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Patient Satisfaction with Pessary Usage In a Nurse-Led Pessary Clinic:

By

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies for acceptance, a thesis entitled "Patient Satisfaction with Pessary Usage In a Nurse-Led Pessary Clinic" submitted by E. Grace Neustaedter in partial fulfillment of the requirements for the degree of Master of Nursing.

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ABSTRACT

Pelvic organ prolapse (POP) and urinary incontinence (UI) are common health problems among women. Pessaries are vaginal devices used to relieve POP and UI. A nurse-led pessary clinic at the Grace Women's Health Centre in Calgary, Alberta provides pessary fittings for many women. There exists only anecdotal evidence of the benefit of pessaries.

In this study, evidence was found to indicate successful outcomes of pessaries fitted for POP and UI. The research method used was a descriptive retrospective chart audit of all patients who attended the pessary clinic for pessary fittings between October 2000 and October 2003. A chart audit tool, developed by the investigator and her supervisor, was used to obtain data. A sample size of n = 700 was obtained. The primary outcome variable was successful fitting of the pessary.

Findings suggest that the majority of women fitted did achieve success. The results indicate that pessaries are a practical and feasible option for women with POP and UI.

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DEDICATION

I dedicate this thesis to Ms Shirley Tyson. She is a wonderful woman and nurse who I had the privilege of working with for a number of years. She has the gift of encouragement and affirmation; without this I would not have tackled graduate school. She saw potential in me and gently pushed me on to face the challenge. Thank-you, Shirley. I am grateful to know you.

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CHAPTER ONE: INTRODUCTION

Pelvic organ prolapse and urinary incontinence among women are common health problems and are not new to this generation (Bash, 2000). These health problems tend to become more challenging following childbirth and as women age (de Mola & Carpenter, 1996). Women are living longer and an increasing aging population increases the need for assistance with these health issues (Farrell, 2003).

Pessaries are devices worn inside the vagina and have been an effective treatment option for pelvic organ prolapse for centuries and, more recently, for urinary incontinence (Cundiff, Alison, Weidner, Visco, Bump, & Addison, 2000). The modern-day pessary is typically made out of flexible silicon and is available in many shapes and sizes. The pessary is easily inserted and removed and the routine for care is simple (Bash, 2000).

A nurse-led pessary clinic has been in operation at the Grace Woman's Health Centre in Calgary since October 2000. Many women have been fitted with pessaries by the Registered Nurses (RNs) at the clinic. Based on the experience of the author, there is at least anecdotal evidence to suggest that the women have benefited from this service.

However there is a lack of empirical evidence of the precise number of women seen and the rates of successful fittings. Evidenced-based practice is essential to ensure that patient care is not merely based on opinions and traditional practices but rather on research findings and expert clinical consensus (Thurston, 2002). Therefore, it is important to obtain some measure of clinical benefit to the patients who attend the clinic.

Statement of the problem

The major problem and gap in knowledge is the lack of clear evidence indicating the success of pessaries as an option for women with pelvic organ prolapse (POP) and urinary incontinence (UI). Pessaries are believed to be helpful for treatment of POP and UI but the evidence has been primarily anecdotal. There is a paucity of research studies to support claims of their benefit among women with these health problems. The investigator addressed this problem in the current study by conducting a systematic chart audit of the women who presented at the clinic for pessary fittings.

The pessary clinic at the Grace Woman's Health Centre has been operating since October 2000. Approximately 700 women have been referred to the clinic and most of these women have been fitted with pessaries. The outcome of the pessary fittings with this group of women has never been investigated. As a first step in evaluating pessary usage, the investigator obtained descriptive data about the outcome of the fittings. The major objective was to determine the effectiveness of the pessary as measured by the length of time of willingness of the patient to continue to use the pessary. If the patient does not continue using it, the pessary is not successful for her. Data were also obtained on the various styles of pessaries used for specific health problems as well as patient demographics.

Significance and Background

North America is experiencing a shift in population demographics with respect to the increasing numbers of aging women. Along with the increase in population, women are living longer than in the past. It is estimated that

approximately 50% of the women aged 50 today will live into their 90's (Morley, 1996). As a greater number of women enter their postmenopausal years, health problems with UI and POP become much more common (Farrell, 2003) due to changes that occur with declining hormones and aging. Pelvic prolapse is one of the most common problems with which gynecologists deal. The incidence of prolapse increases with age and child bearing (Poma, 2000). About 50% of all parous women develop some degree of pelvic organ prolapse (Schultz, 2001), while one in nine of all women in the United States suffers with prolapse (Graul & Hurst, 2002). These problems are not only found in the aging population but also occur in young or nulliparous women, or in neonates with inherent genetic causes frequently associated with spinal defects (de Mola, Loret, & Carpenter, 1996). A history of pelvic surgery or trauma predisposes women to prolapse (Davila, 1996).

Pessaries have been used for pelvic organ prolapse throughout history. References to prolapse date to 1500 B.C. (de Mola et al., 1996) and throughout the ages different forms of pessaries were used to correct this problem. Types of pessaries include pomegranates, sponges dipped in wax, cloth, wood, metal and cork (Bash, 2000; de Mola et al., 1996). Pessaries achieved a peak of popularity in the 1800s but fell from favor with the improvements in anesthesia and surgical techniques in the early 20th century, resulting in more women having surgical interventions (Farrell, 2003). A steady decline in the use and familiarity with pessaries occurred, as well as a lack of instruction in their use in medical training. For many physicians, even today, they are somewhat of a medical

curiosity (Cundiff & Addison, 1998) and not well understood due to the lack of instruction offered and the many different types available.

Flood, Drutz, Cruz and Brown (1997) conducted a survey to determine the exposure of obstetrics and gynecology residents in Canada to specific training in urogynecology and reconstructive pelvic surgery. The investigators achieved a 55% (n = 141/256) response rate. Urogynecology was a required rotation for 23.6% (n = 33) of the respondents. By their fourth year, 17% (n = 24) of the respondents had not received formal instruction on taking a history for UI and only half of these (n = 12) had ever fitted a pessary. According to the authors, this study raises some interesting concerns regarding the training of gynecologists in Canada as it pertains to issues regarding urogynecology and pessary use.

A survey of the American Urogynecologic Society indicated that pessaries are experiencing somewhat of a rebirth in design and use. Seventy-five percent of respondents (n = 359) indicated that they would use pessaries as a first line therapy for prolapse, with 92% believing that pessaries relieve symptoms (Cundiff & Addison, 1998). Pessaries are believed to be an excellent conservative management alternative for the treatment of UI and POP, as well as a diagnostic tool for determining the appropriate surgical option (Flood & Hansen, 2003).

As previously indicated, pessaries have been used for many centuries for POP. They are a relatively new option in the treatment of UI, as their usefulness in stabilizing the urethral-vesicular junction has been realized (Flood & Hansen, 2003; Bhatia, Bergman & Gunning, 1983). In recent years, many devices have

been marketed to control women's incontinence in order to avoid major surgery (Kondo, Yokoyama, Koshiba, Fukui, Gotoh, Yoshikawa, Yamada & Takei, 1997). Kondo et al conducted a study demonstrating that surgery for UI can be effective in most patients but the effectiveness gradually abates with the passage of time. This results in disappointment and frustration for patient and physician. The use of pessaries may prevent these unnecessary surgeries. There is a need for randomized controlled trials of all such devices to define their effectiveness for the nonsurgical management of UI.

The American National Institute of Health requested research to evaluate pessaries compared with surgical intervention for the management of POP in the late 1990's (Cundiff & Addison, 1998). The need for such a study indicates that there is a lack of consensus regarding the use of pessaries. No studies have been conducted that address the effectiveness of pessary use in the management of pelvic organ prolapse as compared to the outcomes of surgery for the same indication. Farrell (2003) states that there is a reluctance to use pessaries due to a lack of familiarity with them. Physicians may be daunted by the prospects of inefficiency and troublesome frequent patient visits (Farrell, 2003).

According to Brubaker (1991), the financial cost of surgical management deserves consideration when compared to the considerably lower costs of nonsurgical management of POP and UI. She suggests that patients are better served by being offered a variety of options for nonsurgical as well as surgical management of these problems. At a nurse-run pessary clinic at the Royal Alexandra Hospital in Edmonton a review was conducted of 1216 patients

referred to the clinic by physicians. Successful fitting, defined as the retention and effective use of the pessary for one month, was accomplished in 75% of patients with prolapse, 67% of patients with mixed UI, 64% of patients with stress incontinence and 58% of patients with urge incontinence (Flood & Hansen, 2003). The authors conclude that, with increasing patient requests for conservative options, a nurse-run clinic is ideal for pessary education, fitting and care. It has the additional benefit of a decrease in health care costs in a time of fiscal restraints.

The significance of the current study is therefore to provide further evidence that the pessaries fitted at the pessary clinic at the Grace Woman's Health Centre are of benefit to the patients and provide a conservative option to women who have UI and POP.

Purpose of Study

In October of 2000, a pessary clinic was established at the Grace Woman's Health Centre in Calgary. Patients were referred to this clinic to be assessed and fitted with a pessary for UI and POP. Referrals came from gynecologists, urogynecologists, urologists, family physicians and physiotherapists. Patient education and follow-up were priorities in the care of the women. In the current study, the investigator's intention was to determine the success of the pessaries in supporting the POP and decreasing the incidence of UI for the women fitted between October 2000 and October 2003. This study will make a contribution to evidence-based practice in relation to pessary usage for POP and UI.

This study is similar to the one conducted in Edmonton (Flood & Hansen, 2003). It will be recalled in that study, "success" was determined by the retention and effective use of the pessary for one month. The major difference in the present study is that the length of time of continuous pessary use will be obtained for each patient, rather than "success" being gauged at one month. From the clinical observations of the investigator, most women will discontinue use in the first six months. The reasons for discontinuing usage will also be determined.

In summary, the history of pessary use extends back over centuries and in the past 10 to 15 years pessaries have once again become a more common alternative to surgery for both POP and UI. Anecdotal evidence suggests that they are a well-received and effective treatment for both conditions, however there remains a paucity of studies that provides evidence of their "success" for these health concerns. The major gap in knowledge is evidence of their benefit and continued usage among women fitted with pessaries for POP and UI. The current systematic chart audit will provide data to support or reject the claims of success of pessaries in addressing the health problems of UI and POP by examining the charts to determine the reasons for pessary fitting, the outcome of the fittings and how long the women continued to use the pessaries, as well as other demographic data.

Research Questions

The present study was guided by the following research questions:

1) What is the success rate of pessaries fitted for POP and UI at the first follow-up visit? For the purpose of this study, "success" is defined as, at the first follow-up visit, usually scheduled at two weeks:

- The pessary remains in place following fitting
- The patient subjectively reports being comfortable with the device
- The pessary facilitates prevention of descent of the prolapsed pelvic organ or decreases urinary leakage as indicated by the patient

2) What is the rate of successful fittings of pessaries used to support POP?
3) What is the rate of successful fittings of pessaries used to reduce UI?
4) How satisfied are women who use pessaries, as determined subjectively by ongoing usage of the pessary?
5) What are the most frequently used styles of pessaries?
6) What are the most common reasons for discontinuing use?

CHAPTER TWO: LITERATURE REVIEW AND THEORETICAL FRAMEWORK

Literature Review

An extensive search of the literature was conducted using the CINAHL and Medline databases. The key words for the search were *pessary, pelvic organ prolapse* and *urinary incontinence*. The time period for the search was from 1980 to 2004. Some articles were already in the possession of the investigator, and some were located through the reference lists of other articles.

The review will be presented in two sections. In the first section, the investigator reviews the articles that are historical reviews of pessaries, descriptions of their uses, types available and instructions regarding their insertion and care. The second section is concerned with a review of research studies related to pessaries.

Review Articles

The review literature available on pessaries indicates that in recent years there has been an apparent renewal of interest in their use for POP, UI as well as for diagnostic use preoperatively. Bartscht (1991), Brubaker (1991), Niemiec (1989), and Sulak (1991) in their individual reviews, all suggest that pessaries have had a history of usefulness in the nonsurgical treatment of pelvic floor relaxation, and offer an effective and safe alternative for patients to consider. Niemiec (1989), Sulak (1991), and Brubaker (1991) highlight the styles and types available and their indications. Sulak (1991) stresses that good patient instruction is key to the successful use of the devices. In addition to their

convenience and low cost, one of the major benefits is that, unlike surgery, they do not cause any permanent physical changes.

Brubaker (1991) states that the modern use of pessaries is largely a function of the individual physician's experience and training and the availability of the devices. Bartscht (1991) points out that some residency programs do not have content concerning pessaries in their curricula, as they are considered outmoded. Farrell (1997) also indicates that the training in pessary use and care is badly neglected in the Canadian obstetrical and gynecology residency programs. Brubaker (1991) recognizes that most pessary-care regimes are anecdotal and there is a need for studies that would aid in determining the optimum method of care for patients with pessaries.

Brubaker (1991) and Bartscht (1991) in their review articles indicate that pessaries require healthy vaginal tissues for optimal results. Well-estrogenized tissues prevent potential complications such as erosions or irritation, therefore older women with lower estrogen levels are more prone to such problems. Bartscht (1991) has outlined various contraindications for pessary use such as marked outlet relaxation and noncompliance. Overall, there are relatively few contraindications for their use.

In 1991, Buckley, McInerney and Stephenson presented a case study of a bladder-uterine fistula that resulted from a wishbone-like pessary placed in a woman in 1945, which was forgotten and left in place for 43 years. Removal of the pessary was done under anesthetic followed by surgical closure of the fistula. Although "the forgotten pessary" has been quoted as a potential complication for pessary use, this is the only documented case of such an event occurring.

Several review articles were published in the early 1990's in which the authors discuss the history of pessaries, indications for use and details about types, fitting methods, and follow-up (Davila, 1996; Deger, Menzin & Mikuta, 1993; Miller, 1992; Moore, Flood & Griffiths, 1994; Morley, 1996; Wood, 1992).

Deger, Menzin and Mikuta (1993) present a fascinating history of the pessaries over centuries to their peak in popularity in the 1800's, and their relegation to a second-line therapy due to the modern-day surgical developments. They discuss their various indications for their use, including POP, uterine retroversion during pregnancy, stress incontinence and use prior to surgery to help determine the type of surgery to be done. Details about insertion and removal of the different styles of pessaries, potential complications encountered and follow-up are described.

Wood (1992), in her review, discusses the merits of hysterectomy as opposed to pessaries for the treatment of uterine prolapse. Prior to the advent of modern surgery pessaries were the only alternative for prolapse but became unpopular in the past quarter century because of the focus on surgeries. She believes that there is an appropriate role for the therapeutic use of pessaries in women. Miller (1992) emphasized the importance of follow-up, indicating that a woman's requirements for a pessary can change over time. Revision of styles and sizes may be necessary, thus ongoing care is essential. He includes details about the various styles and their usage.

Moore, Flood and Griffiths (1994) published a lengthy discussion of pessaries, and their role for women who wish to avoid surgery or who are not good surgical candidates. Complications such as vaginal erosions may arise

from using pessaries due to improper fitting or inadequate follow-up. According to Moore et al, there are contraindications to pessary use such as vaginal or urinary tract infections, constipation, uncontrolled diabetes, and noncompliance for follow-up. They present details about the patient history that is required from each potential pessary wearer and discuss the role of hormone therapy in pessary users.

