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Rates and Risk Factors Associated with Peripheral Intravenous Catheter-Related Infections

by

Karen Myrthu Hope

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies for acceptance, a thesis entitled "Rates and Risk Factors Associated with Peripheral IV-Related Infections", submitted by Karen Myrthu Hope in partial fulfillment of the requirements for the degree of Master of Science (Medical Science).

H. Bryant
____
Supervisor: Dr. H.E. Bryant
Dpt. of Community Health Science

G H Fick
____
Dr. G.H. Fick, Examiner
Dept. of Community Health Sciences

Deirdre Church
____
Dr. D. Church, Examiner
Dept. of Microbiology and
Infectious Diseases

Vanda MacFarland
____
Ms. Vanda McFarland, Examiner
Faculty of Nursing

____

Date: Sept 27, 1990

ABSTRACT

The incidence of nosocomial bloodstream infections is currently on the rise in North America, primarily due to the increasing use of invasive intravascular devices. Peripheral intravenous (IV) catheters are one of the most frequently used type of device and although less invasive than some procedures, still have the potential to initiate local site infection and possibly bacteremia.

A study was undertaken at the Foothills Hospital to determine the rates and risk factors associated with IV infections in a general hospital population. Four hundred seventy six peripheral IV catheter episodes were followed prospectively for 2 months on two hospital units, medical (53%) and surgical (47%). Phlebitis and local IV site infection were monitored by daily visual inspection, the patient chart and microbiological culturing.

The rate of phlebitis was 8.2% (95% C.I. 5.7-10.7) or 3 cases per 100 catheter days. The concurrent rate of local IV site infection was 2.5% (1.1-3.9) or 1 case/100 catheter days. Significant risk factors for phlebitis included: the use of antibiotics (RR 2.46, 95% C.I. 1.32-4.63) and lengthier duration of catheterization (RR 2.37, 95% C.I. 1.29-4.30). The risk of infection was only significantly increased with greater duration of catheterization (RR 12.0, 95% C.I. 3.34-43.47). The proportion of infections was higher when episodes were classified as second or greater. However this was not

statistically significant. Severity of illness was only associated with a slightly increased rate of infections (nonsignificant) when the analysis was not adjusted for duration of catheterization.

There were some deficiencies noted in the compliance of staff with monitoring procedures. Fifty-nine percent of catheters which should have been sent for microbiologic culture based on presenting symptoms, were discarded prematurely. IV recording sheets were frequently not filled out (25.2%), and IV administration apparatus was not dated (25.0%-57.7%). The rate of infections associated with poorly documented episodes was higher than that when IV sheets were adequately filled out ($p<0.02$).

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CHAPTER 1

INTRODUCTION

A peripheral intravenous catheter is one of the most commonly experienced invasive hospital procedures performed on patients. A study by Tager et al. (1983) found that of the general hospital population they surveyed, 80.6% had one or more intravenous catheters in place during their hospital stay.

The introduction of the plastic catheter in 1945 was heralded, since it greatly facilitated the administration of intravenous fluids. However the use of plastic catheters also led to an increase in infectious complications since they were generally left in for longer time periods and were more subject to colonization. As with all invasive devices, the potential of the catheter to cause local infection increases with time left in place. Local infections can lead to further serious complications such as thrombophlebitis, infection of the vein, and bacteremia, bacterial infection of the blood. Data from the National Study indicate that about 18% of primary endemic nosocomial bacteremias could be caused by intravenous (IV) therapy, including central venous, peripheral, and radial artery catheterization. As well as substantially increasing the risk of mortality in the afflicted patient, a nosocomial bacteremia in the U.S. has been estimated to increase the average hospital stay by 7.4 (+/-12.2) days, which would increase the cost of stay by about

$2800.00 in a Canadian hospital (Haley, 1980).

True incidence rates of local catheter infection and bacteremia due to peripheral I.V.'s are very difficult to determine, since rates vary widely depending on the culture methods and case definitions used. As well, a large proportion of the literature is based on studies of central venous catheters in critically ill populations, which are known to have higher rates of infection due to several mitigating factors (Elliot, 1989).

Early studies, which are well summarized in Maki's review (1973), found rates of catheter culture positivity up to 45% and rates of bacteremia up to 5%, when only peripheral lines were included. Central venous catheters had generally higher rates of complications (up to 12%). The early studies depended on a qualitative method of culturing catheters, which gave rise to an overestimate of positives, stemming from contaminants.

Studies of peripheral IV catheters since 1977 generally utilize more specific methods of culture. However even when similar patient populations are used, the culture positive rate can vary from 1.4% to 10% and phlebitis from 2.3% to 32%. The rate of catheter associated bacteremias remains relatively low, usually less than 1%. The variation between studies may depend on the presence or absence of an IV team, differing criteria for defining infection or different culture techniques. A review article by Plit et al. (1988) addressed the lack of consensus associated with catheter infection statistics, and stressed the need for greater standardization in future research. Without it, there is a difficulty in initiating appropriate guidelines and policies which ensure patient safety.

In addition to the need for more consistent research, it is still necessary to have continuous surveillance and evaluation of current catheter management techniques. Current policy manuals set out guidelines for catheter care based on LCDC recommendations. However, there is evidence that specified management is not always carried out. This may be indicative of the need for change. Past studies have proven that certain accepted guidelines, such as catheter and administration set changes every 48 hours, were not always necessary, and brought about changes which were more acceptable to the patient, more convenient for the caregiver, and more cost efficient for the health care system. Peripheral intravenous catheters may also instill more of a laissez-faire attitude amongst care-givers since they are considered to be relatively standard in current patient care. This attitude is not warranted since a peripheral catheter infection is still invasive and has the potential to cause unnecessary morbidity.

In 1988, a twelve week audit of peripheral intravenous infection was carried out by the Departments of Nursing and Infection Control at the Foothills Hospital. During this time

36 peripheral IV-related infections were detected, and the need for further research became evident. It was therefore proposed that following review of the literature, a prospective study would be carried out to observe the rates of peripheral intravenous associated infections in two patient populations representative of a general hospital population. Data would be collected on certain risk factors identified in previous literature to have some association with catheter-associated infection. Collection of data would include such patient-associated factors as underlying illness, use of antibiotics, and previous days of hospital stay. Information would also be collected on other contributing factors such as duration and order of catheterization, as well as insertion and monitoring techniques.

CHAPTER 2

LITERATURE REVIEW

The central purpose of this literature review will be to examine the body of knowledge as it pertains to peripheral catheter infections. However, a large proportion of research involves the study of central lines, and since some of the factors are applicable to peripheral catheters, these studies will be included in the review.

Definitions

This segment of the literature review will attempt to focus on some of the definitions used in previous studies and discuss the lack of consensus among them.

Phlebitis and local infection of the catheter site, are two terms which present problems when comparisons between studies are attempted. Phlebitis is commonly understood to be the presence of at least two of the following: erythema, tenderness, increased warmth, induration, or swelling (Maki and Ringer, 1987; Tully, et al., 1981; Nursing Procedure Manual, Foothills Hospital, 1989). Infectious phlebitis includes the above with the addition of purulence present at the catheter entry site (Hershey, et al., 1984). Studies such as the one by Tager et al. (1983), which do not incorporate microbiological data, often use phlebitis as the marker for infection.

There are two major drawbacks associated with using phlebitis as the sole infection criterion: 1) subjectivity of the diagnosis and 2) multiple etiologies of the signs used to make the diagnosis. Nichols et al. (1983) makes reference to the fact that the measures used to identify phlebitis are prone to bias. Determination of erythema is subject to inter-rater bias when there is more than one person documenting infection. Tager et al. (1983) attempted to address this issue by using a standardized training program for raters, certifying personnel only when they achieved an inter-rater concordance rate of >90%. Pain is also a very subjective measurement, particularly since it depends on verification from the patient who may have a very low or high threshold of sensitivity.

The problem of multiple phlebitis etiologies cannot be adequately addressed without the culture of catheters. Catheters themselves can cause mechanical phlebitis, depending on the composition and gauge, (Larsson et al., 1989) and the infusate is capable of initiating chemical irritation (Falchuk, 1985). These different causes of phlebitis are clinically manifested in similar ways. It is also possible for septic endophlebitis to be present when there are no local, visibles signs of inflammation (Plit, 1988). Moyer et al. (1983) found a "clean" IV site in 3 infected catheters, one of which caused sepsis.

The role which clear definition plays can be illustrated by comparing studies and observing the differences in infection rates. Collins et al. (1968) defined local infection as a positive qualitative culture of the catheter tip and found a rate of 34.3%. Maki (1977) defined local infection as a culture of >15 colony forming units (cfu's)/plate after rolling the distal catheter tip across a growth medium, and found a rate of 10%. Tully et al. (1981) defined local infection as the presence of lymphangitis, purulence, cellulitis or suppurative thrombophlebitis, and found a rate of 0.1%. It is impossible to compare infection rates between studies when the clinical definitions vary so widely.

Other studies have used different definitions within one protocol. Mylotte and McDermott (1987) determined the source of S. aureus bacteremia as being from a peripheral IV catheter if at least one of the following was present: inflammation at the site, purulent drainage from the insertion site positive for S. aureus, or a positive semiquantitative culture. Fourteen peripheral IV associated infections were identified. However, because the criteria by which they were defined differed, the results were questionable. Of 14 suspected peripheral intravenous catheter infections, only one semiquantitative culture was done (and found positive). The other 13 cases showed evidence of inflammation with (4) or without (9) purulent drainage, indicating 9 cases were identified by the criterion for phlebitis alone.

The definitions to be chosen for the current study will be based on a combination of previously used terms, and will be justified by the researcher in a later chapter.

Patient Factors

The risk factors which predispose patients towards the development of catheter related infection can arise from characteristics of the host, mainly the severity of illness responsible for hospitalization.

Many studies have focused on catheter related infections in intensive care populations, owing to the high rate of nosocomial bacteremias occurring on these wards. One group found that 33% of all nosocomial bacteremias identified in a large hospital, occurred in the intensive care unit (ICU). This was a ten fold higher rate than what was found in the general hospital population (Wenzel et al., 1981). Patients on surgical ICU's are reported to routinely have at least one intravascular device in addition to a peripheral catheter. However it is difficult to determine whether the devices are markers in patients so ill that they would be likely to develop a nosocomial infection with or without the device, or whether the devices are themselves the cause of infection. It was found that surgical ICU patients had less chronic underlying diseases than medical ICU patients, but double the incidence of bacteremias and urinary tract infections. Surgical ICU patients were also subject to a higher number of invasive devices and procedures, supporting the hypothesis favouring intravascular devices as a cause of infection. A commentary by Maki (1989) suggests that the probability of reducing nosocomial bacteremias lies with advances in intravascular technology, such as the manufacture of colonization-resistant polymers or innovative designs.

The confounding nature of illness severity is well recognized (Freeman et al., 1988), yet there are few studies which have attempted to control for this when using general medical and surgical patient populations. Some studies of ICU patients have attempted to stratify patients according to the severity of their disease by using APACHE, a scoring system based on physiological parameters (Craven et al., 1988). Although the score variable was not significant in the logistic regression model which predicted nosocomial infection, other variables indicative of physiological status, such as condition on admission (in shock or not) and kidney function (measured by creatinine level), may have acted as masking covariates. Furthermore, rating systems such as APACHE are only appropriate for use in critically ill patients, and cannot be directly applied to other populations.

It is evident that most researchers consider the rates of catheter associated infection in general hospital wards to be low enough to warrant little interest. However, stratification of this population could be useful in determining if there is a group of more seriously ill "low risk" patients who are responsible for presenting with the majority of infections.

Microbiological Issues

The microbiological issues can be divided into four broad categories: 1) source of the microorganisms 2) pathogenesis mechanisms of those organisms 3) methods of culturing to identify infections and 4) trends in the types of organisms cultured.

Source

The source of microorganisms responsible for catheter infections is generally accepted to be from one of three areas: the infusate, the patient's or caregiver's organisms via the cannula, or hematogenous seeding. Early in the 1970's there was an epidemic of nosocomial bacteremia resulting from one manufacturer's intrinsically contaminated infusion product. Between July 1, 1970 and April 1, 1971, 397 cases in 25 hospitals were recorded as stemming from the contaminated product (Maki, 1981). Since then, improvements in quality control at all levels, from manufacturer to pharmacist, have combined to reduce the number of infusion-related bacteremias observed.

Currently it is estimated that the percentage of infusions producing sepsis is extremely low. However it is possible that the actual rate is underestimated, since fluid is rarely cultured. It is known that certain infusion mediums, particularly those containing glucose, are more likely to support the growth and proliferation of microorganisms. Initially, recommendations were made suggesting that administration sets be changed every 24 hours to prevent hazardous contamination. Band and Maki (1979) undertook a study to determine whether this time interval was in fact justified. Of 790 infusions followed, only 5 cases of contaminated infusate were found in administration sets which were used continuously for up to 71 hours, none of which caused bacteremia. Of the 5 cases identified, 1/258 occurred after 1 to 24 hours of use, 3/359 occurred after 25 to 48 hours of use, and 1/173 occurred after 49 to 72 hours of use. It is noteworthy that although they claimed the hospital under study changed sets every 48 hours, 173 (21.8%) were in continuous use 49 to 72 hours. They concluded from this study that administration sets could be safely changed every 48 hours. However from the data presented, it appears that 4 cases of contamination could have been prevented if the sets were changed every 24 hours, precluding the possibility of bacteremia.

Most catheter-associated infections result from contamination of the cannula portion of the catheter, at the point of entry into the skin. Commensal organisms which reside on the patient's skin gain access to the catheter as the tip is pushed into the vein. Several studies have found a strong correlation between cutaneous flora and the organisms cultured from the catheter tip (Maki et al., 1973). Even if the skin is aseptically prepared, there is evidence to suggest that organisms colonizing the outer portion of the catheter are capable of migrating from the outer portion intravascularly where they will colonize and proliferate (Elliot, 1988).

Another hypothesized route of entry is the catheter hub. In a prospective study, Linares et al. (1985) demonstrated a high proportion of infections resulting from colonized hubs. They proposed that bacteria gain entry to the hub during manipulation of the system, after which they are capable of migrating down the intraluminal portion of the catheter to cause infection.

A final method whereby the catheter may become infected is via hematogenous seeding. Although not common, it is possible for another focus of infection (such as a surgical wound) to initiate a secondary bacteremia, which will then seed the catheter. Circulating organisms become trapped in the fibrin sheath which surrounds the intravascular portion of the catheter, maintaining infection. In a retrospective chart review of a four year period, Johnson, et. al. (1986) observed that enteric organisms such as Klebsiella and Enterobacter were most likely to cause suppurative thrombophlebitis in those patients who had undergone abdominal surgery or had an active inflammatory process of the bowel. This could be suggestive of hematogenous seeding, since the majority of catheter associated infections are caused by commensal skin flora, such as coagulase negative staphylococci.

Pathogenesis

Determination of the source of catheter-related infection has been relatively simple. However, distinguishing the individual factors which contribute to the colonization and pathogenesis is more complex and relies on an interaction of host, catheter and microbial factors.

The type and composition of the catheter are important determinants in bacterial colonization. Tulley et al. (1981) found that Teflon catheters were a more frequent cause of phlebitis than steel needles (OR=1.87, 95% C.I. 1.45-2.4) although the steel needles had an overall higher rate of complications. Other studies have identified a higher rate of infection associated with polyvinyl chloride and polyethylene. Sheth (1983) used an in vitro model to demonstrate that coagulase negative staphylococci adhere more readily to polyvinyl chloride than to Teflon. It appears that bacteria can attach themselves to roughened surface areas of the catheter via processes which may depend on the free energy of the bacterial cell wall or on cell surface receptors which have an affinity for certain substrates (Dickinson and Bisno, 1989).

Other microbial factors may enhance colonization of the catheter once attachment has been facilitated. S. epidermidis produces a slime glycocalyx which is reported to decrease the phagocytotic response and maintain the organism on the catheter surface (Costerton and Watkins, 1987). There are also reports of slime embedded S. epidermidis surviving exposure to an antibiotic which they were sensitive to on susceptibility testing (Sheth, 1983).

Host factors which may influence the colonization of microorganisms consist of substances which are produced as part of the immune response to foreign bodies. Invasive devices stimulate the host immune system to generate fibronectin, a substance which then coats the catheter. Some studies have shown fibronectin to be a receptor for different species of Gram positive cocci, particularly S. aureus (Dickinson and Bisno, 1989).

All the aforementioned factors are influenced by the length of time the catheter is in place, a risk which has been established by most research in the area, and which will be discussed more thoroughly in later sections.

Culture Methods

Most of the discrepancies arising in previous studies of catheter-associated infection are due to the variability in microbiological culture methods employed to determine colonization of the catheter.

In the earliest studies, catheters were cultured qualitatively by placing them into sterile broth and recording any growth as positive. When Collins et al. (1968) utilized this method in a prospective study of 213 catheterizations, he obtained an infection rate of >34.3%. This data was "sharpened" by subsequently dividing the cultured organisms into "pathogens" and "contaminants", leaving a local infection rate of 17.4%. This method of honing the data could be very unreliable, since certain bacterial species thought previously to be only contaminants, have been proven to cause local and systemic infection (Eyken, 1984).

Qualitative culture methods cannot distinguish between inadvertent contamination and true infection. However, even after other culture methods were introduced, some researchers continued to rely on the qualitative technique. Maki et al. (1977) demonstrated that qualitative cultures were not very accurate in predicting infection due to the high rate of false positives. When 250 catheters were cultured by both a semiquantitative (SQ) and qualitative method, local inflammation was associated with high density colonization using SQ culture (>15 cfu's/plate, p=.001). Although there was no indication of what the false positive rate was for local inflammation when using the qualitative technique, 16/225 broth cultures gave false positive results for bacteremia, using the semiquantitative technique as the reference standard. From these results, Maki suggested that a colony count of > 15 cfu's/plate was indicative of a pathogen, while less than 15 indicated a contaminant.

Essop et al. (1984) continued to use the qualitative method when observing cannula-related infection rates due to central venous catheters in 57 non-infected hosts. They found 46% of all catheters to give positive culture results; however only six patients developed a catheter-related bacteremia. In van den Broek's study (1989), both semiquantitative and qualitative methods were used on the patient sample. The qualitative method yielded 30% false positives when phlebitis was used as the disease criterion, a finding supportive of Maki's earlier results

Although generally accepted as the gold standard in culturing catheters, the semiquantitative method does not allow for quantitation of colonization of the internal lumen of the catheter, which may also be colonized. Cleri et al. (1980) suggested the use of a modified quantitative method, whereby the distal segment of the catheter was immersed and flushed in broth. The broths were then serially diluted 100-fold, and plated. Catheter-associated bacteremia occurred in 13 cases, all of which grew up $>10^3$ cfu's/plate. Hence this was established as the criterion for predicting systemic infection. This criterion is not a good marker for local infection or phlebitis though, since 60% of patients with marked inflammation cultured $<10^3$ organisms.

Although both the SQ and the quantitative method show good correlation with clinical infection, Cleri suggested that the quantitative method was preferable to the SQ, since it was able to detect organisms in the lumen of the catheter, as well as distinguish relative numbers of different bacterial species. Linares et al. (1985) used both methods in their study; the SQ for the external portion of the tip, and the quantitative for the lumen. Their findings lend credence to the use of one method only, since both types of cultures yielded similar results. They concluded that organisms which are infecting the lumen will eventually migrate to the external surface if given enough time. This assumption may be questionable since the route of entry appears to determine whether the lumen or outer surface of the catheter is initially infected. Correspondingly one type of culture method may detect infection better, depending on the first surface colonized, which will likely sustain heavier growth. The time element involved for total catheter colonization is not clearly defined either and probably differs between patients and types of catheters.

The results of a recent study by Kristinsson et al. (1989), where three methods of culturing catheters were evaluated, do not agree with these findings. The semiquantitative method was used to culture the outside of the catheter, while the quantitative method was used to culture the internal surface. Following this the entire catheter was ultrasonicated and the liquid medium cultured. They found that the results of culture after sonication were not significantly different from the other two methods. However, they suggested that the quantitative method gave less false positives than the SQ, when correlated with actual clinical manifestations of infection, due to the absence of contamination found when the outside portion of the catheter comes into contact with the skin. The likelihood of a positive culture being associated with infection when the threshold was set at 15 cfu's/plate was 46% when a semiquantitative method was used. The corresponding negative predictive value was 99%. When 100 cfu's was set as the cutoff, the respective figures were 56% and 96%. When the quantitative method was used with a threshold of 15 cfu's, the positive predictive value was 66% and the negative predictive value was 95%. The respective results for a cutoff of 100 cfu's were 91% and 93%.

Although it is impossible to calculate the exact sensitivity and specificity from the data presented, an approximation indicates that the specificity increases with use of the quantitative method and a concurrent increase in threshold. However there is a loss of sensitivity as the threshold is raised from 15 cfu's to 100 cfu's. This may be problematic if asymptomatic infections with the potential to develop complications are not culture positive and therefore missed. Conversely, a low specificity may lead to unnecessary treatment of false positives with antibiotic therapy, further aiding the emergence of resistant organisms. Unfortunately the study from which these figures are taken used clinical diagnosis as the standard by which the methods were judged, and it is never clearly stated just what criterion were used to identify clinical infection. The results could be drastically altered depending on the definition of infection used. The data was never clearly presented in table form making it impossible to confirm their results. It should also be noted that the quantitative method they employed cultured only the inner lumen of the catheter. They found this to correlate poorly with exit site infections (local infections?) since these are generally due to commensal skin organisms migrating down the outer surface of the catheter. A culture method should give predictive results for all types of catheter related infection; therefore a quantitative method of the lumen only, may be inadequate.

From the research to date, it appears that neither method is ideal. The quantitative method, which may be a better predictor of hub related infection, lacks sensitivity in predicting local infections. The quantitative method is also time consuming and inefficient for use in medical laboratories which must handle a large volume of samples. The semiquantitative method does not give an adequate culture of the lumen which could potentially harbour a colony of organisms. Nor has the threshold of greater than 15 cfu's been rigorously examined as to its suitability as an indicator of infection. However it does have the advantage of being more efficient to use, and since it is used frequently, it allows for comparisons to be made between studies.

Other researchers (Sitges-Serra et al., 1984) have identified the catheter hub as a potential route for entry of infection. A study by Maki and Ringer (1987) which compared dressing regimens for peripheral IV's, found that colonization of site and contamination of the catheter hub are of primary importance in predicting the occurrence of local catheter infection. Step-wise logistic regression analysis of 2088 catheter episodes indicated the risk of local catheter infection was 3.86 times higher (95% CI 2.46-6.05, $p<.001$), when there was colonization at the skin site and 3.78 times greater (95% C.I. 2.46-5.82, $p<.001$) when the hub was contaminated. Contamination appears to be defined as any growth following swabbing and culture of the hub. Fan et al. (1988) conducted a prospective study of central venous catheters to investigate the potential of surveillance hub and skin cultures in predicting catheter infections. They found that simultaneous hub and skin cultures gave a sensitivity of 79.3% and a specificity of 74.3%. However only 44.2% of those catheters predicted to be at high risk actually developed catheter sepsis. All catheters, when removed, were cultured SQ and quantitatively, and the gold standard for catheter infection was considered to be >15 cfu's/plate or $>10^3$ respectively. Since this study was done on central lines in a high prevalence population (20%), it is likely that the positive predictive value would be decreased in a sample of peripheral catheters.

The most serious problem among some studies is the total lack of any corroborating microbiological data. A major epidemiologic study was conducted by Tager et al. (1983), to determine the risks associated with peripheral IV catheters. The sample size was substantial (5161 catheter episodes); however no microbiologic data was collected in conjunction with the bedside surveillance of phlebitis. Phlebitis was used as a marker for catheter infection, and although many studies have demonstrated a correlation between phlebitis and catheter infection, a study by Tully et al. (1981) found that only 31% of catheter episodes which cultured positive were also positive for phlebitis. Therefore, it is possible that using only phlebitis as a marker could lead to a serious underestimation of the true rate of infection. Conversely, lack of microbiological confirmation could also lead to an overestimation, since it has been demonstrated that phlebitis can have a chemical or mechanical etiology as opposed to an infectious one (Hamory, 1987). Culturing of suspect catheters identifies cases of phlebitis which are truly infected. An earlier paper by Tager et al. (1981) makes reference to the assumption that daily surveillance combined with culture data will successfully identify almost 100% of nosocomial infections occurring. However, this method was not adhered to in his later studies.

Tomford et al. (1984) and Hershey et al. (1984) compared the incidence and natural history of catheter associated phlebitis between wards managed by an IV team and those maintained by regular medical staff. There was a 32% incidence of phlebitis (defined as 3 out of 4 of the following: pain, redness, induration or cord of at least 2.5 cm) and a 2.1% rate of major complications on those wards not maintained by an IV team. Corresponding values for the IV-team maintained catheters were 15.0% and 0.2%. However no microbiological cultures were done to correlate phlebitis with catheter-related infection. It was noted that phlebitis often occurred at the site of the IV catheter after treatment had been discontinued, with >50% developing 12 hours or more after the catheter was removed. Since culture data was not collected, it is impossible to infer any association between colonization of the catheter and phlebitis occurring after removal.

Trends

Microbiologic data allows the determination of problematic organisms currently associated with nosocomial infections, allowing treatment regimens to be planned for optimal management. Maki (1981) suggested that S. aureus was responsible for 12.5% of primary endemic bacteremias occurring in 1976. S. epidermidis was noted as being the causal organism in about 7% of endemic cases at this time. Baker et al. (1979) did a retrospective chart review to identify all cases of septic phlebitis between 1965-1978. They found 41% of cases to be caused by S. aureus. Only 7% were recorded as being due to S. epidermidis. In a later study, Maki and Ringer (1987) found coagulase negative staphylococci responsible for almost 100% of all catheter related infection observed. Eykyn (1984) found that S. epidermidis accounted for only 10% of catheter-related bacteremias identified from 1974 to 1979. In the latter part of his study (1979-1983) this figure rose to 30%, with most isolates being multiply resistant. He blames this on indiscriminate use of antibiotic therapies. Other reports have expressed concern with the emergence of S. epidermidis as a major nosocomial pathogen (Christensen et al., 1985).

Certain bacterial pathogens may be found differentially on wards or in a particular patient population. Gram negative bacilli, such as Pseudomonas or Klebsiella, can be found preferentially in patients suffering from burns, immunosuppression, or granulocytopenia (Hamory, 1987). Garrison et al. (1982) reviewed the records of 35 patients who presented with septic thrombophlebitis. