness with needle procedures because of the encouragement that MEDi® provided beforehand (i.e., informing patients that many other children have also received the same needle procedure).

The timing of when MEDi® was introduced to children may also explain why they were likely to complete the IV induction but did not experience less needle discomfort. That is, study participants might not have had enough time to process the information taught by MEDi® and plan how they would cope [33,140]. Perhaps administering MEDi® within one hour before the surgery did not provide adequate time for families in the surgical setting to process the content delivered in the MEDi® session. However, there is insufficient evidence currently to inform what

time frame is appropriate for administering such technology-enhanced preparations. In an effort to implement the robot preparation at an optimal time, our study considered the importance of minimizing interruptions to the hospital's workflow. Some researchers have proposed that preparations should be administered at least an hour, or even up to one day, before the needle procedure and the application of topical anesthetics [140]. They further highlighted that "[a] preparation should not be performed too far in advance - this may cause children to become fixated on the event, or forget details about the procedure or intervention". However, Roberts et al. presented a different perspective, suggesting that children ages 6 years or older should receive the preparation at a minimum of 5 days before the procedure, while younger children may likely benefit within a shorter time frame [125]. Here, the authors argue that careful considerations should be undertaken to avoid giving preparation too close to the scheduled procedure, which could exacerbate feelings of anxiety or distress because it does not give the child sufficient time to process information or consolidate any coping strategies learned. Hence, given the ongoing debate on the delivery of preparations, the reasons mentioned above could have contributed to why some children might seem apprehensive to needles but were still able to complete the IV induction.

6.2.5 MEDi® and the Multi-Disciplinary Care Team

In efforts to provide a novel multimodal strategy to help patients undergo IV inductions, this collaboration between pediatric anesthesiologists and child life specialists has supported the implementation of MEDi® in pediatric surgical settings. Perhaps this short, easily accessible intervention with a humanoid robot on the day of surgery can accompany the various high-quality strategies demonstrated by healthcare professionals to bring some fun and enjoyment to children and their families during the hospital visit. Through this study, we evaluated the impact

of a preparation delivered by MEDi®, as part of the "gold standard of care" offered to pediatric patients undergoing painful needle procedures. The varied responses from study participants, related to the application of pain management modalities, suggest that the presence of technology-enhanced tools should not diminish the central role of health professionals, who ultimately determine the best approach to prepare patients for upcoming needle procedures. This interdisciplinary endeavour required the assistance of many individuals involved with children's care: pediatric anesthesiologists and nurses to administer pharmacological adjuvants in SSSU, surgical staff and parents to provide other forms of comfort when needed, and child life specialists for the operation of MEDi® in clinical practice.

In relevance to MEDi®, health professionals serve as key facilitators who ensure the integrity of how these tools will be operated and should be adequately trained to deliver the intervention in an engaging manner. Especially in the occurrence of technical issues, MEDi® users need to be competent in resolving these unexpected events and continue to offer coaching support without its assistance. In our study, only one participant enrolled had received an incomplete MEDi® intervention due to technical issues and the data collected were excluded from the analyses conducted above. Thus, despite the convenience offered to families and healthcare providers with the technology of artificial intelligence, the crucial role of healthcare providers should not be undermined.

6.3 Future Research Directions

Based on our findings, several research avenues can be explored in future studies. Investigations that inform the effectiveness of MEDi® with specific patients in Surgical Short Stay will be advantageous. In particular, efforts to conduct a multi-centered study with high statistical power will improve the generalizability of our current findings.

Future research aiming to integrate MEDi® into a comprehensive best practices pain management approach should strive to maximize the opportunity for all planned interventions to be completed within a given time frame. For our study, we utilized Ametop© as our choice of topical numbing cream for both groups, which required an application time of 30 to 45 minutes for maximum analgesic effectiveness. Besides Ametop©, there are several pharmacological interventions currently recommended for needle pain management (e.g., tetracaine formulations, oral sedatives) [130]. Given the variable duration of wait times in the SSSU, optimizing an approach to deliver pain management strategies under time-limiting circumstances is crucial. For example, using pre-operative local anesthetics with short preparation time can be considered. Evidence suggests that a 30-minute application of Maxilene©, a liposomal lidocaine topical cream, can provide similar analgesic effects with children undergoing venipunctures or IV cannulation [78,80,86,143]. Thus, future studies investigating other pharmacological agents in combination with MEDi® intervention can be undertaken.

Learning in healthcare settings can be a highly emotional endeavor - different emotional states are likely to affect what information individuals attend to and remember when under stressful conditions [82]. Based on our findings, most children and their parents recalled the needle procedures with positive-, negative-, or neutral-related emotions. Thus, future research can inform which aspects of the MEDi® intervention are perceived by families to be effective in improving their experience with IV-related procedures at the hospital. This information can further guide the optimization of MEDi® interventions and future uses of the robot with pediatric patients who require additional support to cope with the same procedure.

In addition to self-reports regarding the intensity of procedural pain or fear, making valid decisions about pain management requires a variety of information [148]. As described by Berde

and McGrath [9], “it is a clinical art to combine patients’ reports, behavioral observation, and physiological measurement with the history, physical exam, laboratory information, and overall clinical context in guiding clinical judgements and therapeutic interventions” [9]. For future research, it may be advantageous to examine other constructs of patients’ discomfort, such as perioperative levels of behavioral distress or anxiety, to inform the optimal use of MEDi® for pain management for pediatric surgical patient undergoing IV inductions.

Future considerations can explore other opportunities to offer MEDi® preparation during the pre-procedural phase - on the day of surgery or days prior to coming to the hospital. For example, web-based approaches may be an accessible modality to introduce MEDi® to families, if they require more preparation time for medical procedures. With repeated MEDi® sessions, surgical patients may benefit from a series of preparations to help children reinforce the use of coping strategies, even when the robot is not present. On the day of surgery, children have wait-times at different areas of the Surgical Unit – first at the SSSU and then in the holding area, where distractions are available in both locations for patients to use. Given that surgical patients may also spend a substantial period of time in the holding area, perhaps children may also benefit from having the robot in this area, especially if families were not able complete a MEDi® preparation earlier in the SSSU.

6.4 Study Limitations

There are several limitations to this study that must be considered when interpreting the results. These are discussed in detail, along with how we attempted to mitigate them.

6.4.1 Potential Threats to External Validity

The generalizability of these results is limited as this study was conducted at one pediatric tertiary hospital. The response rate of eligible patients could not be reported or

calculated as the research team members were only called when families had agreed to participate. Thus, it was not possible to count the number of families that chose not to participate in the study and their reasons (i.e., if they were apprehensive of the robot). The generalizability of these results is also limited by the setting in which IV inductions took place. Pain and fear ratings were gathered in the SSSU or OR, and not in other clinical environments where pediatric patients can also receive the IV induction procedure, such as emergency departments.

Another limitation is that our study participants were not randomly selected for study participation. That is, patients were approached for consent based on their interest in participating, availability, and not having a preference for the breathing mask. Furthermore, as the majority of pediatric anesthesiologists at our institution primarily offered inhalational induction, only those willing to perform the IV insertion awake participated in this study. Given that a few pediatric anesthesiologists did not wish to participate (i.e., choose to administer mask-based anesthesia over the IV induction when both methods were appropriate), their patients were neither approached for research purposes. Consequently, data from those children may not be well-represented in our study sample. However, prior to launching the study, all pediatric anesthesiologists were invited to attend an informative session about the IV induction approach; and overall, most were involved in the study.

6.4.2 Potential Threats to Internal Validity

Although multiple administrations of pain and fear measures over time and multiple rater sources were major strengths of this study, there are many potential biases to this approach [69]. Despite adhering to an established administration protocol, the uniqueness of each patient's hospital experience could have contributed to missing or biased reports of needle distress. Also, faces scales are dependent on children's social, cognitive and communicative ability to interpret

the instrument, such as their ability to match items, place items in an ordered continuum, and listen to the instructions of the person administering the measure while looking at materials [149]. Consequently, older children tend to provide more reliable self-reported scores compared to younger children [134]. That is, ratings from very young children or those who are unable to understand the self-report task due to high levels of distress in the OR may not be an accurate representation of their experienced pain. Furthermore, children's self-reports can also be influenced by their context. That is, compared to quiet clinical environments, administering faces scales while children are in a busy OR environment can be challenging with many potential distractions. Thus, participants may have given non-representative responses. Of concern, researchers have also debated that reducing the experience of pain (or fear) to a single number is an oversimplification of this construct [147].

Our findings also suggested that observers generally agreed with child-reported needle pain and fear; however, there were varied scores reported between raters. These discrepancies suggest that observers might be aware of children's pain and fear, but reported it differently than do children. Thus, concerns with over- or under-estimating the intensities of pain or fear not only depend on how a child expresses his or her pain, adult caregivers' past experiences with pain can also influence their judgement of how much discomfort children are enduring [122]; thereby, contributing to the discrepancies between patients and other raters. Research suggests that parents generally underestimate their children's pain [27,60]; however, they may be more accurate in their estimation of pain compared to health professionals [16]. When interpreting these results, the following explanations for why children's scores are not always reliable measures for their actual pain or fear should be considered: 1) young children might not understand the scale or not cognitively developed to respond appropriately, 2) children might be

inclined to deny or minimize discomfort because they believe there are negative consequences if a high score was provided, or 3) contrarily, children might overestimate their ill state if they anticipate benefits for being in an unwell state [148]. Hence, self-reported ratings are to be considered as an approximation of the actual discomfort experienced during the IV induction procedure.

Pre-Procedural Phase

Unexpected changes to surgery wait times had also introduced several challenges that the research team was not able to mitigate during the recruitment phase of this study. In cases of major delays in the surgical unit (i.e., greater than two hours), the anesthetic effect of topical numbing cream applied on the site for needle insertion may have faded prior to administering IV procedures. With extended wait times for surgery, researchers should facilitate effective communication with the medical team to ensure that the application of numbing cream is prolonged. More often, the fast-paced work environment resulted in surgeries occurring earlier than expected. The early arrival of porters to transport patients into the OR in some cases did not allow the randomization process to take place, resulting in 22 patients who had not completed an allocated intervention. In some instances, short wait times in the SSSU and holding area did not allow sufficient time for the application of Ametop© to be effective. For one patient who expressed heightened fear upon seeing the needle, the pediatric anesthesiologist decided to use inhalational anesthesia, without attempting the IV induction procedure. Furthermore, children who had the numbing cream removed early might have experienced greater needle distress, compared to patients whose cream had enough time to take effect. Due to time constraints, some patients were not able to complete the allocated intervention with MEDi® and/or Ametop©. In addition, the unexpected arrival of porters introduced unintended interruptions to the intervention

with MEDi®. Under these circumstances, the MEDi® intervention was discontinued, as patients and families were taken immediately for surgery. Each of these scenarios could have also jeopardized the ability for one researcher to remain blinded from the randomization, and they continued with rating the pain and fear assessments in the OR to complete the enrolment. In a few cases, the pediatric anesthesiologist switched to mask-based inhalational induction and did not proceed with a needle attempt if Ametop© was not applied. For the above reasons, data from 15 participants were excluded from analyses, which may have affected the results. This decision resulted in the loss of several participants, which could have also affected the outcomes of the study.

Technical issues with the robot also resulted in a disrupted intervention, given that trouble-shooting was unsuccessful or immediate assistance was unavailable. Consequently, if the pre-operative education was incomplete, children might have anticipated greater distress towards the needle procedure compared to those who received the entire intervention. Thus, to accurately examine the efficacy of MEDi® on participants' experience with IV induction, data gathered from children who received the complete intervention were included in final analyses and only one participant was excluded due to this reason.

Procedural Phase

Variations in how IV inductions proceeded within the OR could have affected the measurement of children's pain and fear. Prior to and during the IV insertion, patients might have been occupied by other medical staff (i.e., physicians, surgical nurses, respiratory therapist). As a result, RAs were not able to approach children to assess their fear level before or after a needle insertion was made. In other instances, if the bolus of propofol was administered quickly after IV placement, then RAs may not have had enough time to obtain pain scores from children

before they were unconscious. In a few occasions, pediatric anesthesiologists were occupied by other clinical priorities and the surgery commenced directly thereafter. Hence, RAs were not able to obtain pain or fear ratings from the pediatric anesthesiologist. Although these circumstances may be unavoidable, reminders to medical staff about the research procedure may have helped reduce their frequency. In managing the complex, fast-changing workflow in the OR, these circumstances might have also compromised the RAs' ability to accurately score each child's pain during the IV procedure in the same manner. Furthermore, several RAs were involved with this two-year study, and though they were trained to conduct pain-related assessments in the OR, their perceptions for what is considered high fear or pain may be different from one another.

The research team also encountered challenges in conducting pain and fear assessments with participants using the breathing mask in the OR. Although IV inductions are frequently performed in pediatric centers, patients were able to opt out of this medical procedure and continued the induction using inhalational anesthetics. This decision could also be made by the pediatric anesthesiologist if the child appeared very distressed during the process of needle insertion. That is, despite having Ametop© applied sufficiently for 30-45 minutes, pediatric anesthesiologists may also choose to forego IV induction, given that circumstances suggest the mask-based induction to be a more medically appropriate option. Overall, most patients who received inhalational induction due to medical-related reasons, such as not being able to locate a visible vein on either dorsum of child's hands for the pediatric anesthesiologist to obtain IV access. However, this scenario did not occur for those three children who received the sevoflurane gas for general anesthesia without any prior needle attempts. Since needle pain and fear in the OR could not be collected for these patients, they were not included in the final analyses for children's distress. This observation also suggested that pediatric anesthesiologists

in this study were accepting to attempt IV insertion in most children - our data might not have fully captured the perceptions of other physicians who may favor using the mask over IV induction. Perhaps they may choose to switch over to inhalational anesthesia early in the OR and appear resistant to pursue a needle attempt when Ametop© is not effective. There were also factors that might have limited pediatric anesthesiologists' opportunity to attempt the initial or subsequent IV insertions. For instance, only having the numbing cream applied on one hand, as opposed to both or only to a small area of the dorsum, might influence their ability to find an appropriate site for needle insertion. Of note, with children who completed the IV induction, there were about a dozen patients that were given an oxygen mask by the pediatric anesthesiologist but before the child was under sedation (i.e., before propofol infusion). This inconsistency in mask use for non-sedative purposes may have altered fear perceptions for this heterogeneous group of pediatric patients. Although the breathing mask did not contain any volatile anesthetic to assist with induction, it is not known whether its application had influenced how children perceived pain or fear during the IV procedure.

Another limitation to consider was the potential interrater bias of pain and fear ratings during the IV procedure. As all raters were present in the OR, pain and fear ratings might not have been scored independently if raters were aware of what the other had rated for needle distress. That is, children were first asked to rate their level of pain and fear, and then other observers provided their ratings. When an attempt was being conducted for the needle insertion, the RAs provided a self-reported rating for the patients' pain and fear (this step was also repeated when the bolus of propofol was administered through the IV). Shortly after the needle insertion was completed and when appropriate to do so, RAs gathered pain and fear scores from the child first, and then from their parent and the pediatric anesthesiologist who performed the procedure.

However, since the same rating scales were utilized to assess pain and fear across different time points, raters might have remembered the children's responses.

Despite the occurrence of such unexpected events described above, there were no study-related adverse events reported. Overall, lessons learned from these observations indicate that research protocols in Surgical Short Stay and OR face particular challenges that may not be completely resolvable.

Post-Procedural Phase

Although our study focused on assessing needle discomfort over time, our interpretations regarding the follow-up data were limited data on recalled and anticipatory pain and fear gathered. Since only 47% of participants completed memory recall interviews, results from the follow-up phase may not be generalizable to inform how well children had coped with needle procedures after receiving MEDi® coaching. Most participants were lost to follow-up because they could not be reached at the scheduled time after several attempts were made. In addition, some children who avoided using IV inductions in the OR were not able to complete the related interview questions. Without at least one attempt for needle insertion, these study participants would not have been able to recall their experience with the IV needle procedure. Hence, the amount of available data for analysis was limited. Additionally, though efforts were made to conduct child and parent interviews separately, some young children had experienced difficulty in understanding and responding to questions over the telephone. These children might have received assistance or prompting from their parents; thereby influencing children's ability to recall their memories independently. This observation further implies that the participants may have heard each other's responses, which can lead to the sharing of pain-related memories during

the follow-up interview. The moderate to strong association between recalled fear scores from children and their parents also supports this speculation.

In the initial design of this study, the intent of these open-ended questions sought to understand whether children who receive pre-operative education with MEDi® were less likely to develop negative memories about the hospital visit. Due to the free-recall nature of open-ended interview items, there was great variability across responses. Hence, decisions were made *post-hoc* to determine an appropriate coding scheme to use in this study – one that can best reflect the diversity of content found in interview responses (see Appendix A; Table A.1). These responses were also limited by their inability to fully capture children's and their parents' perspectives about the MEDi® robot, which was not included as an interview question in the present study. In Noel et al. (2016), researchers adopt non-directive approaches to interview children and their parents about pain experiences. Thus, the addition of questions to inquire which coping strategies were effective for children to endure IV inductions may be advantageous.

6.5 Conclusion

For children undergoing elective surgery, an IV line is required for all patients for several purposes, including the induction and maintenance of general anesthesia. Several medical-related reasons may also suggest that the IV route is preferable for inducing anesthesia. The research presented here shows that the MEDi® robot helped children tolerate IV induction despite having no effect on their experiences of needle pain or fear. We learned that MEDi® is 1) a plausible method for helping families learn breathing strategies, 2) feasible to offer for surgical patients undergoing IV induction procedures, and 3) remembered by some study participants as part of their hospital experience. Importantly, this work is the first clinical study to provide evidence

that links the use of pre-operative education with children who received a brief teaching session with MEDi® about breathing strategies and the completion of needle procedures in the OR.

APPENDICES

Appendix A: Qualitative Coding Scheme

Table A.1. Content coding scheme for memory recall interviews. Revised and adapted from Noel et al. (2016) to analyze children and parent responses about their hospital experience [107].

Primary codes				Secondary codes		
Number	Code	Description	Examples	Letter/ Number	Code	Examples
1	Emotion – positive	Information referring to an emotion with a positive valence, including emotional states, and words indicative of emotional states	• Happy, excited, joy, calm • Fun ("We had fun") • Like (as in "I liked __"), love • Laugh, smile • "Feel good/better" (*not* "*get* better") • Seamless, everything went well	None	None	None
2	Emotion – negative	Information referring to an emotion with a negative valence, including emotional states, and words indicative of emotional states	See secondary code	A	Mad	• Hate, angry
				B	Sad	• Upset, frowning • Crying, tears
				C	Pain	• Pain, hurt, "owie", "boo-boo" • Scrape, cut, fall, hit, punch, bang • Blood, swelling

				D		Anxiety/ Fear	• Scared, anxious, worried, nervous, tense • mind racing, other symptoms of anxiety
				E		Bad	• Feel bad/worse, don't like, not pleased
				F		Unspecified	• Meltdown, overwhelmed, breakdown
3	Emotion – neutral	Information referring to an emotion with neither a positive nor negative valence	See secondary code	A		Emotion present	• "I felt okay" • "didn't feel so bad" • "not concerned"
				B		No emotions	None
4	Coping	Any mention of how to cope with the stressor or emotion caused by the stressful situation	See secondary code	A (Yes)	i	Breathing	Taking breaths, tissue breathing
					ii	Robot	MEDi, robot
					iii	Breathing + Robot	Combination of (i) and (ii)
					iv	Cream	Ametop
					v	Distraction	Video, games, music
					vi	Talk	Conversations with staff/parents
					vii	Other	Please clarify
				B (No)	None	None	None
5	Body	Any references to body parts or sensations aside from pain	• Body parts: throat, arm, tummy, etc. • Swallowing • Sensations: nauseous, sick, throwing up, sleepy (but *not* "asleep" or	None	None	None	None

			"sleeping", dizzy, hungry • Numbness				
6	Medical/ Procedural	Any references to medical or surgical procedures	• Hospital, surgery, operation, "tonsils out", etc. • Needle, vaccination, stitches • Medicine • Mask, gas	None	None	None	None
7	Other	Any information related to MEDi® robot or IV but not coded	• Explanations referring to MEDi® or IV procedure	None	None	None	None

General notes for coding:

- Do not split up utterances unless there is a period.
    - Except: don't split up utterances that start off with "yeah." or "um." unless already transcribed as split up.
- If child is inaudible/unintelligible and parent repeats for researcher, trust that parent perfectly repeated child and use child code for what parent said.
- Can have multiple codes per utterance, but if same code in utterance count it once

Appendix B: Consent Form

Faculty of Medicine
Department of Community Health Sciences
Telephone: [redacted]
Fax:
Email:

Research Project Title: **Efficacy of a Preparation Intervention for the Management of Children's Pain and Fear during Induction: Help from a Robot Named MEDi**

Principal Investigator: Dr. Tanya Beran
Co-Investigators: Dr. Melanie Noel, Dr. Adam Spencer, Jackie Pearson, Lisa Bell-Graham, Christine O'Leary

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form, to keep.

BACKGROUND

We are asking if you and your child will agree to be part of a research study. You are being asked because your child requires an intravenous (IV) line as part of the induction for surgery.

WHAT IS THE PURPOSE OF THE STUDY?

We are trying to find things we can do to help children who will require an IV line for their surgery, as they can cause anxiety, pain and stress. One thing we can do to help a child is teach coping strategies. This helps them to manage the pain and stress of the IV line placement.

WHAT WOULD MY CHILD AND I HAVE TO DO?

Children who require an anesthetic prior to a surgical procedure at the Alberta Children's Hospital require an IV for most procedures. An IV is routinely inserted using two approaches. One approach is to apply a numbing agent (local anesthetic cream) to the back of the hand or forearm about 30 minutes prior to IV insertion to minimize discomfort. With distraction this approach is well tolerated by most and kids are off to sleep quickly. When deemed safe to do so, Pediatric Anesthesiologists may offer your child to breathe an anesthetic gas using a mask and place the IV once the child is asleep. A flavored scent (e.g., orange) is applied to the mask to help with acceptance of the anesthetic gas which has an unpleasant odor to some kids. There are specific circumstances where the Pediatric Anesthesiologist may feel that one approach is safer than the other. However, both techniques are safe, well tolerated and are used routinely with kids of all ages.

We are interested in those children and parents who choose to have the IV line placed while the child is awake. This group of children will receive numbing cream and be randomly assigned (i.e., will have an equal chance of being assigned) to one of two study groups.

GROUP 1. Numbing cream will be applied to the back of the hand or forearm. The Pediatric Anesthesiologist will discuss IV line placement with you and your child and may offer various distraction techniques that he or she normally uses on a daily basis to help kids relax during IV line placement. This includes the use of parents or staff members to distract the child, music or singing. In cases where the child is distressed and the child or parent refuses the IV line placement, the anesthesiologist will offer sedation (using the anesthetic mask) and the line will be placed after the child is asleep.

GROUP 2. In the intervention group your child will have the additional distraction and coaching tool of a robot who will talk to your child, say comforting and supportive things, and teach coping strategies such as deep breathing. As above, numbing cream will be applied to the back of the hand or forearm. The Pediatric Anesthesiologist will discuss IV line placement with you and your child and may offer various distraction techniques that he or she normally uses on a daily basis to help kids relax during IV line placement. This includes the use of parents or staff members to distract the child, music or singing. In cases where the child is distressed and the child or parent refuses the IV line placement, the anesthesiologist will offer sedation (using the anesthetic mask) and the line will be placed after the child is asleep.

A researcher will be in the operating room while your child has the IV line inserted by one of the Pediatric Anesthesiologists. You and your child will be asked some questions about your child's pain and distress before and after the IV line is placed. The questionnaires are about how much pain and fear the child feels, how confident they are in managing the pain, your perception of your child's pain and fear, your anxiety, and demographic information. These questions take about 3 minutes to complete so your time in day surgery may be a few minutes longer if you agree to be in this study.

There will be a follow-up phone call two weeks after you leave Day Surgery for a 5-10 minute interview to ask you and your child about your experiences of pain, fear, anxiety, and confidence during the visit to day surgery.

WHAT ARE THE RISKS?

There are no risks to participation in this study other than those ordinarily experienced during routine IV line insertion. It is possible that the robot distraction/preparation will not work to reduce the child's anxiety. If this occurs, children will be given a mask by the anesthesiologist. Please note that many children also experience fear, agitation, crying while using a flavoured breathing mask regardless of distraction/preparation techniques or parent presence

WILL I BENEFIT IF I TAKE PART?

Your child may enjoy the distraction/preparation tool, as many kids like robots, but the benefit may not be realized. Once the IV is inserted your child will be off to sleep more quickly when compared to using a breathing mask. This study may contribute to finding ways to help children cope with IV placement while being more comfortable with the overall anesthetic experience.

DO I HAVE TO PARTICIPATE?

Your participation in this research is completely voluntary. You may choose not to let your child participate in the study. You can refuse to allow your information to be included in the study, and you can later withdraw your information up to 6 months after the date you initially agreed to have your information included in the study, without consequence to you or your child. You do not have to answer

any questions you do not want to. You should not feel any pressure from the Day Surgery Unit if you do not want to join the study. Your child's care will not be affected in any way

WHAT ELSE DOES MY PARTICIPATION INVOLVE?
There is no other request for participation.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?
There is no compensation for participating and you do not have to pay for anything.

WILL MY RECORDS BE KEPT PRIVATE?
Your information will be gathered and used in such a way as to ensure confidentially. Only the research team will see your information. Each child in the study is identified by a number, so your names are not recorded in the questionnaires. Only Study Identification Numbers will be used for data analysis, and results will be presented in a way that no names are ever used. Your name, your child's name, and any personal health information will not be attached to your information.
Signed consent forms, completed questionnaires, and audio recordings/transcriptions of interview responses will be kept in a locked filing cabinet at the Alberta Children's Hospital for seven years after completion of the research, and will then be destroyed. The computer with the data will be password protected. The results may be submitted for publication in scientific journals. No identifying features of any individual will be included in such reports. All information will be held private, except when professional codes of ethics or the law requires reporting.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?
In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the Alberta Children's Hospital, University of Calgary, the Faculty of Medicine or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

ADDITIONAL INFORMATION
Dr. Tanya Beran, one of the research members of this project, wishes to disclose that she is both a university professor and also owns the company that sells the MEDi® robot to hospitals. Please be aware that she financially benefits from the sale of the robots and the potential outcomes of this study.

SIGNATURES
Your signature on this form indicates that you have understood the information about participation in this research project and agree to have your child participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without affecting your health care. Your continued participation should be as informed as your initial consent, so you should feel free to ask for information throughout the study. If you have further questions concerning matters related to this research, please contact:

Dr. Tanya Beran at [redacted]

If you have any questions concerning your rights as a possible participant in this research, or research in general, please contact the Chair of the Conjoint Health Research Ethics Board, University of Calgary at [redacted].

Ethics ID: REB16-0148
Study Title: Efficacy of a Preparation Intervention for the Management of Children's Pain and Fear during Induction: Help from a Robot Named MEDi
PI: Dr. Tanya Beran
Version number/date: version 5/May 13, 2016

Please indicate if you agree to participate in the following:

Completing questionnaires	I give permission ☐ I do not give permission ☐
Being contacted 2 weeks from now for a 10 minute phone interview that will be audio recorded. If give permission, phone #, email _____	I give permission ☐ I do not give permission ☐

_____ _____

Parent's Signature Date

For 7-12 year-olds:

We're doing a research project to see what children think and feel when getting an IV. Do you agree to be in our research?

Child's Signature _____	Yes ☐ No ☐

Appendix C: Data Collection Form

Data Collection **Form**

Innovative Tech for Pediatric Pain

Induction Study

Protocol Version: 5
Form Version: July 6, 2016

Name of RA: _____

Study Arm:
- ○ Robot
- ○ Standard care

ID#

_____

Short Title:	Innovative Tech for Pediatric Pain
Principal Investigator:	Dr. Tanya Beran Department of Community Health Sciences University of Calgary [redacted]
Study Team:	Jackie Pearson, Adam Spencer, Melanie Noel, Lisa Bell-Graham (ACH), Rachelle Lee
Grant Support/Funding:	Student Funding

Inclusion Criteria

1. Check slate if child has a professional diagnosis of needle phobia. ○ Yes ○ No
   If yes, stop at p.8
2. RA assesses if child cognitively able to answer pain scale ○ Yes ○ No
   If no, stop at p.8
3. RA assesses if family can speak English ○ Yes ○ No
   If no, stop at p.8

If family asks for mask, they cannot be included in the study. You can tell them that all children get Ametop – a topical anesthetic and distraction strategies, and ask if they wouldn't mind if the nurse talked to them about the advantages/disadvantages of mask vs no mask.
If family concerned that did not get MEDi®, then invite them to ask for MEDi® next time they visit the hospital and write on consent form if they want to be invited to a get together with MEDi® at the hospital in the future (make sure they record contact info).

Informed Consent

4. Has written informed consent been obtained? ○ Yes ○ No
   If no, thank family and leave.
5. Has a copy of signed informed consent been given to the parent/guardian in envelope with 2 week scales? ○ Yes ○ No
6. Date of Informed Consent/Assent: __ __ / __ __ __ / 2016
7. Date scheduled for phone interview: __ __ / __ __ __ / 2016

Surgery Information

8. Is the subject currently participating in any other study in day surgery (short stay surgical unit)? If yes, which one ○ Yes ○ No
   _____
   If yes, thank family and leave.
9. Who is going to operating room with [child name]?
   Try to insist that a parent can go. If they refuse, stop at p.8

Day Surgery (Short Stay Surgical Unit) Visit Information

1. Date of Visit (RA records) __ __ / __ __ __ / 2016
2. Time meet family (RA records) __ __ __ __ am/pm
3. Time of Surgery (from slate) __ __ __ __ am/pm
4. # of previous hospital admissions _____
5. # of previous surgeries _____

6. Level of child's pain after last surgery

0-10 0=no pain, 10=worst pain possible _____

7. Any allergic reactions?

○ Yes List: ○ No

8. Does your child have any conditions involving pain?

○ Yes ○ No

9. Previous severe illness diagnosed _____

10. Any previous IV starts (IV in the hand)

○ Yes # _____
○ No

Demographics

1. Gender ○ Male ○ Female

2. Child's date of birth:
(must be age 4-12 years)

_____
m/d/y

3. What race or ethnicity do you identify your child as?: **(must ask caregiver, directly)**

☐ Caucasian ☐ Aboriginal
☐ Métis ☐ Black
☐ Asian ☐ Arab
☐ East Indian ☐ Hispanic
☐ Other (Specify)

_____

☐ Declined to Answer

4. Highest level of education for each parent

Mom _____
Dad _____

Pain Treatment

1. Any treatments used (i.e. splint, sling, medication, ice, cast) to help manage your child's pain today? Please enter each treatment below. ○ Yes ○ No

_____
_____
_____
_____

2. Other strategies used for pain (i.e. toy, websites like on ACH, parent/nurse strategies)? Please enter each type below. ○ Yes ○ No

   _____

   _____

   _____

3. Did you and your child attend Surgery 101? ○ Yes ○ No
4. Before the scheduled surgery, did you access support for your child to prepare for it? If so, what type of support was it?

   _____
5. Before the scheduled surgery, did you talk with your child about the surgery? If so, what did you talk about?

   _____

Child Rating

These faces are showing different amounts of being **scared**. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared you are right now.

Parent Rating

These faces are showing different amounts of being **scared**. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared your child is right now.

Parent Rating

Pain: "How much do you think that you will be able to help (child's name) feel less pain at his/her needle procedure? 0 means that you think you will have no ability to reduce (child's name)'s pain and 10 means that you think that you will have complete and total ability to reduce his/her pain". _____

Fear: "How much do you think that you will be able to help (child's name) feel less fear at his/her needle procedure? 0 means that you think you will have no ability to reduce (child's name)'s fear and 10 means that you think that you will have complete and total ability to reduce his/her fear". _____

Anxiety: "How anxious do you think you will feel during the needle procedure on a scale from 0 ('not at all nervous or anxious') to 10 ('most nervous or anxious')". _____

PCS-Parent

Thoughts and feelings when your child is in pain

We are interested in the thoughts and feelings you have when your child is in pain. Below are 13 sentences of different thoughts and feelings. Please put a circle around the word or phrase under each sentence that best reflects how strongly you have each thought when your child is in pain.

---

1. When my child is in pain, I worry all the time about whether the pain will end.
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

2. When my child is in pain, I feel I can't go on like this much longer.
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

3. When my child is in pain, it's terrible and I think it's never going to get better.
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

4. When my child is in pain, it's awful and I feel that it overwhelms me
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

5. When my child is in pain, I can't stand it anymore
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

6. When my child is in pain, I become afraid that the pain will get worse
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

7. When my child is in pain, I keep thinking of other painful events
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

8. When my child is in pain, I want the pain to go away
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

9. When my child is in pain, I can't keep it out of my mind
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

10. When my child is in pain, I keep thinking about how much he/she is suffering
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

11. When my child is in pain, I keep thinking about how much I want the pain to stop
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

12. When my child is in pain, there is nothing I can do to stop the pain.
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

13. When my child is in pain, I wonder whether something serious may happen
NOT AT ALL MILDLY MODERATELY SEVERELY EXTREMELY

Topical anesthetic given before the IV start (e.g. Ametop)? ○ Yes ○ No

Check if have a patch on each hand. If no, stop here

<u>End data collection with family if did not meet all inclusion criteria.**</u>**

<u>Open envelope. Record arm family was randomized to on front of form.</u>

Treatment/control Start time: _____ End time: _____

Time porter arrives: _____

Record observations of behaviors before started timing length of IV start:

_____

_____

_____

_____

_____

Other observations:

_____

_____

_____

_____

_____

IV Start Procedure

1. Duration of IV start procedure from time needle touches skin to when start to put on tape (Use stopwatch) _____ Time in seconds
2. # of IV attempts (including final one)
3. List any pain management strategies used (rubbing hand, singing, talking to child) by

   Staff:

   Parents:
4. Was IV start successful (no mask)? ○ Yes ○ No
   If mask used, what was the reason? _____
   _____

RA Information

11. Time left family _____

DURING (JUST AFTER) IV START

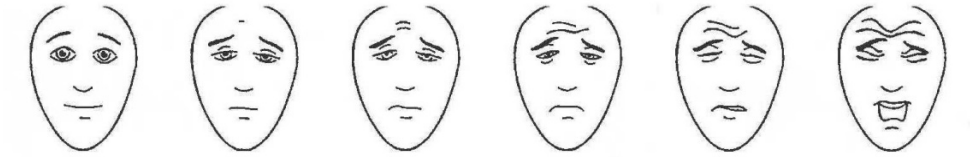
Child Rating (as they walk into OR)

These faces are showing different amounts of being **scared**. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared you are right now.

0 1 2 3 4

Child Rating (just after IV start)

These faces show how much something can **hurt**. This face (point to left-most face) shows no pain – faces show more and more pain (point to each from left to right) up to this one (point to right-most face) – it shows very much pain. Point to the face that shows how much you hurt when they were putting in/trying to put in the needle during the IV start.



0 2 4 6 8 10

Child Rating (just after IV start)

These faces are showing different amounts of being **scared**. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared you are right now.

0 1 2 3 4

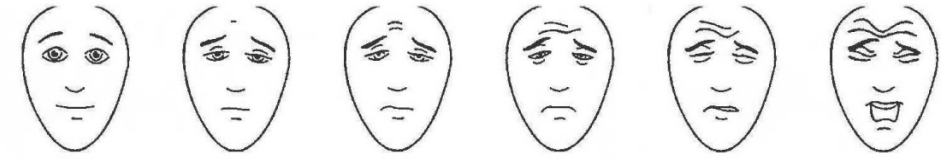
Parent Rating (as walk into OR)

These faces are showing different amounts of being **scared**. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared **your child** is right now.

0 1 2 3 4

Parent Rating (just after IV start)

These faces show how much something can **hurt**. This face (left most face) shows no pain. The faces show more pain and more pain (point to each from left to right) up to this one (right most face) – it shows very much pain. Point to the face that shows how much **your child** was hurting when they were putting in/trying to put in the needle during the IV start.



0 2 4 6 8 10

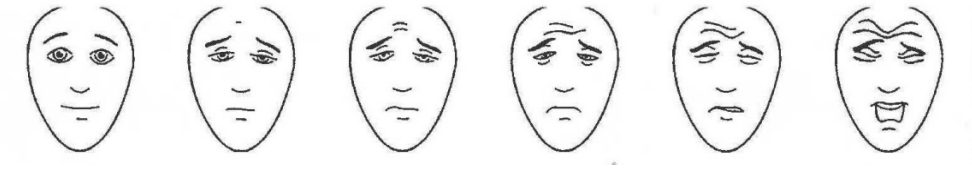
Parent Rating (just after IV start)

These faces are showing different amounts of being **scared**. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared **your child** was when they were putting in/trying to put in the needle during the IV start.

0 1 2 3 4

Research Assistant Rating – **putting in IV**

These faces show how much something can **hurt**. This face (left most face) shows no pain. The faces show more pain and more pain (point to each from left to right) up to this one (right most face) – it shows very much pain. Point to the face that shows how much the child was hurting when they were putting in/trying to put in the needle during the IV start.



0 2 4 6 8 10

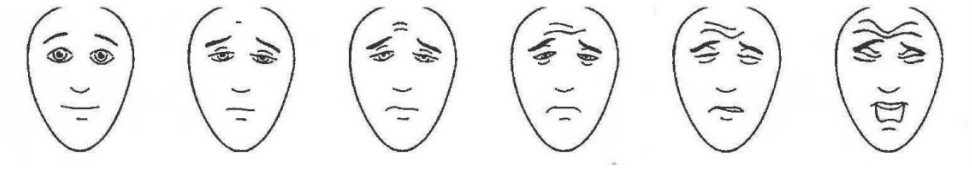
Research Assistant Rating – **putting in IV**

These faces are showing different amounts of being **scared**. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared the child was when they were putting in/trying to put in the needle during the IV start.

0 1 2 3 4

Research Assistant Rating – **pushing in propofol**

These faces show how much something can **hurt**. This face (left most face) shows no pain. The faces show more pain and more pain (point to each from left to right) up to this one (right most face) – it shows very much pain. Point to the face that shows how much the child was hurting when they were putting in/trying to put in the needle during the IV start.



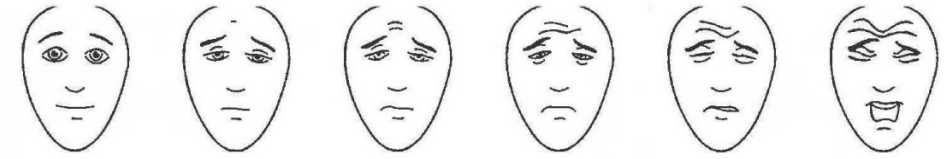
0 2 4 6 8 10

Research Assistant Rating - **pushing in propofol**

These faces are showing different amounts of being **scared**. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared the child was when they were putting in/trying to put in the needle during the IV start.

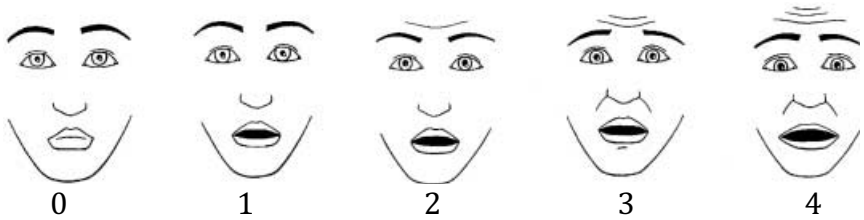
Anesthesiologist Rating

These faces show how much something can **hurt**. This face (left most face) shows no pain. The faces show more pain and more pain (point to each from left to right) up to this one (right most face) – it shows very much pain. Point to the face that shows how much the child was hurting when putting in/trying to put in the needle during the IV start.



Anesthesiologist Rating

These faces are showing different amounts of being **scared**. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared the child was when putting in/trying to put in the needle during the IV start.



Appendix D: Two-Week Follow-Up Interview Questions

Date: _____

RA Name: _____

My name is ____. I'm a research assistant with the Alberta Children's Hospital & University of Calgary. I'm contacting you as part of the study where you participated at the Alberta Children's Hospital while your daughter/son _____ was having surgery. In the consent you had agreed to be contacted 2 weeks after the surgery. Is now a good time or should we schedule another time? I would like to turn on the audio recorder now as it helps me remember everything you say. Is that ok with you?

Questions to Parent:

We ask that you answer the questions out of earshot of (child's name) so that he/she can't hear your answers. Then, we will ask (child's name) to answer the questions with the scales we gave you at the hospital. You will be there with him/her but we ask that you let them answer the questions on their own.

First I would like you to tell me everything that you can remember about when you and (child's name) came to the hospital for his/her surgery.

(Allow time for parent to think and respond)

Prompts: "What else happened?" "Tell me more" "Uh huh" "What else?"
Repeat the last thing said. Probe at least three times.

_____

_____

_____

_____

_____

_____

Now I would like you to tell me everything that you can remember about when (child's name) was getting their IV in just before their surgery.

(Allow time for parent to think and respond)

Prompts: "What else happened?" "Tell me more" "Uh huh" "What else?"
Repeat the last thing said. Probe at least three times.

_____

_____

_____

_____

_____

_____

Do you have the envelope the research assistant gave you at the hospital? It says Day Surgery Research on it? Please pull it out and let's look at it together. [If they don't have it, email it to the participant while on the phone and ask them to retrieve it from their email. If they can't retrieve it, ask to schedule a follow-up call.]

Parent Rating

Now look at the scale with 5 faces that says "Fear Scale" on the back and that starts with the letter G. I want you to remember **when (child's name) first walked into the operating room**.

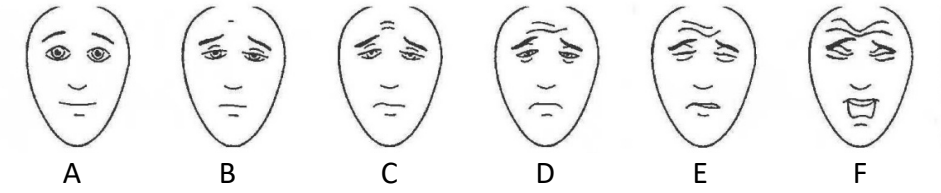
These faces are showing different amounts of being scared. The face above G is not scared at all, the next face above H is a little bit more scared, the next is a bit more scared, right up until the face above K, it shows the most scared possible. Have a look at these faces and tell me the letter under the face that shows how scared you think (child's name) was when he/she first walked into the operating room.

G H I J K

Parent Rating

Please look at the scale with 6 faces, the one that starts with the letter A.

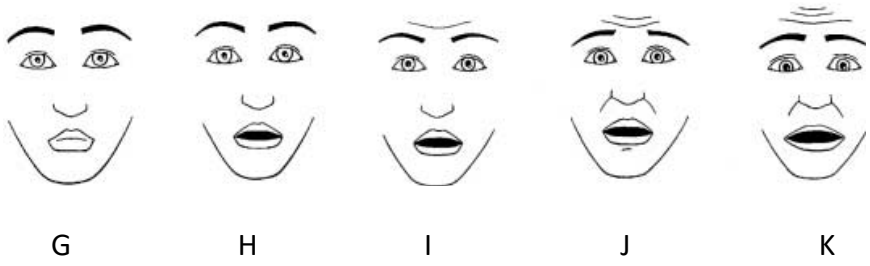
I want you to remember when (child's name) was getting the needle for his/her IV start and look at this scale.
These faces show how much something can **hurt**. The face above A shows no pain. The faces show more pain and more pain up to the face above F – it shows very much pain. Tell me the letter under the face that shows how much you think **your child** was hurting when they were putting in/trying to put in the needle during the IV start.



Parent Rating

Now look at the scale with 5 faces that says "Fear Scale" on the back and that starts with the letter G. I want you to again remember when (child's name) was getting the needle for his/her IV start and look at this scale.

These faces are showing different amounts of being scared. The face above G is not scared at all, the next face above H is a little bit more scared, the next is a bit more scared, right up until the face above K, it shows the most scared possible. Have a look at these faces and tell me the letter under the face that shows how scared you think your child was when they were putting in/trying to put in the needle during the IV start.



Now I want you to think about the next time your child has to get a needle and imagine what that will be like.

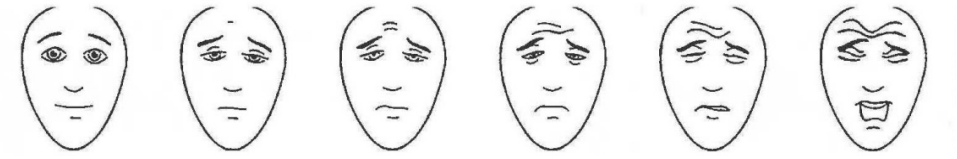
Look again at the scale with the 5 faces from G to K and choose the face that shows how scared you think your child will be the next time he/she has to get a needle.

G H I J K

Parent Rating

Please look again at the scale with 6 faces. The one that starts with the letter A.

I want you to think about the next time (child's name) has to get a needle and look at this scale. These faces show how much something can **hurt**. The face above A shows no pain. The faces show more pain and more pain up to the face above F – it shows very much pain. Tell me the letter under the face that shows how much you think **your child** will hurt the next time he/she has a needle.



A B C D E F

Pain: How much do you think that you will be able to help (child's name) feel less pain at his/her next needle procedure? 0 means that you think you will have no ability to reduce (child's name)'s pain and 10 means that you think that you will have complete and total ability to reduce his/her pain. _____

Fear: How much do you think that you will be able to help (child's name) feel less fear at his/her next needle procedure? 0 means that you think you will have no ability to reduce (child's name)'s fear and 10 means that you think that you will have complete and total ability to reduce his/her fear. _____

Since your child's surgery, has he/she had any painful events? This could be things like injuries, broken bones, needles, etc.

_____

On a scale from 0 (not at all) to 10 (very much), how much have you and (child's name) talked about their surgery since it happened? _____

Could I talk to [child's name] to ask a few questions? I need them to answer the questions all by themselves but I may ask you to help me show them the scales if that's okay.

Child Questions

I'm going to ask you some questions about what you remember when you came to Alberta Children's Hospital to have your surgery a few weeks ago. Do you remember that? I'm going to ask you some questions and there are no right or wrong answers! We just want you to tell us everything you can remember. So….

First I would like you to tell me everything that you can remember about when you came to the hospital for your surgery.

Prompts: "What else happened?" "Tell me more" "Uh huh" "What else?"
Repeat the last thing said. Probe at least three times.

_____

_____

_____

When the child is unable to provide more information, move on to the next question.

Now I would like you to tell me everything that you can remember about when you were getting the IV in your hand just before your surgery. (Check to see child knows what that means). Allow time for child to think and respond.

Prompts: "What else happened?" "Tell me more" "Uh huh" "What else?"
Repeat the last thing said. Probe at least three times.

_____

_____

_____

Ask them to look at the same faces used with the parent. (For younger children) you can get parent to put on speaker phone but again remind the parents to please not answer for their child as we need them to tell us what they remember all by themselves.

Child Rating

Now look at the scale with 5 faces that says “Fear Scale” on the back and that starts with the letter G. I want you to remember **when you first walked into the operating room** before your surgery.

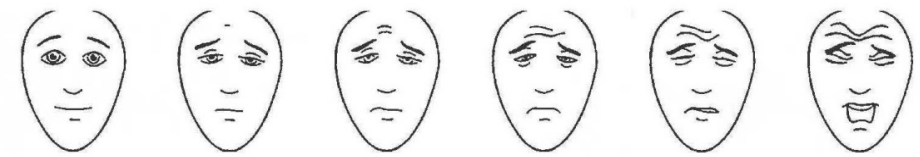
These faces are showing different amounts of being scared. The face above G is not scared at all, the next face above H is a little bit more scared, the next is a bit more scared, right up until the face about K, it shows the most scared possible. Have a look at these faces and tell me the letter under the face that shows how scared you were when you first walked into the operating room.

G H I J K

Child Rating

Please look at the scale with 6 faces. The one that starts with the letter A.

I want you to remember when you were getting the needle for your IV start and look at this scale. These faces show how much something can **hurt**. This face above A shows no pain. The faces show more pain and more pain up to the face above F – it shows very much pain. Tell me the letter under the face that shows how much **you** hurt when they were putting in/trying to put in the needle during the IV start.



A B C D E F

Child Rating

Now look again at the scale with 5 faces that says “Fear Scale” on the back and that starts with the letter G. I want you to remember when you had the IV start.

These faces are showing different amounts of being scared. The face above G is not scared at all, the next face above H is a little bit more scared, the next is a bit more scared, right up until the face about K, it shows the most scared possible. Have a look at these faces and tell me the letter under the face that shows how scared you were when they were putting in/trying to put the needle during the IV start.

G H I J K

Now I want you to think about the next time you have to get a needle and imagine what that will be like.

Now look again at the scale with 5 faces that says “Fear Scale” on the back and that starts with the letter G. I want you to think about the next time you have to get a needle.

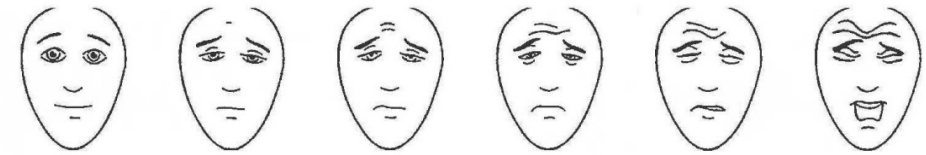
These faces are showing different amounts of being scared. The face above G is not scared at all, the next face above H is a little bit more scared, the next is a bit more scared, right up until the face about K, it shows the most scared possible. Have a look at these faces and tell me the letter under the face that shows how scared you think you will be the next time you have to get a needle.

G H I J K

Child Rating

Please look at the scale with 6 faces. The one that starts with the letter A.

I want you to think about the next time you have to have a needle and look at this scale. These faces show how much something can **hurt**. This face above A shows no pain. The faces show more pain and more pain (point to each from left to right) up to the face above F – it shows very much pain. Tell me the letter under the face that shows how much you think **you** will hurt the next time you have to get a needle.



A B C D E F

Thank the child and then say to parent:

Thank you for answering these questions and helping us understand how children experience pain at the hospital. We couldn't do this without your help. Have a good day. [For children in the control group, let parents know you'll email them to invite them to a visit with MEDi® that will be scheduled when the study is completed.]

Other comments:

_____

_____

_____

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