Morley (1996) discusses pessaries as they are used for vaginal organ prolapse, an issue he believes will increase significantly as women are living longer and the population grows. He mentions the primary underlying cause of uterine prolapse as related to some inherent weakness in the supporting connective tissues of the pelvic structures, thus allowing for the development of uterine descensus secondary to other causes such as obstetrical trauma or heavy lifting. He also discusses the various surgical approaches used for POP. Morley believes that the education of younger physicians is compromised in the use of pessaries due to a lack of familiarity with their styles, their use and care. This may lead to unsatisfactory results and a negative experience for patient and physician.

In their review, De Mola and Carpenter (1996) present a detailed historical overview of genital prolapse in neonates and young women, a rare condition usually associated with congenital spinal defects. Successful correction of genital prolapse in the neonates can be achieved with simple digital reduction or the use of small pessaries made from materials such as a 1-inch, rolled, sterile Penrose drain with a string attached, or a placing a nipple in the vagina, fixed with adhesive paper tape across the infant's buttocks. Pessaries are also a

feasible option for young and nulliparous women. Surgical approaches to correcting the genital prolapse such as cervical amputation or hysterectomy are also presented in this review.

In the late 1990's, two practical reviews were published about the selection, fitting and management of pessaries (Cundiff & Addison,1998; Farrell, 1997). Farrell considers the pessary as an indispensable option for the conservative management of symptomatic vaginal prolapse. He offers step-by-step information for the fitting, insertion and removal of the common covered ring pessary as well as a thorough discussion of the follow-up and management of problems.

Cundiff and Addison (1998) also comment on the use of pessaries among gynecologists. They suggest that there is a perception that pessaries should only be reserved for use with women who are not surgical candidates instead of an alternative to surgery. They believe that there are benefits for women in avoiding major surgery and its potential complications. Lack of precise knowledge on what can be accomplished by specific pessaries in patients presenting with certain anatomic defects is a major reason why pessaries are not used to their full benefit.

Amuzo (1998) briefly reviewed all the non-surgical therapies for UI. She does not recommend pessaries as they may cause urethral irritation or urinary tract infections (UTI's). She states that certain newer types of pessaries may be helpful but believes that there is not enough data on their safety to recommend them.

Payne (1999) discusses the recent advances in nonsurgical treatment of UI. Along with a brief description of pessaries and their cost-effectiveness, he also discusses medications, pelvic floor rehabilitation techniques and neuromodulation. He believes that pessaries have not been tested to any great extent and further research is necessary.

Johnson (2000) reviewed behavioral treatments for UI resulting from pelvic floor relaxation. Three case studies were presented dealing with pelvic floor muscle rehabilitation, pharmacologic management and pessaries. The case study on the pessary describes the patient's history, her pessary fitting and her outcome. The pessary proved to be beneficial in her condition. The follow-up process was considered to be very important. Johnson believes that the pessary is an excellent option for the treatment of UI.

Bash (2000) provided a review of the history, indications for use, patient evaluation and placement of the vaginal pessary. Although serious complications are rare with pessary use, Bash discusses some minor complications that may arise. These include an increase in vaginitis and infections. Estrogen therapy is an excellent way of avoiding these complications and Bash explains the protocol for use of estrogen cream.

Farrell (2003) provides an excellent historical and descriptive review of pessaries. He believes that family doctors and gynecologists must be equipped to meet the growing demand for conservative approaches to POP and UI, resulting from the greater numbers of women entering the post-menopausal age group. From his experience as a gynecologist, he recommends pessaries as an option for women with POP and UI. He emphasized the need for a thorough

patient evaluation, detailed instructions to the patient and a specific follow-up protocol. By paying careful attention to these areas, potential complications are avoided and patient satisfaction will be enhanced.

Flood and Hanson (2003) also provide a detailed historical perspective on pessary use. Indications for contemporary use are provided, and pessary fitting and care is explained in detail. They indicate that one of the reasons physicians avoid pessaries are a lack of familiarity with pessary fitting and management. They believe that the expense of stocking various types and sizes of pessaries in doctor's clinics is a deterrent to their use. Many physicians are also concerned that using pessaries in their practice will result in time-consuming follow-up visits due to complications arising from their use. Flood and Hanson (2003) believe that instead of pessaries remaining an option used only in physicians' practices, pessary clinics are an alternative for women requiring pessaries, meeting their needs for fitting, follow-up and care. They also believe that professional registered nurses are very effective in providing the necessary skills of fitting and following women with pessaries in these clinics. Nurses are educated and trained in providing effective patient education and follow-up.

Research Studies

A prospective cohort study conducted by Bhatia, Bergman and Gunning (1983) provides an explanation for how vaginal pessaries restore urinary continence. They placed pessaries in 12 women with stress urinary incontinence (SUI) undergoing detailed urodynamic studies and found that there was a significant ($p < 0.005$) increase in urethral functional length and urethral closure pressure, compared with the urodynamic studies done previously without the

pessary. Ten of the 12 women became continent with the use of the pessary. Although the study was conducted on a small number of participants, the results provide evidence for how the pessary works for restoring continence by stabilizing the urethra and the urethral vesicular junction.

The use of pessaries to help select the type of surgery to be done was demonstrated in a prospective cohort study (Bergman, Koomings & Ballard, 1988). Sixty-seven women who were to have surgical correction of a cystocele (anterior vaginal wall prolapse) that extended beyond the urethral orifice, had pessaries inserted to reduce the prolapse. Under these circumstances, the pessary mimicked the effect of an operative repair of the cystocele. Following insertion of the pessary they were clinically and urodynamically evaluated. It was found that twenty-four had SUI with the pessaries in place ($p < .05$). That is, they leaked urine with the pessary holding up the prolapse. They therefore had surgery done that included correction of the SUI revealed by the pessary insertion. The other 43 women did not leak with the pessaries inserted, thus they only had their cystoceles repaired. This study demonstrates how women, with significant anterior wall prolapse, may be continent prior to surgery in spite of a weak urethral sphincter. This was because the urethra sagged along with the bladder, causing kinking of a poorly supported urethra. This kinking prevented leakage of urine. The pessary was useful in predicting the potential outcome of SUI with a surgical repair designed only to correct the prolapse. The use of the pessary caused a more satisfactory outcome of surgery for these women, because the surgery used for those who had leakage with the pessary was altered to include a repair of their SUI.

Sulak (1991) conducted a retrospective study of 116 patients fitted for pessaries for symptomatic pelvic relaxation and found that 30% of the patients continued to use the pessary two years later. The remainder went on to have surgery (n = 29), died or were lost to follow-up (n = 31). None of the patients wearing pessaries had major complications and 90% of them were able to care for the pessary themselves. Ten percent needed the assistance of their physicians to care for the pessaries as they were unable to care for them unaided. The research indicates that pessaries can be a useful treatment for women with symptomatic pelvic relaxation when a protocol is followed that includes specific and thorough patient instruction.

In 1991, Suarez, Baum and Jacobs conducted a prospective cohort study on 12 patients with SUI who were fitted with a standard contraceptive diaphragm. Eleven of the twelve patients (91%) achieved continence with the device in place. Two withdrew from the study due to discomfort associated with the diaphragm. Although the number of participants was small, the investigators concluded that vaginal devices were a viable alternative for the appropriate patients, a temporizing measure until surgery for some, or a diagnostic test in predicting successful outcome for surgical correction.

Kondo, Yokoyama, Koshiba, Fukui, Gotoh, Yoshikawa et al. (1997) conducted a 12-week prospective clinical trial using both subjective and objective evaluation tools to determine the usefulness and safety of a bladder neck support prosthesis in patients with SUI (n = 57) or mixed incontinence (stress and urge) (n = 20). Results showed improvement in UI in subjective indices, and also improvement in objective tests including a pad weight test reduction of urine loss

($p < 0.001$) as compared to the tests prior to insertion of the prosthesis. Twenty-two women (29%) reported complete continence and 39 (51%) had decreased severity of incontinence by 50%. The investigators concluded that this vaginal prosthesis was safe, well tolerated and clinically effective for the reduction of UI.

Vierhout and Lose (1997) conducted a review of nine studies done on vaginal (n = 6) and urethral (n = 3) devices designed to cure or improve urinary leakage. Vaginal devices work by stabilizing the bladder neck, and urethral devices simply obstruct the urethra. Results showed an improvement or cure of 63% with vaginal devices and 43% with urethral devices in the studies that were reviewed. There was a high dropout rate for the urethral devices, which was correlated with a high incidence of urinary tract infections (UTI's) and complaints of discomfort. Fewer side effects were noticed with the vaginal devices, with minor discomfort, placement problems and difficulty with removal being mentioned.

Wu, Farrell, Basket and Flowerdew (1997) conducted a valuable prospective cohort study that evaluated a simplified protocol for pessary management for symptomatic POP. Of the 110 women enrolled, 74% (n = 81) were successfully fitted. The fitting was judged successful if:

1) the pessary was not expelled
2) the patient could not feel the pessary
3) the pessary did not descend to the introitus during testing.

After one year, 66% (n = 73) were still using the pessary, and 53% (n = 58) were still users after three years. Results indicated that patients who had SUI were

less likely to have successful fittings ($p > .03$) and more likely to opt for surgery. Of the 81 successfully fitted, 13 discontinued pessary use within the first month and six were lost to follow-up. The highest rate of discontinuation occurred within the first year ($n = 20$). In the second year, only one woman discontinued use. In the first year of pessary use, follow-up was scheduled for two weeks, and then at three-month intervals, assuming the patient remained free of complications. The visits were then extended to every six months in the second and subsequent years.

Several studies appeared in the late 1990's and early 2000's that evaluated pessaries for various indications. Sander, Thyssen, Lose and Anderson (1999) assessed the effect of the "Continence Guard" (a foam vaginal pessary) on urinary leakage and quality of life. This three-month study was conducted on 55 women with SUI using questionnaires, objective testing such as urodynamic studies and a voiding diary to measure the effectiveness of this device. Of those who started, 74.5% ($n = 41$) completed the study. Of these, 20% ($n = 11$) subjectively felt themselves cured, and 49% ($n = 27$) felt an improvement in their urinary loss. After the study was over 58% wanted to continue using the device. The number of pads used in 24 hours decreased ($p < .001$) and the number of leakage episodes decreased ($p < .001$). There was a highly significant improvement in the quality of life ($p < .001$) based on a subjective questionnaire given to the patients.

Similar to the study by Bergman et al (1988), Romanzi, Chaikin and Blaivas (1999) evaluated 60 women with cystoceles before and after pessary insertion. They concluded that voiding difficulty, bladder outlet obstruction and

occult SUI may coexist and are associated with prolapse. In women with severe cystoceles, ring pessary reduction before urodynamic studies is useful to determine these occult conditions. Stress urinary incontinence is often unmasked by pessary support of the prolapse and thus can be used prognostically before surgical correction.

A prospective cohort study by Chaiken, Groutz and Blaivas (2000) also demonstrated that the use of pessaries reduced prolapse as a method to unmask sphincteric incontinence in 58% (n = 14) of women. The women had prolapses but were continent before the pessary was inserted. This demonstrates the use of pessaries preoperatively as a means to determine the most appropriate type of surgical intervention to be used.

As previously stated, a survey was conducted to assess pessary use by members of the American Urogynecologic Society (Cundiff, Weidner, Visco, Bump & Addison, 2000). The purpose was to describe current trends in pessary use for POP. Of the 359 respondents out of 748 (a 48% response rate), 77% (n = 276) claimed to use pessaries for first-line therapy for prolapse, while 12% (n = 44) used them only for women who were not surgical candidates. Ninety-eight percent (n = 352) of the respondents reported using pessaries in their practice. The investigators believe that the high results in the study may be due to selection bias. It is possible that those that did not respond were more likely to be those who did not use pessaries in their practice or that had stronger negative opinions about them.

A prospective cohort study was conducted on 38 women with SUI (Robert & Mainprize, 2002). The investigators focused on the patient's response and

their acceptance of the vaginal pessary over one year, or until they dropped out of the study. After one year, 16% (n = 6) wished to continue using the pessary. Those who were successful were younger women, and those who had undergone less pelvic surgery. Sixty-nine percent (n = 22) reported no change, 16% (n = 5) were unable to retain the pessary, one patient was never successfully fitted and one developed a skin rash on her leg. Adverse events included increased vaginal discharge, discomfort and difficulties with self-care. Forty-one percent (n = 16) went on to have incontinence surgery within a year. The investigators concluded that although the incontinence pessary used was successful in only a small proportion of women with SUI, it remains a safe alternative for those seeking conservative measures.

Flood and Hanson (2003) retrospectively reviewed the charts of 1216 women referred to the pessary clinic at the Royal Alexandra Hospital located in Edmonton. The presenting diagnoses for fittings were prolapse (54%, n = 656), SUI (30%, n = 364), mixed incontinence (10%, n = 122) and urge incontinence (6%, n = 74). Successful fittings were defined as satisfaction by the patient fitted with the pessary for both comfort and treatment of the presenting complaint for the first month afterwards. Success rates for those fitted for prolapse was 75% (n = 492), for SUI 64% (n = 233), for mixed incontinence 67% (n = 82), and for urge incontinence, 58% (n = 43). The investigators believe that their high success rates were due to the teaching, follow-up and care of the women.

Flood and Hanson described their protocol for fitting and follow up, including frequency of removal and cleaning. They included the protocol used for

local estrogen therapy to prevent vaginal irritation. They discuss in detail how to deal with common concerns and problems that may arise.

The present study is similar to the Edmonton one (Flood & Hansen, 2003) in that a retrospective review of pessary fittings was conducted. In addition, the clinics in Edmonton and Calgary both have Registered Nurses fitting the pessaries, providing teaching, follow-up and care. The major differences in this present study are:

1) The total length of time the women used the pessary was determined rather than "success" at one month only
2) The number of women having problems after one month was determined
3) The reasons for pessary discontinuation after one month were documented.

In summary, the search of the literature revealed that that there is a rebirth in the interest and use of vaginal pessaries for UI and POP in this generation. Although some skepticism remains, more investigators and clinicians are advocating the use of pessaries as an option for the treatment of UI and POP. The consensus of some authors is that pessaries are not given enough attention in the training programs for physicians. There are some research studies that also provide support for the use of pessaries, but they are limited in their scope.

Theoretical Model

The Roy Adaptation Model offers a theoretical approach to this research as it describes patient adaptation to a constantly changing environment (Artinian, 1990). Philosophically, this model assumes the creativity, purposefulness and

holistic ability of the individual to adapt positively to external forces. Thus, the woman who presents with UI or POP is faced with options to adapt to the changes in her bodily functions. These changes would be interpreted as focal stimuli. Contextual stimuli would involve the woman's personal world and how interactions with it contribute to her responses to her altered physical changes. These stimuli may involve her family, her work and alterations in relationships as a result of her physical changes. Residual stimuli refer to all the other stimuli present, which might include the philosophical assumptions of the patient, her personal views about surgery perhaps due to previous experiences (Roy & Corliss, 1993).

In Roy's conceptual model, the goal of nursing is to promote adaptation and thereby contribute to health. Health is a state and a process of being and becoming integrated and whole. In the case of a woman with UI or POP, the process of adapting positively to her situation would be by the use of a pessary or possibly deciding on a surgical intervention.

The assessment focuses specifically on her adaptive behavior to the present, perhaps the use of pads, or the avoidance of certain activities. The goal would be to decrease UI, or provide physical relief from symptoms of POP. The fitting of a pessary would constitute the intervention. Evaluation would consist of the follow-up to the fitting, and would include evaluation of outcomes and results achieved by the fitting of the pessary. It may lead to reassessment and refitting as required (Roy & Corliss, 1993).

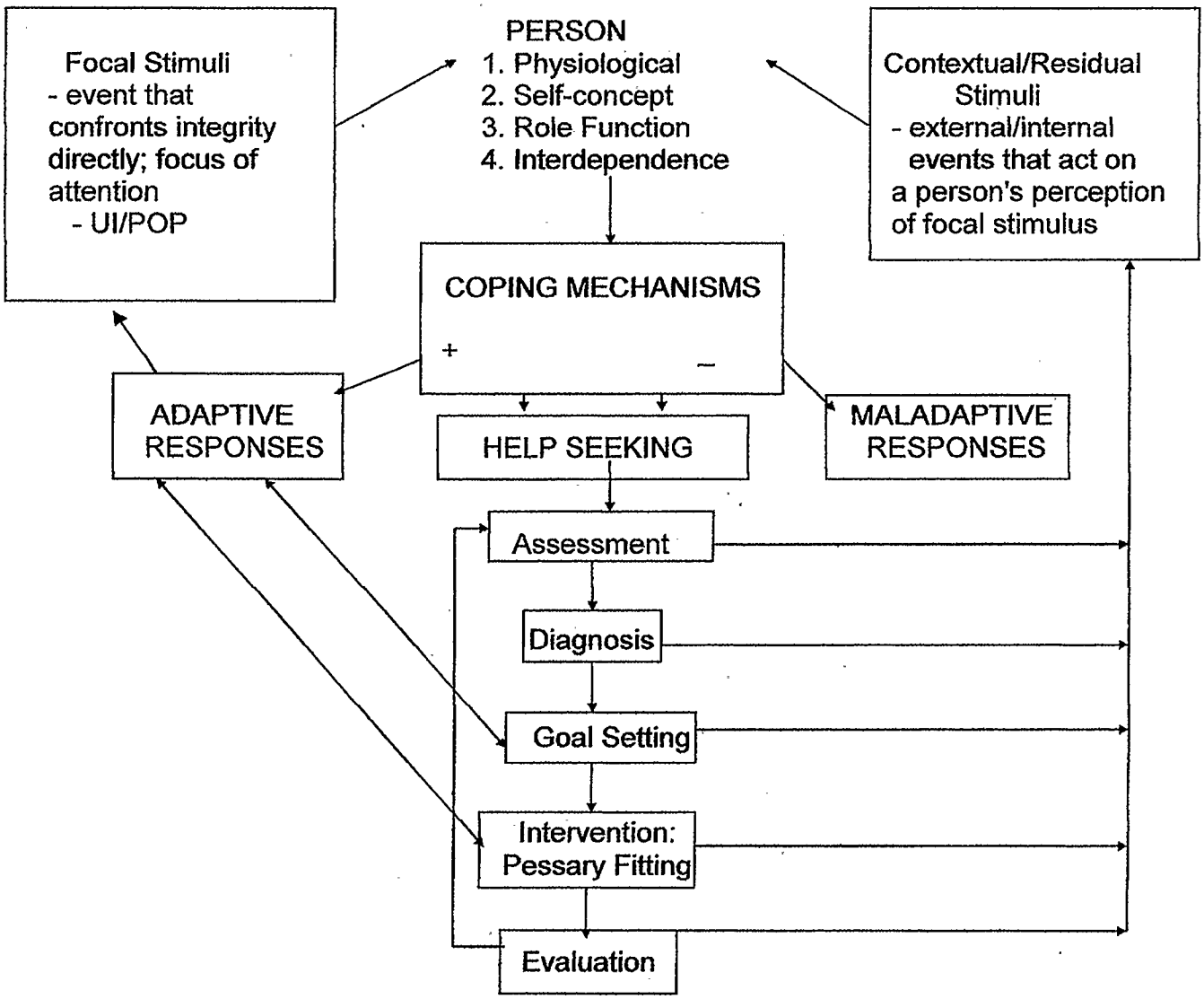

Figure 2.1 Roy's Adaptation Model

- Based on Roy's Adaptation Model (RAM) which views the person as an adaptive system with coping processes and as a whole comprised of parts (physiological, etc) (Roy & Andrews, 1999)
- Based in part also on Leventhal's self-regulatory model of illness behavior, with built-in feedback mechanisms and coping strategies (Leventhal & Cameron, 1987)

CHAPTER THREE: RESEARCH METHOD

Research Design

The research method is a descriptive retrospective chart audit of all patients who attended the pessary clinic for the purpose of being fitted with a pessary between October 2000 and October 2003. The charts were audited using an chart audit tool devised by the investigators (see Appendix A), to obtain data concerning patient demographics, the success rate of the pessaries, the types used and stated reasons for discontinuance of the pessaries.

Sample

The sample consisted of the entire population of women that attended the clinic between October 2000 and October 2003 for the purpose of being fitted with a pessary. The total sample consisted of 700 women. A sample size of 700 provides a margin of error of four percent.

Recruitment

The charts of all patients seen at the clinic between October 2000 and October 2003 for pessary fittings were included. Those not successfully fitted were also included in the study. These include:

- patients who could not retain a pessary comfortably
- those who decided against usage before the first follow-up visit
- those who did not return for follow-up after the initial fitting appointment.

Research Protocol

The following protocol was adhered to:

- approval by the Center for Advancement of Health (CAH)

- approval by the Calgary Health Research Ethics Board (CHREB)
- approval by the Spiritual Values Advisory Committee (SVAC) of the Salvation Army Health Council
- auditing of the charts of the patients seen for pessary fittings between October 2000 and October 2003. The charts were reviewed in the Health Records Department of the Foothills Medical Centre
- the data were entered into an SPSS© (Version 12.0, 2003) database
- analysis of the data was carried out.

SPSS© (Version 12.0, 2003) software package was used to analyze the data. Descriptive statistics are presented including means, standard deviations, ranges, cross tabulations, bar charts and box plots.

The investigator undertook analysis to examine the number of pessaries used for UI compared with the number of pessaries used for POP. These groups are compared on age, type of pessary used, complications, prior pelvic surgeries, and weight of heaviest baby.

Ethical Considerations

The research proposal was submitted to the Calgary Health Research Ethics Board (CHREB), University of Calgary, for approval. In addition, approval was obtained from the Spiritual Values Advisory Committee of the Salvation Army Health Council, required for research conducted at the Grace Women's Health Centre.

None of the personal data available in the patient charts was retrieved. No personal identifying variables were collected on any of the patients.

Demographic data did not include any personal information or any items that could be linked with any particular person. Only aggregate data will be used for reports in subsequent publications and presentations. Client confidentiality was maintained at every stage of the research. All the data collected are stored in a password-protected computer to which only the investigator and her supervisor has access. The computer is housed in a locked office. The data will be stored for 5 years and, following completion of the study, hard copies will be shredded and electronic data will be erased.

CHAPTER FOUR: RESULTS

The sample included 700 women who presented at the Pelvic Floor Clinic at the Grace Women's Health Centre for pessary fitting between October 2000 and October 2003. The age range was 19 to 99 years, with the mean being 62.9 years (Table 4.1). The median age was 65 years.

Table 4.1 Age of women at first fitting

N	Minimum	Maximum	Mean	s.d.	Median
700	19	99	62.9	14.9	65.0

When the ages of the patients are divided into three categories, one can see that over 90% of them are over the age of 39 years. There were 338 patients (48.3%) in the oldest grouping (Table 4.2).

Table 4.2 Age groupings

Age Groupings	n	Percent
19-39	48	6.9
40-65	314	44.9
66-99	338	48.3
Total	700	100.0

The middle age group contained 44.9% (n = 314) of the women. Only 6.9% (n = 48) of them were between 19 and 39 years of age.

As may be seen from table 4.3, 18.7% (n = 131) were premenopausal and 81.7% (n = 569) of the women were postmenopausal.

Table 4.3 Menopausal status

Menopausal status	n	Percent
Premenopausal	131	18.7
Postmenopausal	569	81.3
Total	700	100

The geographic location of the women was primarily the city of Calgary (81.2%, n = 568), with the Northwest quadrant (where the clinic is located) having the largest representation (32.6%, n = 228).

Table 4.4 Geographic location of referrals

Location	N	Percent
Calgary NW	228	32.6
Calgary NE	69	9.9
Calgary SW	175	25.0
Calgary SE	96	13.7
Other Alberta	126	18.0
BC	3	0.4
SK	2	0.3
Other	1	0.1
Total	700	100.0

BC = British Columbia SK = Saskatchewan

However, 18% (n = 126) of the patients came from other parts of Alberta and 0.8% (n = 6) from outside the province (Table 4.4).

The source of referral to the clinic was predominantly from urogynecologists within the Clinic (60%, n = 420), with family doctors referring 21.5% (n = 150) and gynecologists referring 122 patients (17.4%) as may be seen in table 4.5.

Table 4.5 Clinic patients source of referral

Source of referral	N	Percent
Family Doctor	150	21.5
Gynecologist	122	17.4
Urogynecologist	420	60.0
Urologist	3	0.4
Physiotherapist	3	0.4
Nurse Continence Advisor	2	0.3
Total	700	100.0

Eight patients (1.1%) were referred from urologists, physiotherapists or nurse continence advisors (Table 4.5).

The reason for referral is not exclusive to one category. Many patients had more than one indication for a pessary, which might include more than one type of incontinence and type of prolapse. The total number of indications for pessary fittings was greater than 700. The predominant category for incontinence was stress incontinence (n = 392) and for prolapse was cystocele (n = 577) (Table 4.6).

Table 4.6 Primary indications for pessary use

Indication for pessary fitting	N
Urinary Incontinence: Stress	392
Urge	258
Mixed	179
Overflow	66
Prolapse: Uterine	195
Cystocele	577
Rectocele	314
Vault/Enterocele	146
Procidentia	65
Preoperative testing	11
Other	4
Total	2207

Only eleven patients were fitted with pessaries for the purpose of preoperative testing.

Table 4.7 categorizes the various types of pelvic surgeries that the patients in the study had undergone. Some patients had undergone more than one type, thus the total number of surgeries was 1,159. Only 18.3% (n = 128) of those referred for pessary fitting (n = 700) had never had any type of pelvic surgery. Close to half of the 700 women in the study (42.4%, n = 297) indicated

that they had undergone hysterectomies, 12.4% (n = 87) had anterior repairs, and 7.4% had (n = 52) posterior repairs.

Table 4.7 Past pelvic surgeries

Type of Surgery	n	Percent (of n = 700)
Hysterectomy	297	42.4
Anterior Repair	87	12.4
Posterior Repair	52	7.4
Incontinence Surgery	123	17.6
Other	472	67.4
None	128	18.3
Total	1,159	--

One hundred and twenty-three women (17.6%) had some type of incontinence surgery, while 67.4% (n = 472) had some "other" type of pelvic surgery, including surgeries such as tubal ligation and dilatation and curettage.

Table 4.8 presents the existing medical problems that patients had who visited the clinic. Hypertension was the most common with 32.6% (n = 228). The prevalence of arthritis and constipation were similar at 27.7% (n = 194) and 23.1% (n = 162) respectively. Twenty-one percent (n = 147) of the women did not have any history of existing medical conditions prior to pessary fitting.

Table 4.8 History of medical conditions

Medical condition	n	Percent
Other	399	57.0
Hypertension	228	32.6
Arthritis	194	27.7
Constipation	162	23.1
None	147	21.0
Asthma	47	6.7
Cancer: Uterine	11	1.6
Breast	27	3.9
Ovarian	6	0.9
Other	35	5.0
Diabetes	38	5.4
Chronic UTI's	37	5.3
DVT/PE	2.4	17

UTI = Urinary Tract Infection DVT = Deep Vein Thrombosis
PE = Pulmonary Embolism

Fifty-seven percent (n = 399) of the patients claimed to have other conditions not identified on the list.

Medications used by patients were categorized as seen in table 4.9. Approximately half of the women (48.4%, n = 339) used some form of hormone replacement. Of the group, 29.8% (n = 208) were on some form of antihypertensive, while 23.1% were on some form of NSAID (nonsteroidal anti-

inflammatory drug). Those using diuretics made up 14.6% (n = 102), and 17.6% (n = 123) did not use any type of medication,

Table 4.9 Medications used by patients

Types of Medications	n	Percent (of n = 700)
Other	402	57.4
Hormone Replacement Therapy	339	48.4
Antihypertensives	208	29.8
NSAIDS	162	23.1
Anxiolytics/Antidepressants	126	18.0
None	123	17.6
Diuretics	102	14.6

Over half of the sample (57.4%, n = 402) used some "other" type of medication not listed. The women who used hormone replacement therapy are further categorized in table 4.10. The largest category of hormone use is estrogen only (47.2%, n = 330). Nearly one third (30.3%, n = 212) used hormones systemically. Of those who used local therapy, 30% (n = 210) used Premarin™ vaginal cream. Other forms of local therapy were the Estring™ (4.4%, n = 31) and Vagifem™ (6.1%, n = 43). Women may fall into more than one category of hormone usage, thus frequencies and percentages are more than 700 and 100% respectively.

Table 4.10 Hormone replacement usage

Type of Hormone	n	Percent
None	334	47.7
Systemic	212	30.3
Estrogen Only	330	47.2
Progesterone Only	69	9.9
Estrogen & Progesterone	63	9.0
Premarin™ Vaginal Cream	210	30.0
Estring™	31	4.4
Vagifem™	43	6.1
Systemic & Local	128	18.3
Other	4	0.6

Nearly half of the women did not use of hormones of any form (47.7%, n = 334).

A total of 6.6% (n = 42) of women gave birth by Cesarean section. Of the total, 3% (n = 21) had either one or two surgeries (Table 4.11).

Table 4.11 Number of babies born by Cesarean section

Cesarean Births	n	Percent
1	21	3.0
2	21	3.0
3	4	0.6
Total	46	6.6

Less than one percent (0.6%, n = 4) had three Cesarean births.

The majority of the women had given birth vaginally to two (36.1%, n = 249) or three babies (24.8%, n = 171), whereas only 6.1% (n = 42) of the patients had never given birth (Table 4.12). The range of vaginal births is from one to ten.

Table 4.12 Numbers of babies delivered vaginally

Vaginal Births	n	Percent
0	42	6.1
1	81	11.7
2	249	36.1
3	171	24.8
4	70	10.1
5	46	6.7
6	17	2.5
7	8	1.2
8	5	0.7
9	0	0.0
10	1	0.1
Total	690	100.0

Just over 50% (n = 354) of the women did not indicate any complications with their deliveries (Table 4.13). Of this group, some of the women did not recall that their deliveries involved any complications. For other patients, information regarding their deliveries was not included in their charts as this is not routinely collected on all patients. For those with complications documented (n = 523), 32.6% (n = 228) had episiotomies. Nearly 22% (n = 152) of the women had

some type of tear, and 17.6% (n = 123) recalled the use of forceps. There were no infections that were associated with childbirth that was recalled or documented with any of the patients.

Table 4.13 Delivery complications

Delivery Complications	n	Percent (of n = 700)
Not Known	354	50.8
Episiotomy	228	32.6
Tears	152	21.7
Forceps	123	17.6
Other	16	2.3
Vacuum Delivery	4	0.6
Infections	0	0
Total	877	--

Because some women had more than one type of delivery complication, the totals do not equal 700 or 100%. The average weight of the heaviest baby delivered was 3675.3 grams, or 8.1 pounds (Table 4.14). Some of the patient charts did not have the deliveries documented or the weights of the babies recorded. Therefore, data of weights of babies delivered was limited to n = 471.

Table 4.14 Weight of heaviest baby born to pessary wearers

Weight of baby	Minimum	Maximum	Mean	Median	s.d.
Grams	1362	5266	3675.25	3632.0	553.42

Table 4.15 indicates the number of women who were currently sexually active at the time of pessary fitting.

Table 4.15 Sexually active

Sexually Active	n	Percent
Yes	337	48.1
No	363	51.9
Total	700	100.0

Approximately half of the women were sexually active. For those who were sexually active, the average age at first fitting was 54 years. For those not sexually active, the age at first fitting was 72 (Table 4.16).

Table 4.16 Sexual activity by age at first fitting

Sexually Active	Mean Age	n
Yes	54	337
No	72	363

The average age for those sexually active who came for pessary fittings were younger than those who were no longer sexually active.

Successful fitting of the pessary

The primary outcome variable was successful fitting of the pessary as determined by the first follow-up visit, usually held between two to six weeks following initial fitting. It will be recalled that success was defined as:

- The pessary remains in place following fitting
- The patient subjectively reports being comfortable with the device
- The pessary facilitates prevention of descent of the prolapsed pelvic organ or decreases urinary leakage as indicated by the patient.

To determine the rate of success by the first follow-up visit, the length of usage was computed for all those still wearing the pessary for greater than one month as seen in figure 4.1. This eliminates those who discontinued usage within the first month. Thus, those who did not achieve successful fitting by the first follow-up visit, providing it fell within the first month, were not included. The rate of ongoing pessary usage declines gradually over the 37-month time frame of the study as seen in figure 4.1.

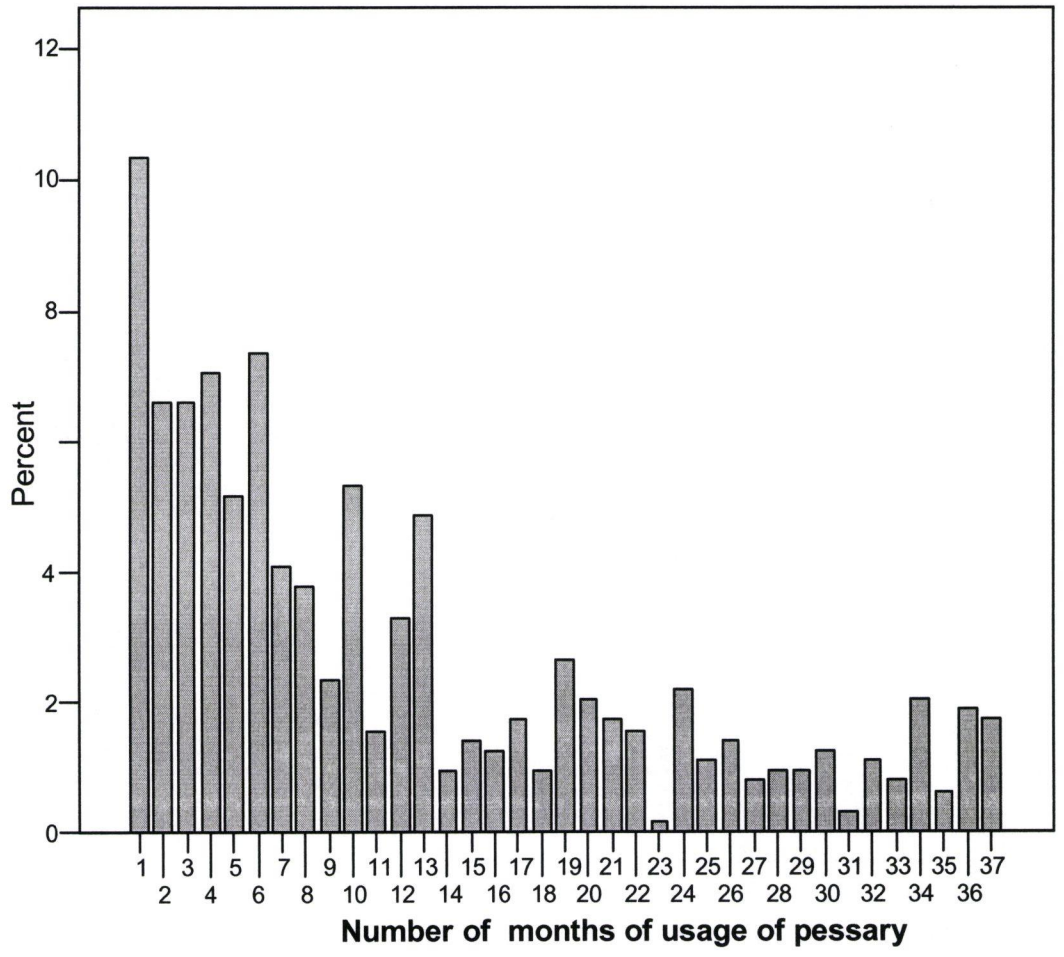

Figure 4.1 Months of pessary usage

The success rate is 91% (n = 637) for those who wore the pessary for longer than one month as seen in table 4.17.

Table 4.17 Length of pessary usage greater than one month

Length of usage	n	Percent
Worn > 1 Month	637	91.0
Worn < 1 Month	63	9.0
Total	700	100.0

If those wearing the pessary for less than two months are eliminated, the success rate decreases to 81.6% (n = 571). Table 4.18 indicates that 63 (9%) of the women wore the pessary for less than one month, and 66 additional women (9.4%) discontinued use in the second month.

Table 4.18 Length of pessary usage greater than two months

Months worn	n	Percent
Worn > 2 months	571	81.6
Worn 1 –2 months	66	9.4
Worn < 1 month	63	9.0
Total	700	100

Some women may not have had their first follow-up visit until the second month. Thus 81.6% (n = 571) wore the pessary for longer than the first two months.

The remaining five research questions were addressed.

How successful are pessaries for POP?

The second research question determines the rate of successful fittings of pessaries used to support specifically POP. Figure 4.2 shows the frequency of the various types of prolapse. The categories are not mutually exclusive; some people have more than one type of prolapse.

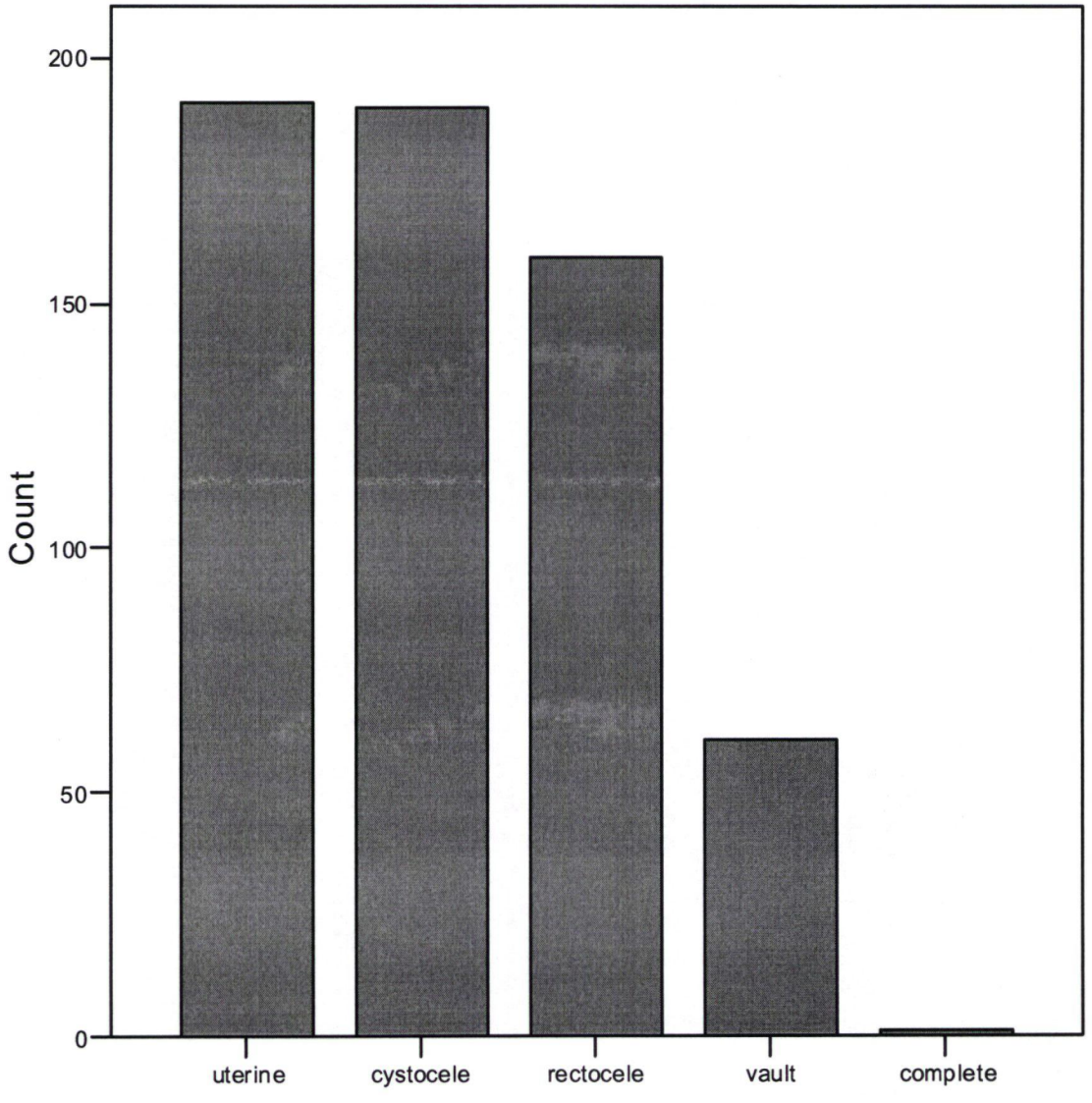

Figure 4.2 Patients with pelvic organ prolapse

As may be seen, uterine prolapse and cystocele occurred at nearly the same rate, followed by rectocele. Vault prolapse is less frequent and complete prolapse is the least frequent type of POP.

As seen in table 4.19, uterine prolapse was documented in 27.3% of the women (n = 191). Cystoceles occurred nearly as frequently with n = 190 (27.1%) followed by rectocele (n = 159, 22.7%).

Table 4.19 Patients with pelvic organ prolapse

Types of Prolapse	n	Percent (of n = 700)
Uterine	191	27.3
Cystocele	190	27.1
Rectocele	159	22.7
Vault	61	8.7
Complete	1	0.1
Total Prolapse	602	86.0
No prolapse	98	14.0
Total	1302	-

Only 14% (n = 98) of the women had no type of prolapse documented.

Figure 4.3 shows the numbers of patients who were still wearing pessaries for the various types of prolapse by the end of the study, and those who discontinued their use.

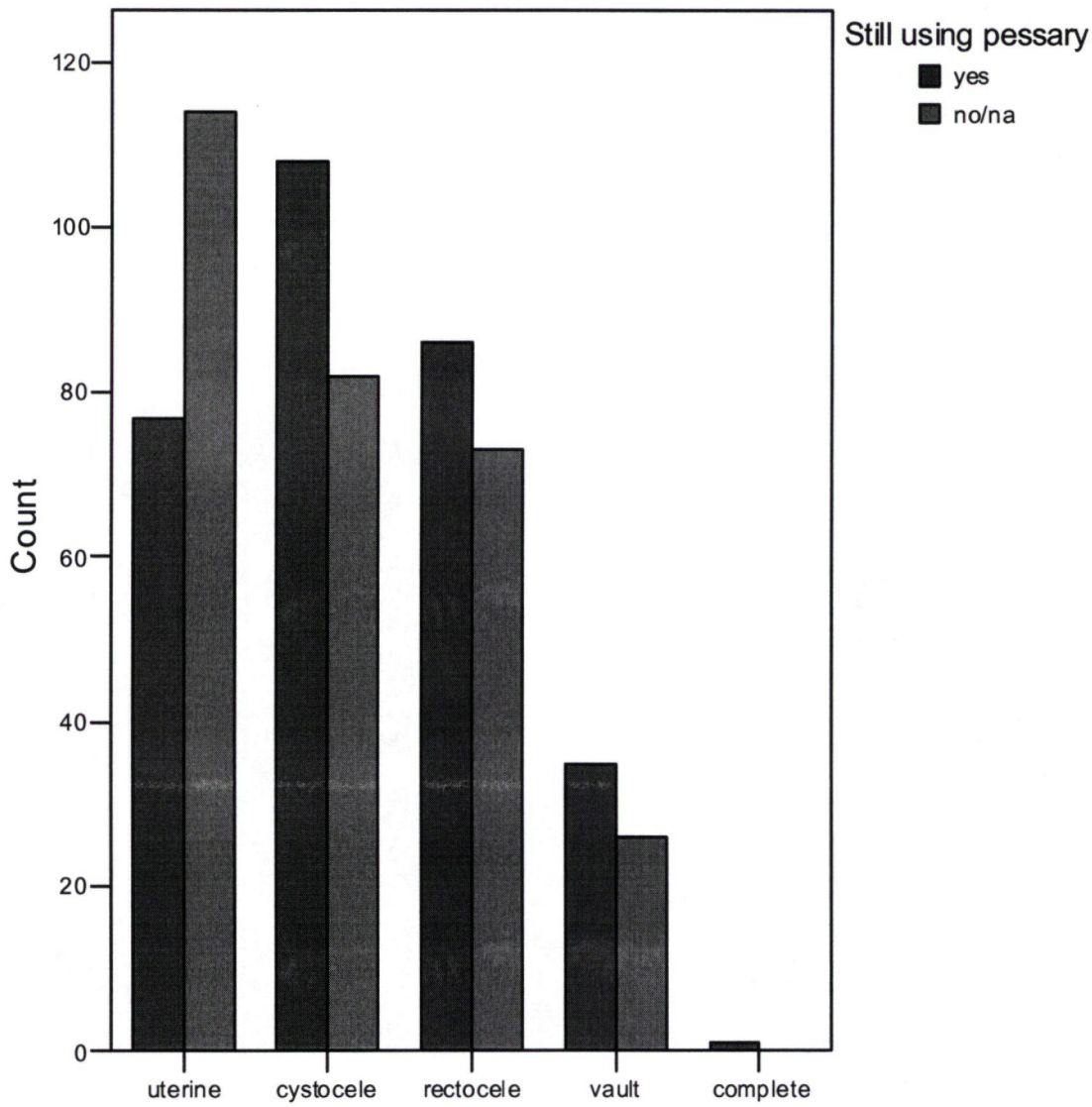

Figure 4.3 Pelvic organ prolapse and pessary usage at study close

The "no/na" category includes those who discontinued use of the pessary.

Table 4.20 indicates that over half of those with cystoceles (56.8%, n = 103), rectoceles (54.7%, n = 87) and vault prolapse (57.4%, n = 35) still continued wearing pessaries by the end of the study period. Those with uterine prolapse were more likely to discontinue use of the pessary (40.8%, n = 78).

Table 4.20 Pelvic organ prolapse and pessary usage

Types of Prolapse	Still Wearing		Not Wearing	
	n	Percent	N	Percent
Uterine prolapse	78	40.8	113	59.2
Cystocele	108	56.8	82	43.2
Rectocele	87	54.7	72	42.3
Vaginal vault prolapse	35	57.4	26	42.6
Complete prolapse	1	100.0	0	0
Total	309	--	293	--

One patient with total procidentia was still wearing the pessary by the end of the study.

How successful are pessaries for UI?

This question relates to the women with different types of UI, and their success with pessary fittings.

Figure 4.4 indicates the proportion of patients with the different types of UI. The types of incontinence are not mutually exclusive as patients may have more than one type of UI.

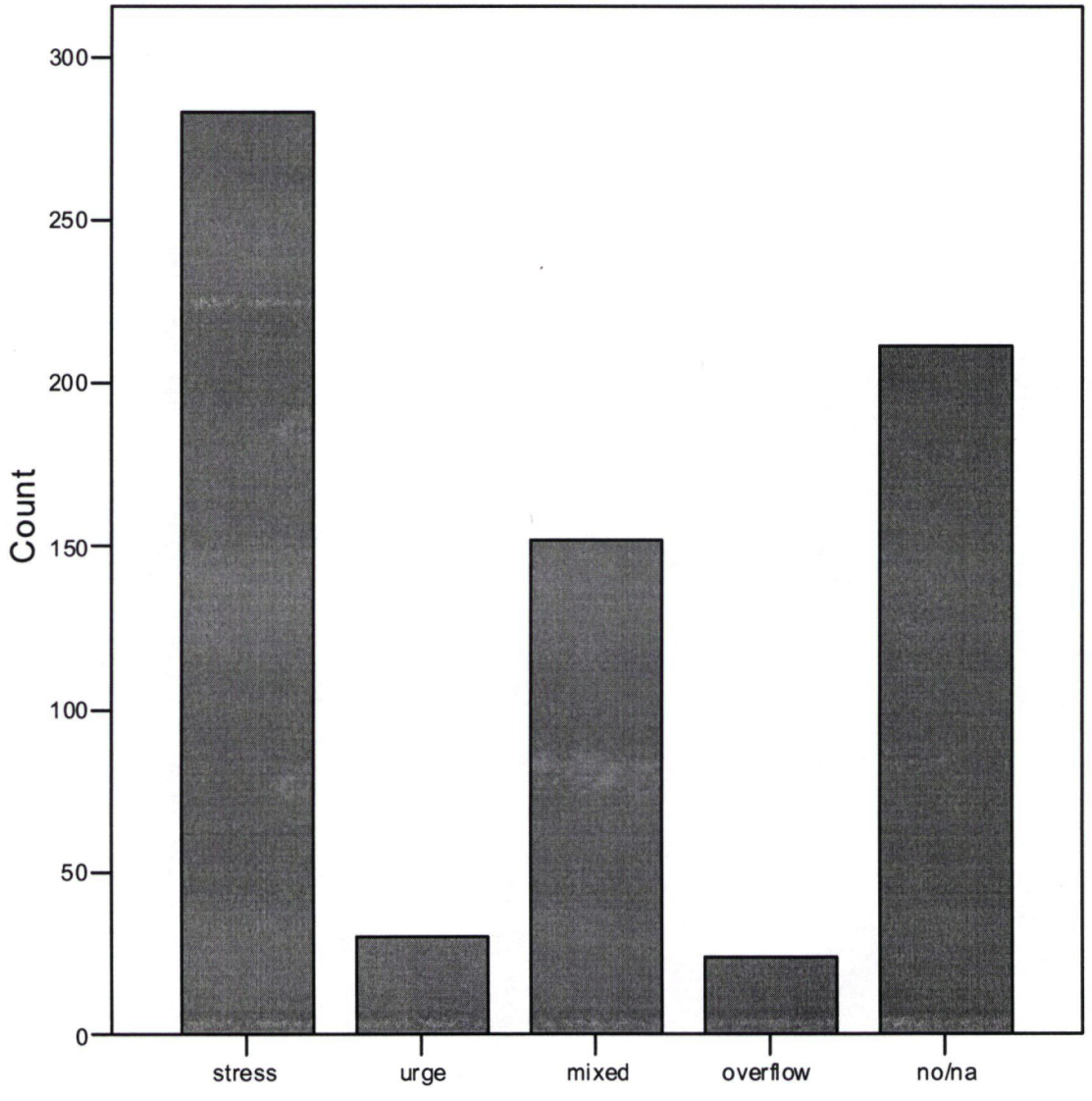

Figure 4.4 Types of urinary incontinence

The "no/na" category includes those who did not have any type of UI or were not fitted with pessaries. Stress UI is the most common type followed by mixed UI. The least frequent type of UI was in those women with urge UI and overflow UI.

Stress incontinence was the most frequent type of UI with 40.4% (n = 283) in this category (Table 4.21). Mixed incontinence was the next most frequent with 21.7% (n = 152). Urge and overflow incontinence occur less frequently.

Table 4.2 Frequency of type of urinary incontinence

Type of UI	n	Percent
Stress	283	40.4
Urge	30	4.3
Mixed	152	21.7
Overflow	24	3.4
None	211	30.1
Total	700	100.0

Thirty percent of the patients indicated that they did not have any type of urinary incontinence (n = 211). Those women indicating "yes" in figure 4.5 represents the proportion of those still wearing the pessary at the study close. Those with urge incontinence were the most likely to continue wearing the pessary at the completion of the study. This is followed by mixed incontinence, stress incontinence, and overflow incontinence.

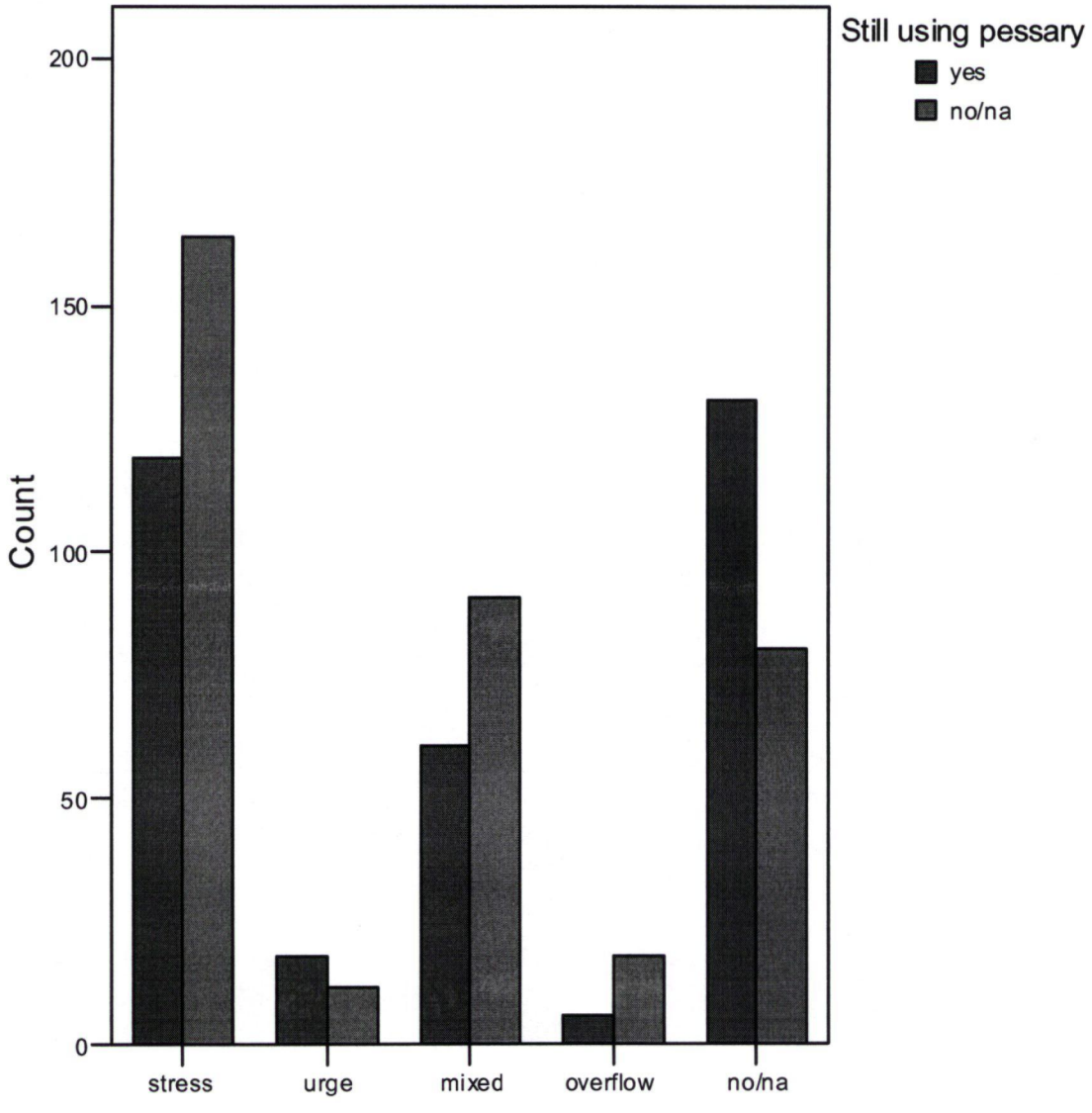

Figure 4.5 Types of urinary incontinence and pessary usage

The "no/na" category refers to the women who did not have incontinence.

Table 4.22 indicates the specific numbers of women with different types of incontinence who still continued wearing the pessary at the close of the study. Those with urge incontinence had the highest percentage of continued usage (66.7%, n = 20). Those with stress incontinence and mixed incontinence had similar results, with 44.2% (n = 125) and 41.4% (n = 63) of women still using the pessary at the close of the study.

Table 4.22 Urinary incontinence and pessary usage

Types of Incontinence	Still Wearing		Not Wearing		Total
	n	Percent	n	Percent	N
Stress Incontinence	125	44.2	158	55.8	283
Urge Incontinence	20	66.7	10	33.3	30
Mixed Incontinence	63	41.4	89	68.6	152
Overflow Incontinence	5	20.8	19	79.2	24
Total	213	--	276	--	489

Those with overflow incontinence were the least likely to continue with usage of the pessary, as only 20.8% (n = 5) were still wearing the pessary by the end of the study. Overall, there were fewer women who continued using the pessary for incontinence (n = 213) than those who discontinued use (n = 276).

How satisfied are women who use pessaries (demonstrated by ongoing usage)?

The fourth question addressed the issue of satisfaction with pessaries as determined by ongoing usage. Figure 4.6 shows the overall results for all the patients (n = 700) who presented at the clinic for pessary fitting.

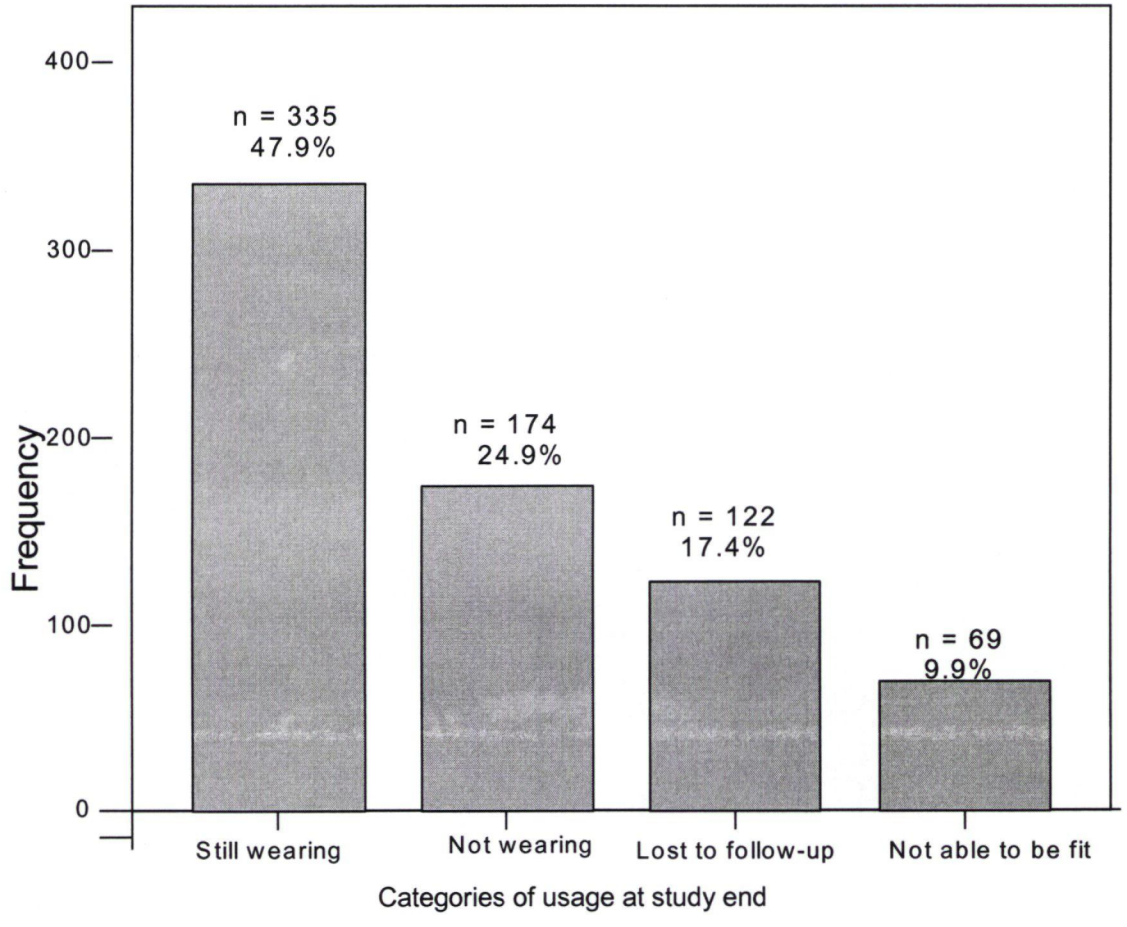

Figure 4.6 Overall success of those fit with pessaries

The largest category is the women who are still wearing their pessaries (n = 335), while 174 women discontinued using them. A group of women (17.4%, n = 122) did not return to the clinic for follow-up appointments as scheduled and are classified as lost to follow-up. Sixty-nine women of the 700 were not able to be successfully fitted.

Figure 4.7 indicates the length of use in six-month time periods for those who continued pessary use. These 6-month intervals are dependent on when they were fitted within the 37-month time-frame of the study.

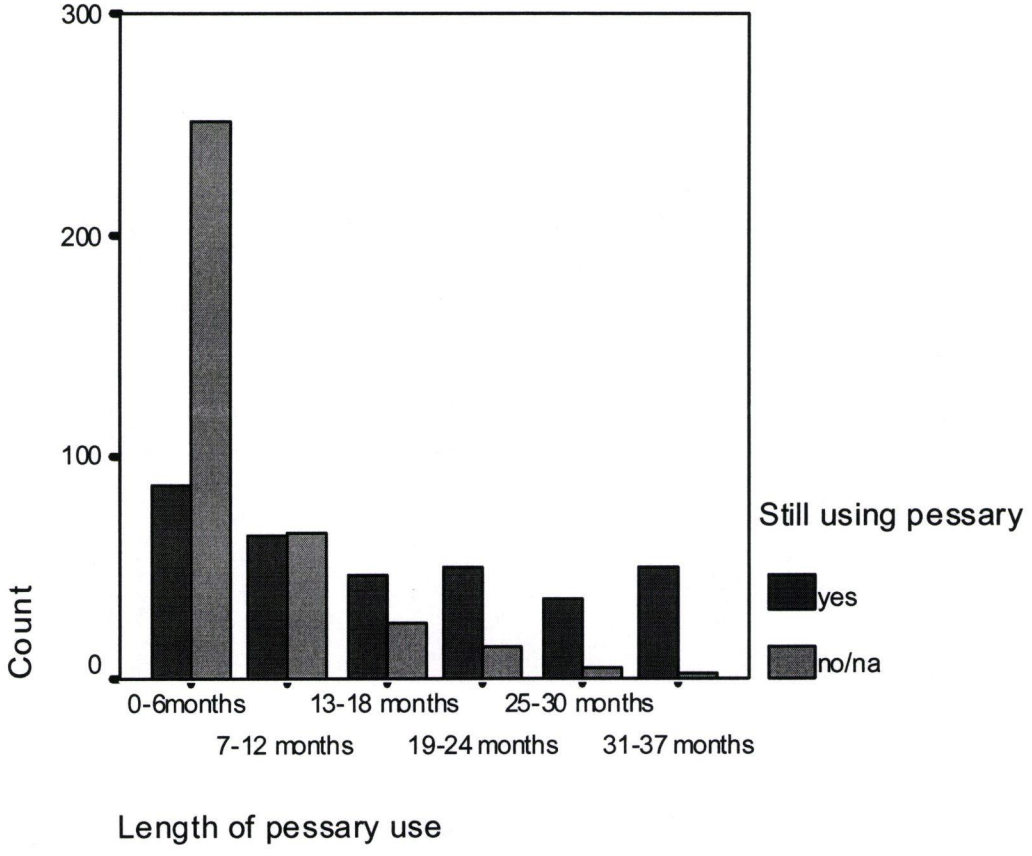

Figure 4.7 Length of usage of pessary

Those who wore the pessary for 0-6 months and continue to use it were fitted within the last six months of the study. Those who continue to wear the pessary for 31 to 37 months were fitted in the first six months of the study and continue to use it. Figure 4.7 indicates that the number of women who discontinued usage tended to do so in the first six months. The dropout rate declined after the first six months. Those who continued wearing pessaries beyond that point were more likely to continue using them. There are two categories of "still using" and

"no/na". The "no/na" category includes all patients who discontinued usage, who are lost to follow-up and who were not able to be fitted initially. Only two women who wore their pessaries for 31 – 37 months discontinued using them (table 4.23) before the study close.

Table 4.23 shows the percentage and frequency of women who were were still wearing or not wearing their pessaries, in six-month categories.

Table 4.23 Length of usage for those wearing and not wearing the pessary

Months of Usage	Still Wearing n	Still Wearing Percent	Not Wearing n	Not Wearing Percent
0-6 months	90	12.9	251	35.8
7-12 months	62	8.8	64	9.1
13-18 months	46	6.6	26	3.7
19-24 months	48	6.9	16	2.3
25-30 months	38	5.4	6	0.9
31-37 months	51	7.3	2	0.3

The numbers of those who continued wearing the pessary and those who did not were similar in the second category of 7-12 months of usage, at 8.8% (n = 62) and 9.1% (n = 64) respectively. In all the other 6-month time periods, there was a larger difference in numbers in those who were still wearing the pessary, and those who discontinued use. Those who discontinued use in the 31 – 37 months group were the lowest in number (0.3%, n = 2).

What are the most frequently used styles of pessaries?

This fifth question addressed the particular styles of pessaries worn by patients in the clinic.

As can be seen from figure 4.8, the most frequently used style of pessary is the covered ring (16.7%, n = 117) followed by the Shaatz pessary (14.3%, n = 100). These pessaries are used primarily for prolapse.

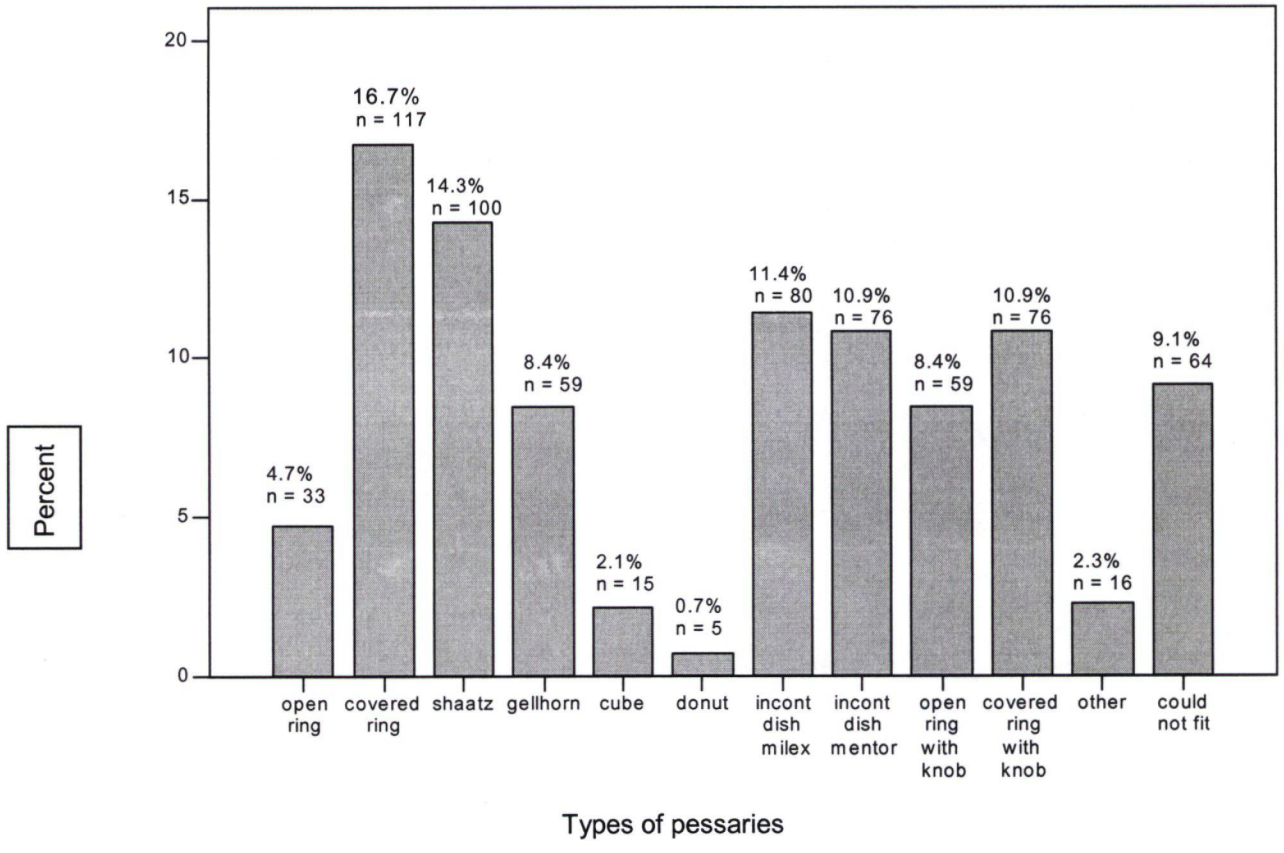

Figure 4.8 Final style of pessary selected

The third and fourth commonly used types of pessaries are incontinence dishes, the Milex™ dish (11.4%, n = 80) and Mentor™ dish (10.9%, n = 76). They are

used primarily for stress incontinence, although may be useful if there is some prolapse. The covered ring with knob was also used in 10.9% (n = 76) of the women. The gellhorn pessary is used in 8.4% (n = 59) of the cases, for significant prolapse. The open ring, cube, donut and other types are less commonly used.

Some of the women continue wearing the first pessary they were fitted with and others try different styles or sizes before they are satisfactorily fitted. Tables 4.24 and 4.25 indicate the frequency and percentages of styles and sizes tried.

Table 4.24 Number of styles tried

Number of styles	n	Percent
1	365	57.8
2	201	31.9
3	52	8.2
4	9	1.4
5	3	0.5
6	1	0.2
Total	631	100.0

Over half (57.8%, n = 365) continue with the initial style they were fitted with (table 4.24), while 31.9% (n = 201) tried two styles. Only 8.2% (n = 52) tried three styles. One woman tried up to six styles (0.2%) before settling on her final pessary style.

Table 4.25 indicates that 61.8% (n = 390) of women fitted were satisfied with the first size tried, 27.3% (n = 172) tried two sizes. A maximum of five sizes were tried on two patients before they were satisfied with the fit (0.3%).

Table 4.25 Number of sizes tried

Number tried	n	Percent
1	390	61.8
2	172	27.3
3	55	8.7
4	12	1.9
5	2	0.3
Total	631	100.0

The total of numbers of pessaries tried indicated in table 4.25 is n = 631, as 69 women (9.9%) were unable to be fitted.

The women were placed into into three age groupings (see table 4.26). The oldest age group (66-99) wore more pessaries used for the treatment of POP (covered ring, Shaatz, gellhorn), while the 40-65 age group wore more pessaries associated with UI (incontinence dishes and rings with knobs). The youngest age group did not appear to use any particular style of pessary with more frequency.

Table 4.26 Type of pessary and age groupings

Type of Pessary	Total of pessaries for all age groups	Age Group					
		19-39		40-65		66-99	
		n	Percent	n	Percent	n	Percent
Open Ring	33	3	9.1	14	42.4	16	48.5
Covered Ring	116	4	3.5	39	33.6	73	62.9
Shaatz	100	10	10.0	38	38.0	52	52.0
Gellhorn	58	2	3.5	9	15.5	47	81.0
Cube	15	0	0.0	9	60.0	6	40.0
Donut	5	0	0.0	0	0.0	5	100.0
Incontinence Dish (Milex™)	79	8	10.1	50	63.3	21	26.6
Incontinence Dish (Mentor™)	75	4	5.3	35	46.7	36	48.0
Open Ring with Knob	59	8	13.6	36	61.0	15	25.4
Covered Ring with Knob	75	7	9.2	42	56.0	26	34.2
Other	16	2	12.5	12	75.0	2	12.5
Total	631	48	7.6	284	45.0	299	47.4

The most common reasons for discontinuing usage

The researcher addressed the question of the women who did not carry on with pessary use, and the reasons that they discontinued their use.

Table 4.7 indicates the most common reasons that women discontinue using pessaries. The largest group who discontinued use were those who chose a surgical alternative (20.3% n = 101), while 20.1% (n = 100) discontinued use

because they did not find the pessary effective for their problems. Over 16% of women (n = 81) indicated that they did not like using the pessary.

Table 4.27 Reasons for discontinuing usage of pessary

Reasons	n	Percent
Infections	2	0.4
Deceased	3	0.6
Voiding Dysfunction	4	0.8
Bowel Dysfunction	6	1.2
Other	16	3.2
Discomfort	62	12.5
Did not like	81	16.3
Not Effective	100	20.1
Surgery	101	20.3
Lost to follow-up	123	24.7
Total	498	100.0

Fewer women discontinued use due to voiding (0.8%, n = 4) or bowel dysfunction (1.2%, n = 6), while only 0.4% (n = 2) discontinued use due to infections.

More women in the 40-65 year-old age group discontinued usage (table 4.28). The pessary was discontinued due to ineffectiveness (58 %, n = 58), surgery (58.4%, n = 59) and dislike (58%, n = 47).

Table 4.28 Age groups and discontinuation of pessary use

Reason for Discontinuing Use of Pessary	Total	Age Groups					
		19-39		40-65		66-99	
		n	Percent	n	Percent	n	Percent
Voiding Dysfunction	4	1	25.0	2	50.0	1	25.0
Bowel Dysfunction	6	1	16.7	3	30.0	2	33.3
Discomfort	62	7	11.3	27	43.5	28	45.2
Not Effective	100	14	14.0	58	58.0	28	28.0
Surgery	101	12	11.9	59	58.4	30	29.7
Did Not Like	81	6	7.4	47	58.0	28	34.6
Lost to follow-up	122	15	12.2	70	56.9	38	30.9
Known Deceased	3	1	33.3	0	0	2	66.7
Other	16	0	0	4	25.0	12	75.0

Seventy patients in the middle age group were lost to follow-up (56.9%). The majority of those lost to follow-up were in the 40-65 year-old category (56.9%, n = 70). A total of 62 women in all three age groups experienced some discomfort with usage.

As may be seen from table 4.29, 48.1% (n = 344) of women experience no complications from using the pessary. The most frequent complication indicated was discomfort, with 15.5% (n = 111) in that category. Leakage of urine was next in frequency (14.4%, n = 103). Nearly ten percent fell in the category "other" (n = 71), for which an example might be sensation of pressure.

Table 4.29 Complications from using the pessary

Complications	n	Percent
None	344	48.1
Discomfort	111	15.5
Leakage	103	14.4
Other	71	9.9
Erosions	47	6.6
Discharge	29	4.1
Infection	10	1.4
Total	715	100.0

Some women experienced more than one type of complication, thus the total in table 4.29 is 715. Among the three age groups (table 4.30), the total complication rate in the 66-99 year-old age group (49.8%, n = 357) was higher than in the 40-66 year-old group (42.8%, n = 307). Erosions of the vagina (72.3%, n = 34) and discharge (65.5%, n = 19) were the most frequent complication in the oldest group. Leakage of urine (56.3, n = 58) was the most common complication in the 40–65 year-old group.

Table 4.30 Complication rates and age groups

Type of Complication	Total	Age Groups					
		19-39		40-65		66-99	
		n	Percent	n	Percent	n	Percent
None	344	24	7.0	146	42.4	174	50.6
Discomfort	111	11	9.9	46	41.4	54	48.6
Leakage	103	9	8.7	58	56.3	36	35.0
Other	71	4	5.7	32	45.0	35	49.3
Erosions	47	2	4.3	11	23.4	34	72.3
Discharge	29	1	3.5	9	31.0	19	65.5
Infection	10	0	0.0	5	50.0	5	50.0
Total	717	51	7.1	307	42.8	357	49.8

The youngest age group had the lowest complication rates (7.1%, n = 51). Discomfort (9.9%, n = 11) and leakage (8.7%, n = 9) were the most frequent complications in this category.

Summary

The demographics of the patients were summarized, with the mean age being 62.9 years. More than 90% of the women were over 39 years of age. Most were menopausal, from Calgary, and referred by urogynecologists. Stress incontinence was the most frequent type of UI, and cystoceles were the predominant type of POP. Only 18.3% of the woman had no previous pelvic surgery, with 42.4% having undergone hysterectomies. Nearly a third of the

women had hypertension. Half of the patients used some type of HRT. More than 90% of the women had given birth, with most having two children. Only 6.6% had undergone Cesarean sections. Half of the women were still sexually active.

Over 90% of the women fitted with pessaries continued to use them after the first month. Over 80% continued beyond the second month. By the end of the study, over half of the women with prolapse continued to use their pessaries. Of those with UI, 44.2% of women with stress incontinence were still using their pessaries and 66.7% with urge incontinence still used them. Overall, 47.9% of all women fitted continued with use by the study close. One quarter of them discontinued use, while 174 (24.9%) were lost to follow-up. One out of ten women were not able to be fitted (9.9%, n = 69).

The covered ring and shaatz style of pessaries were the most commonly used. Two different styles of incontinence dishes were used most commonly for stress incontinence. The 66-99 year-old age group of women were the largest group wearing pessaries for POP, while the 39-65 year-olds used more pessaries for UI. Complications occurred in approximately half of pessary wearers. The most common reasons for discontinuing usage was elective surgery, followed by those who did not find the pessary effective. The 40 to 65 year old group had the highest rate of discontinuation.

CHAPTER FIVE: DISCUSSION

A systematic chart audit was conducted of the women (n = 700) who presented at the pessary clinic at the Grace Women's Health Centre from October 2000 to October 2003 for pessary fittings. The data from this study have added to the growing body of evidence that indicates that pessaries are successful as an option for women with POP and UI. This was achieved by determining the rate of success with the pessary as measured by the length of time of pessary use.

The mean age of the women was 62.9 years and the median age was 65 years. The range was between 19 to 99 years of age. The Edmonton study (Hanson, et al, 2003) had similar results, with the median age being 63 years, and the range from 22 to 95 years. The age range indicates that problems of UI and POP clearly affect adult women of all ages. More postmenopausal women are affected as the data indicated that 81.3% (n = 569) of the women were postmenopausal. These data are similar to the Edmonton study, where 80% (n = 967) of the women were postmenopausal. It should be recalled that 42.9% (n = 297) of the women had previous hysterectomies.

Demographic information indicating the geographic location of the patients shows that nearly a third of the patients came from the northwest quadrant of Calgary where the clinic is located, and over 80% came from within the city itself. Less than 20% came from other parts of Alberta. Nearly two thirds of the patients were referred to the clinic by urogynecologists who work within the clinic setting and are familiar with pessaries and their role in assisting women. The high number of referrals from these specialists also indicates their understanding of the benefits of this type of nurse-led clinic, where the nurses are allowed enough time to

educate and instruct patients. Follow-up is critical in the prevention of problems and patients are made aware of its importance. Family doctors are becoming more aware of the pessary clinic and referred over 20% of the patients. Gynecologists were the third major referral group.

The reason for referral for a pessary is not always limited to one specific clinical indication. Many patients referred have more than one type of incontinence and/or prolapse. However, for UI, most women had stress incontinence. The severity of the leakage problems was not documented as there is no tool or scale currently being used in the clinic to measure this.

Patients with cystoceles constituted the largest group of women referred for POP. Patients with rectoceles were the next largest group, with uterine prolapse and procidentia in smaller numbers. The severity of prolapse was not documented consistently on all the charts as there are different ways of categorizing prolapse (McCrink, 2003). Clinicians use different scales such as the Modified Oxford scale, the Baden-Walker scale, or the newer pelvic organ prolapse quantification (POPQ) classification system, considered to be more objective (McCrink, 2003). Only a small number (n = 11) were fitted with pessaries solely for the purpose of preoperative testing and not for ongoing use.

Only 18.3% (n = 128) of the women had no prior pelvic surgery before coming for a pessary fitting, thus the majority had undergone some surgical intervention involving the pelvic structures. Some women had more than one type of previous pelvic surgery, thus the total number of pelvic surgeries comes to 1159. Nearly two thirds had undergone pelvic surgery classified as "other". These surgeries would include procedures such as dilatation and curettage, tubal ligations and

laparotomies. Just under half of the women (42.4%, n = 297) had hysterectomies. The method of surgery (abdominal or vaginal) was not consistently documented. Anecdotally, the investigator recalls that many women refer to their hysterectomies as the beginning of their leakage or prolapse problems. Given the large proportion of patients who had hysterectomies, these data strengthen that impression.

The general classification of "incontinence surgery" was used for the women who did not recall what type of bladder surgery they had undergone (n = 123). Eighty- seven women (12.4%) had prior surgery to correct cystoceles (anterior repair) and 52 (7.4%) had previous correction of rectoceles (posterior repair). In spite of the fact that these women had previous surgeries to correct bladder or prolapse problems, many returned to seek further help. It is not known if the surgery corrected one defect but caused another, or if the original surgery failed. It is imperative that women enter the prospect of any type of surgery well informed about potential risks and outcomes. According to Farrell (2003), surgery for POP can be effective but the recurrence rate of prolapse over time is significant. Surgical correction does not guarantee perfect outcomes.

It is important to assess if the patient's health history is significant for UI and POP when considering pessary use. Rarely is an isolated symptom or sign enough to establish a diagnosis or treatment plan. All available data must be considered when assessing women for these conditions and providing pessaries as an option for them (Resnick, 1990). In particular, neurologic, metabolic, musculoskeletal, gynecologic and urologic conditions should be determined (Penn, et al, 1996). The investigator recalls that many women present with a history of

hypertension and use medications that aggravate their incontinence. With the exception of the category "other", the largest pre-existing condition was hypertension with 32.6% (n = 228). Many of these patients use antihypertensives and diuretics, which can worsen their symptoms of incontinence by causing polyuria, frequency and urgency.

Another large category of patients with a pre-existing medical condition were those with a history of arthritis. This condition causes more difficulties with pessary management, especially if it affects the hands. Nearly a quarter of the women had problems with chronic constipation (23.1%, n = 162). Bearing down and straining (from constipation) puts pressure on the pelvic floor muscles as well as the organs, aggravating leakage and prolapse. Asthma affects 6.7% (n = 47), often causing coughing and again, pressure and strain on the organs of the pelvic floor and the muscles, leading to incontinence of urine and prolapse.

In assessing women for pessary fittings, a review of medications determines the extent to which they adversely affect continence and organ prolapse. There are certain categories of drugs that are associated with lower urinary tract dysfunction including diuretics, anticholinergics, alpha-adrenergic agonists, beta-adrenergic agonists, alpha agonists, calcium channel blockers and central nervous system (CNS) depressants (Penn et al, 1996). Eighteen percent of the patients (n = 126) used some type of anxiolytic or antidepressant. Many of these medications have an anticholinergic effect that decreases sensitivity to bladder cues (Smith, 1997; Sourander, 1990)). Nearly one quarter of the women (23.1%, n = 162) used some type of nonsteroidal anti-inflammatory drug (NSAID) for pain. There are a large variety of drugs that fall into this category. Some NSAIDS are

known to aggravate the bladder or bowels, especially as they contribute to constipation. Constipation can be a cause, or factor, that may worsen problems of UI and POP (Penn et al, 1996; Smith, 1997).

Nearly half of the women use some type of hormone replacement therapy (48.4%, n = 339). This differs from the Edmonton study where 85% were on HRT prior to fitting (Hanson et al, 2003). This may be due to the timing of the study, as the study in Edmonton was completed prior to the report from the American Woman's Health Initiative study (WHI) that caused significant controversy regarding hormone replacement (Yetman, 2004). The large American study on long-term usage of HRT was halted in the spring of 2002 due to data indicating that women were at greater risk for developing breast cancer (Rossouw, 2002; Wassertheil-Smoller et al, 2003). Many newscasts and publications with limited information were released, and many women and health care professionals questioned whether taking and/or prescribing HRT was the right thing to do (Yetman, 2004). According to Yetman, the studies, articles and media attention appeared to report new evidence, but much of what was reported was known for many years. Media releases caused a great deal of anxiety and confusion among women and many chose to discontinue the use of HRT as a result. These media releases occurred during the time frame of this study in 2002.

The study by Hanson et al (2003) also cites 78% of women successfully fitted used a combination of systemic and local HRT. In this study, only 18.3% (n = 128) of the women using HRT used both. One explanation for the discrepancy between the results may be the timing of this study as it coincided with the WHI study reports.

The majority of patients fitted with pessaries had delivered children; only 5% (n = 42) were nulliparous. Nearly seven percent (n = 46) had delivered by Cesarean section. The proportion of women who had delivered by this method in the study falls below the national rate of 22.5% for Cesarean sections in Canada for 2001 and 2002 (CTV.ca NewsStaff, 2004).

Over thirty-five percent had delivered two children vaginally. The range of vaginal deliveries was one to ten. The investigator recalls anecdotally that many women indicate that childbearing marked the start of their bladder problems. Although nulliparous women can experience UI, Sampselle et al (1997) states that evidence does identify vaginal birth as a significant predictor of UI. Women who have had even one vaginal birth are more than two and one half times as likely to report incontinence than are their nulliparous counterparts (Sommer, et al, 1990). Rates of UI increase with parity (Viera & Larkins-Pettigrew, 2000). Specific reasons for effects that are birth-related are not clearly identified at the present time, however, a growing body of evidence points to neurologic and musculofascial damage (DeLancey, 1993).

Difficult deliveries and the use of instrumentation have been linked with higher risk of UI (Penn et al, 1996). Over half of the women did not have chart documentation concerning any complications or problems that occurred during their deliveries but of those that did, 32.6% (n = 228) had episiotomies and 21.7% (n =152) had tears. It is not known whether smaller tears have less effect than larger tears, or if the extent of the episiotomy has any greater impact on the outcome of their incontinence or prolapse problems. The use of forceps during delivery was identified as a complication in 123 cases (17.6%).

From discussion with patients, it was the author's impression that many of the women who came for pessary fittings had delivered large babies. High birth weight is a factor linking childbirth with UI (Johnson, 2000; Penn et al, 1996). Results in this study show that the mean weight of the heaviest baby was 3675.25 grams, or nearly 8.1 pounds. This weight is not excessive, thus the author's impressions were not accurate. However, it is worth noting that the weight of the heaviest baby was not documented in 329 charts.

Some clinicians feel that pessaries are useful primarily for the elderly patient (Bartscht, 1991; Friedman, 1991, Moore, et al., 1994). Current sexual activity has been considered a contraindication to pessary use (Farrell, 2003). Others (Bash, 2000; Deger, 1993; de Mola & Carpenter,1996; Farrell, 2003; Miller, 1991)) maintain their usefulness for women of all ages and for those who are still sexually active. The definition of "sexual activity" is not given, but vaginal intercourse is assumed. Certain types of pessaries must be removed before intercourse and using certain styles precludes sexual intercourse (Deger et al, 1993). About half of the women in this study were sexually active. Therefore, this means that wearing a pessary does not exclude them from vaginal sexual activity.

The number of pessaries that were fitted successfully (i.e., remained in place, comfortable and decreased symptoms of UI/POP) until the first follow-up visit was used to define the success of the pessary. The timing of the first follow-up visit varied from patient to patient. This visit ranges from a minimum of a week to about six weeks, with most occurring at two weeks. Those who continued to wear their pessaries beyond the first month had an overall success rate of 91% (n = 637). The overall success rate of those wearing the pessary beyond two months was

81.6% (n = 571). The Edmonton study (Hanson et al, 2003) had a success rate for a two-week follow-up after pessary fitting of 75% for prolapse, 67% for mixed incontinence, 64% for stress incontinence and 58% for urge incontinence. Suarez, Baum and Jacobs (1991) conducted a small study where they fitted twelve women with a contraceptive diaphragm for stress incontinence. They claimed a success rate of 91% (n = 11), but lowered it to 75% (n = 9) as two women found the device too uncomfortable to use. The length of time used in the Suarez et al study (1991) to determine success was initially two weeks. The results from the Hanson study (2003) and the Suarez (1991 study are all quite similar for success rates in the early weeks of pessary usage when compared with the current study. However, the success rate beyond the first two weeks is unknown in these other two studies.

The overall percentage of patients who were still wearing their pessaries at the close of the current study, was 47.9% (n = 335). It is important to understand that these results include the women who wore the pessary for the full duration of the study and those who wore it for at least six months. Of the 700 women included in the data, 69 (9.9%) of them could not be fitted initially. Nearly one quarter of the 700 patients (24.9%, n=174) discontinued using the pessary at some point in the 37 months and 17.4% (n =122) women may or may not be wearing the pessary (lost to follow-up). Over the course of the study, they failed to return for follow-up appointments at the clinic and thus their outcomes are not known. The investigator assumes that some may have discontinued usage, while some may be happily wearing the pessary at home and not coming for follow-up visits, or seeing their own family doctor or gynecologist for follow-up. For the purpose of the results, they must be considered as likely failures. There was no information in the

literature obtained for this study that referred to losses to follow-up for pessary fittings.

Sulak (1991) conducted a retrospective study of 116 patients who had been fitted with a pessary for POP. Fifty-five (47.4%) of these patients continued to use the pessary 22 months after fitting. Although the sample size was smaller than the current study, the long-term success results were comparable to the present study. However, in Sulak's study, the pessary was indicated for POP only. Sulak believes that good patient instruction is a key to the device's success (Sulak, 1991). Wu et al (1997) also conducted a study of 110 women fitted for POP. One year later, 66% were still wearing their pessaries and at three years, 53% were still wearing them. Although the study size is smaller than the current study, the results of those who continued to use the pessary are comparable. As in the Sulak study (1991), the pessaries were fitted for POP only, not for UI. These two studies (Sulak, 1991; Wu, 1997) considered only pessaries fitted for POP. There were no studies found that indicate long-term results for pessaries that were fitted for UI.

It will be recalled that patients were fitted with pessaries throughout the duration of this study, so some may have worn a pessary for a maximum of 37 months, and others for varying lengths of time, the minimum being one month. One can see from the bar chart in chapter 4, page 51, that the majority of patients who discontinued usage did so in the first six months. Those that were fitted and continued to wear pessaries for longer lengths of time have successively lower discontinuation rates. The numbers who wore the pessary for the different six-month periods of time remains similar, from 8.8% for the 7-12 month interval to a low of 5.4% for the 25-30 month interval of fitting and still wearing. These results

are consistent with the author's clinical observations that the greatest number of people who discontinue use of the pessary do so within the first six months. The study by Wu et al (1997) also revealed that the highest rate of discontinuation occurred in the first 12 months of follow-up.

In considering patients with different types of prolapse, those with cystocele and vaginal vault prolapse have similar results with respect to the percentage of patients still wearing the pessary at the close of the study. Over half of those with cystocele, rectocele and vault prolapse still continued to wear the pessary, while those with pessaries for rectoceles were more difficult to achieve successful fitting. The reason for a lower success rate with uterine prolapse is somewhat of a puzzle. There was no research found to satisfactorily explain these results. One possible explanation is that a pessary may be more difficult to retain due to stretching of the introitus from the cervix protruding against it. Over time, the introitus becomes more gaping and wide as the weight of the uterus bears down against and into the opening to the vagina.

The results from the Edmonton study (Hanson et al, 2203) considered success of pessary fittings for the first two-week period only. Their success rates for POP were 83% for those with uterine prolapse, 82% for those with cystocele, 69% for those with vault prolapse/enterocele and 66% for those with both cystocele and rectocele. They are not unlike the results of success from the present study for the first one (91%) or two months (81.6%) only.

When considering use of pessaries for UI, the results from this study at the end of 37 months showed that 44.2% continued using the pessary for stress incontinence, 66.7% for urge incontinence, 41.4% for mixed incontinence and

20.8% for overflow incontinence. The Edmonton group claimed success (at 2 weeks) of 64% of those with stress incontinence, 67% with mixed incontinence and 64% with urge incontinence. Kondo et al (1997) in their study on a specific pessary fitted for stress (n = 57) or mixed incontinence (n = 20), showed at a 12 week follow-up visit that 22 of these patients (29%) reported complete continence and 39 (51%) showed decreased severity of incontinence by more than 50%. It may be seen that there is a large variation in results when considering the three studies cited above. Wu et al (1997) states that those wearing pessaries for UI were less likely to have successful fittings and more likely to opt for surgery. Women with pessaries for UI were less likely to consider ongoing use of a pessary a satisfactory long-term measure.

Vierhout and Lose (1997) reviewed nine studies on intravaginal devices similar to pessaries (n = 6) and intra-urethral devices (n = 3) used for female stress urinary incontinence and found a 63% reported subjective improvement or cure rate. The length of time used in the nine studies to determine success was not documented. Sander et al (1999) tested the effect of a vaginal device (Continence Guard) on urinary leakage and quality of life with 55 women, over a 3-month period. The device was associated with a subjective cure (not measured objectively) of 20% (n = 11) and improvement in 49% (n = 27).

Robert and Mainprize (2002) conducted a prospective cohort study (n = 38) for the treatment of stress incontinence using an incontinence dish and found that after one year, only 16% (n = 6) wished to continue using the pessary, while 41% (n = 16) went on to have surgery. When compared with this current study, the study by Robert and Mainprize had much smaller numbers, a lower success

rate and tested only one specific pessary style for one type of incontinence for a period of one year.

Eleven different types of pessaries were compared in terms of frequency of usage (including the category "other"). The most commonly used style of pessary was the covered ring. The second most commonly used was the Shaatz pessary. The covered ring is considered a more traditional style of pessary used commonly by gynecologists; it is a useful and popular pessary for the treatment of prolapse. The Shaatz pessary is thicker and stiffer and used in cases where the traditional pessary is not sufficient to support the prolapse. The gellhorn pessary is an unusual style and shape, and is somewhat difficult to use, but 8.4% of the women fitted continued to use it for more severe cases of prolapse. The most commonly used styles of pessary for incontinence was the Milex™ incontinence dish, followed by the Mentor™ incontinence dish and the covered ring with knob. If the two incontinence dishes were combined in a single category, they would comprise the largest style of pessary used. Patients find that the dish style and shape of pessary is effective and comfortable.

In their study, Hanson et al (2003) also discussed the usage of different styles of pessaries. Their results indicate that the incontinence dish (both types combined) was the one used for 31.7% of their patients. These results are similar to the current study with the two types of incontinence dishes were selected for 22.3% of the patients. The incontinence dish pessaries are helpful not only for stress incontinence but also to support prolapsed organs. These pessaries are relatively simple to insert and remove and most women find them comfortable. The Shaatz style is used 17.4% (n = 180) of the time in Edmonton, compared

with14.3% for the current study. The covered ring pessary (the most commonly used in the Calgary study at 16.7%) is used 15% of the time (n = 155) in Edmonton. In general, the styles of pessaries used in the study by Hanson et al (2003) are quite similar to the styles used in the current study.

Over half of the women in this study continue to use the first style of pessary fitted but 29.1% tried two styles. The maximum number tried was six styles before achieving satisfaction. In Edmonton (Hanson et al, 2003) the most common number of pessaries tried was two, with a range of one to seven. More than half of the women fitted for pessaries were satisfied with the first size, while 25% settled with the second size.

What is worth noting is that with pessary fitting, the first style and size are the correct ones about half of the time. If patients are not satisfied with the first size and/or style, persevering with fitting different styles and/or sizes is worthwhile for the other half of the patients. A patient's needs may change over time, so ongoing follow-up to determine satisfaction with the pessary, as well as the health of the vaginal tissues, is essential (Deger, 1993; Farrell, 2003; Millar, 1991).

By the end of the present study, 122 women were lost to follow-up. Of the remaining 578 women, 174 were not wearing the pessary at the end of the 37 months. Of these women, 14.4% went on to have surgery and 14.3% indicated that the pessary was not effective for their symptoms. Some women discontinued use because they did not like using the pessary (16%). Various reasons may cause the dislike – some women don't like the idea of wearing a foreign body internally, others may not like to take care of it and some do not indicate the reason they do not like it. Some women find the pessary uncomfortable (12.5%)

and this causes them to discontinue use. Other reasons less frequently cited for discontinuation of pessary use were voiding and bowel dysfunction. Only two patients discontinued use due to infection. These reasons for discontinuation are not mutually exclusive; some women discontinued using the pessary for more than one reason.

Women may experience complications with the use of a pessary. Many complications can be prevented or managed with medications, different styles/sizes, or altering care routines used with the pessary. Nearly half of pessary wearers in this study did not have any complications documented, while 15.9% had some type of discomfort using the pessary. Leakage occurred in 14.4% of the women. Some leakage is not uncommon with pessaries used for prolapse. The presence of the pessary may unmask stress incontinence by supporting the bladder back into its normal position and allowing the urethra to leak (Bergman et al, 1988; Chaikin, Groutz & Blaivis, 2000; Romanzi, Chaikin & Blaivis, 1999). The presence of the prolapse prevents the urethra from leaking by kinking or bending it as it sags along with the sagging bladder. For some patients this leakage is just a temporary condition, while other women may continue to have some ongoing leakage.

"Other" complications account for 10.1%, which includes things such as bowel pressure or temporary cramping. Of note is the low frequency of erosions or infection; 6.7% (n = 47) had some type of erosion. Only 1.4% (n = 10) of the patients had any type of infection due to pessary use. One of the reasons the infection rate was so low is the education and follow-up offered to the patients. Major complications due to pessary use occur only rarely, and historically are

almost always due to pessaries left inside the pelvis, cared for only sporadically or forgotten.

As may be seen from the present discussion, there are many factors that were addressed concerning pessaries and successful fittings in the present study. It is apparent that they are an effective option for POP and UI in women.

CHAPTER SIX: IMPLICATIONS AND CONCLUSION

The results from this study provide further empirical evidence of the benefit and role of vaginal pessaries for women suffering from vaginal organ prolapse and urinary incontinence. These problems are common and will become more so as the elderly population increases and women live longer (Farrell, 2003). The option of pessary usage should become more widely known, understood and made available to women. It is important to ensure that care of patients is not merely based on anecdotal opinions and practices but on research findings and clinical consensus (Thurston, 2002). This study provides further evidence on the effectiveness of the pessary as nearly half of the women involved in this retrospective study continued with pessary use up to three years after being fitted and obtained relief from their problems with UI and POP.

As Flood et al (1997), Morley (1996) and Farrell (2003) recommend, there should be more emphasis placed on the role of the pessary in the training of obstetrics and gynecology residents and to increase the familiarity of all physicians with them while in training. Pessaries should be brought to the attention of women and made available as a first-line option for the non-surgical management of UI and POP (Brubaker, 1991). While pessaries are not a perfect solution for all women, neither is surgery. Women should never be directed towards surgery without unbiased counseling and full awareness of all of the options available to them (Deger et al, 1993). Physicians should be fully aware of the use of a pessary as an option for their patients and optimistic that it may be of benefit to them.

As Flood and Hansen (2003) conclude, nurse-led clinics are ideal for pessary education, fitting and care. Various authors (Farrell, 2003; Miller, 1993; Moore et al., 1994) state that the requirements for the most beneficial outcomes of pessary fittings are a thorough focused patient history and evaluation, detailed and ongoing patient education and specific and individualized patient follow-up. Patient requirements may change over time (Miller, 1992) and ongoing care is essential. Nurse-led clinics can meet these needs and referrals from family doctors or gynecologists should be readily available. Training programs for advanced practice nurses should be made more readily available with specialized instruction about pessary fitting and insertion. Nurses in their basic training should also be made aware of the role of pessaries for women as many have no knowledge of what pessaries are or their uses.

Limitations

Retrospective studies have limitations. Specific information may not be available to the researcher. Documentation for certain variables may not be available in patient charts. In this study, information about the smoking status of the women was not available in most charts as it is not routinely asked or documented. Information about childbirth and delivery was not consistently available in the charts for the same reasons. New patients to the clinic are now being assessed using standardized assessment forms that ask these questions, but there were not used in the early years.

A possible source of bias may have been the timing of the referrals in the course of the study. The majority of the early referrals were from the urogynecologists as they were instrumental in the formation of the clinic.

Throughout the course of the 37 month study, other physicians became aware of the clinic and more of the referrals came from outside sources. It is not known if the cohort of women referred differed in their type or severity of problem and how this may have affected the outcomes of their fittings for pessaries.

The majority of pessaries were fitted by one RN at the clinic (the investigator). The type of pessary used was based on the clinical experience of the investigator. There are no empirical studies in the literature that would indicate what the "best" pessary is, given the variety of factors that may influence a "successful" fitting.

The results obtained were taken from the time span of 37 months. The patients were fitted within this time period and the length of time for which they wore they pessaries thus varied. A survival-curve analysis would have been helpful to analyze the results and determine more accurately the success of pessary fittings.

Future Research

Ongoing research will only serve to enhance the awareness of the health community to the benefit and role of pessaries for their patients. More studies need to be done, especially focusing on long-term usage and benefits of pessaries. Many questions regarding pessaries and their use remain unanswered. There may be a role for pessaries in the prevention of potential prolapse or incontinence problems. The potential of long-term use of pessaries curing these problems should be explored. A comparison of the cost-effectiveness of pessaries as opposed to surgical intervention would be useful.

Modifications of current styles of pessaries might further enhance their effectiveness.

There is some nursing literature available promoting the use of pessaries, but it is sparse. Nurse clinicians are in ideal positions to educate nurses and promote the understanding and use of pessaries by publishing articles and presenting research such as this study. Prospective studies involving pessary usage would shed further information about their effectiveness and benefit to the women wearing them. The effect of pessaries on the quality-of-life of users would provide useful information in regards to their limitations and benefits. Comparing the use of estrogen and non-estrogen containing vaginal preparations would provide valuable information for the patient faced with the decision of selection of a product to use while wearing a pessary. Investigating the satisfaction of the patient in a nurse-led clinic might serve to increase the availability of this type of service for women.

Conclusion

In conclusion, this study serves to demonstrate that pessaries can be an effective and safe option for women of all ages suffering from POP and UI. The results show that nearly half of the women fitted for pessaries within the 37-month duration of the study were still wearing them at the close of the study. This would include those fitted throughout the study time frame, wearing the pessary for at least six months and up to 37 months. The option of pessaries should be readily available to women who are looking for an alternative to a surgical intervention.

Nurse-led clinics are viable and successful options for the conservative management of POP and UI. Nurses with increasing knowledge of and comfort with the use of vaginal pessaries can make a significant difference in the treatment of these conditions.

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APPENDIX A

PESSARY AUDIT TOOL

1. ID# (study number assigned by investigator)
2. Foothills Hospital Identification #
3. Age (at fitting first)
4. Postal Code
5. Geographic Location
    (1) NW Calgary
    (2) NE Calgary
    (3) SW Calgary
    (4) SE Calgary
    (5) Outside Calgary (in Alberta)
    (6) British Columbia
    (7) Saskatchewan
    (8) Other (specify)
6. Referred from:
    (1) Family Doctor
    (2) Gynecologist
    (3) Urogynecologist
    (4) Urologist
    (5) Physiotherapist
    (6) Nurse
    (7) Other (specify)

7. Primary Indication:

(1) Urinary: Stress

(2) Urge

(3) Mixed

(4) Overflow

(5) Prolapse: Uterine

(6) Cystocele

(7) Rectocele

(8) Vault/Enterocele

(9) Mixed

(10) Preoperative

(11) Other (specify)

8. Past Pelvic Surgeries (check all that apply):

(1) Hysterectomy

(2) Anterior Repair

(3) Posterior Repair

(4) Incontinence Surgery

(5) Other

(6) None

9. Pertinent Medical Conditions

These are all conditions that have a direct implication on the patient's ability tolerate and experience a benefit from pessary use. Some conditions such as cancer and DVT have a bearing on their ability to use estrogens. Check all that apply.

(1) Diabetes

(2) Arthritis

(3) Constipation

(4) UTI's (>4/year)

(5) Cancer:

(6) Uterine

(7) Breast

(8) Ovarian

(9) Other

(10) Asthma

(11) Hypertension

(12) DVT/PE

(13) Other

(14) None

10. Current Medications Used: (at initial visit)

(1) Diuretics

(2) Antihypertensive

(3) NSAIDS

(4) Anxiolytics/Antidepressants

(5) HRT

(6) Others

(7) None

10. Menopausal Status:

(1) Premenopausal

(2) Postmenopausal

11. Hormone Replacement Therapy (with pessary use) (check all that apply)

(1) None

(2) Systemic

(3) Estrogen only

(4) Estrogen/Progesterone

(5) Progesterone only

(6) Premarin Vaginal Cream

(8) Estring

(9) Vagifem

(8) Both Systemic and Local

(9) Other

12. Smoker:

(1) Yes

(2) No

13. Final Style of Pessary Selected

(1) Open Ring

(2) Covered Ring

(3) Shaatz

(4) Gellhorn

(5) Cube

(6) Donut

(7) Incontinence Dish Milex

(8) Incontinence Dish Mentor

(9) Open Ring with Knob

(10) Covered Ring with Knob

(11) Other

14. # of Sizes Tried

15. # Styles Tried

16. Length of Time Used After Fitted (months of use)

17. Complications: (check all that apply)

(1) Erosions

(2) Discharge (excessive)

(3) Discomfort

(4) Leakage

(5) Infections

(6) Others

(7) None

18. Reasons for Discontinuing Use: (check all that apply)

(1) Voiding Dysfunction

(2) Bowel Dysfunction

(3) Discomfort

(4) Loss of Effectiveness

(5) Surgery

(6) Infections

(7) Did not like to use

(8) Lost to follow-up

(9) Deceased

(10) Other

(11) Still wearing

19. Number of Deliveries:

(1) C/S

(2) Vaginal

(3) None

20. Weight of Heaviest Baby (grams)

21. Complications of Delivery or Postpartum

(1) Not Known

(2) Episiotomy

(3) Forceps

(4) Vacuum

(5) Tears (4^{th} degree)

(6) Infections

(7) Other

22. Sexually Active

(1) Yes

(2) No

APPENDIX B

ETHICAL APPROVAL

Foothills Medical Centre
1403 29 Street NW
Calgary, Alberta, Canada T2N 2T9
website www.calgaryhealthregion.ca

calgary health region
Foothills Medical Centre

22 September 2003

Dr. James Rankin
Faculty of Nursing
University of Calgary

Dear Dr. Rankin:

Re: #17368 – Satisfaction with Pessary Usage in a Nurse-Led Pessary Clinic: A Chart Review

Thank you for submitting an application regarding the above project for review by the Adult Research Committee of the Calgary Health Region (CHR). This will confirm that the committee has granted institutional approval for this project, and that the CHR has granted approval under Sections 53 and 54 of the Health Information Act. **This approval is contingent on approval by the Conjoint Health Research Ethics Board.**

It is understood from your submission that your study will be entirely funded through external sources and that the CHR will be reimbursed for all research costs associated with this project. To facilitate a smooth startup of your project, please notify affected departments in the Region well in advance of your intent to initiate this study.

Please note that it is a requirement that you communicate in writing the study results to the CHR Adult Research Committee, and provide any copies of publications arising from the research as well as provide feedback regarding any problems encountered during the course of the study.

Please accept the committee's best wishes for success in your research.

Yours sincerely,

Elizabeth MacKay, MD
Acting Chair, Adult Research Committee

cc: Dr. D. Hughes, Conjoint Health Research Ethics Board

UNIVERSITY OF CALGARY

FACULTY OF MEDICINE

Office of Medical Bioethics
Heritage Medical Research Building/Rm 93
Telephone (403) 220-7990
Fax (403) 283-8524

2003-09-19

Dr. J.A. Rankin
Faculty of Nursing
University of Calgary
PF 2212
Calgary, Alberta

Dear Dr. Rankin:

RE: Patient Satisfaction with Pessary Usage in a Nurse-Led Pessay Clinic
Student: E. Grace Neustaedter

Grant-ID: 17368

The above-noted research proposal has been submitted for Committee review and found to be ethically acceptable. Please note that this approval is subject to the following conditions:

(1) a copy of the informed consent form must have been given to each research subject, if required for this study;
(2) a Progress Report must be submitted by 2004-09-19, containing the following information:
    (i) the number of subjects recruited;
    (ii) a description of any protocol modification;
    (iii) any unusual and/or severe complications, adverse events or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, or complaints about the research;
    (iv) a summary of any recent literature, finding, or other relevant information, especially information about risks associated with the research;
    (v) a copy of the current informed consent form;
    (vi) the expected date of termination of this project;
(3) a Final Report must be submitted at the termination of the project.

Please note that you have been named as the principal collaborator on this study because students are not permitted to serve as principal investigators. Please accept the Board's best wishes for success in your research.

Yours sincerely,

Christopher J. Doig, MD, MSc, FRCPC
Chair, Conjoint Health Research Ethics Board

cc Adult Research Committee
Dr. M. Reimer (information)
Ms. E. Grace Neustaedter
Research Services

calgary health region
Grace Women's Health Centre

Agapé Hospice
...Continuing a tradition of unconditional love

September 10th, 2003

Dear Ms. Neustaedter:

The Spiritual Values Advisory Committee of the Salvation Army Health Council met recently to discuss your research proposal "Satisfaction with Pessary Usage in a Nurse-Led Pessary Clinic." The committee felt that your research protocols met our ethical guidelines and that the information you seek will contribute to the body of knowledge in this area.

We look forward to learning the results of this study.

Regards,

Barbara Ferguson, Chairperson
Spiritual Values Advisory Committee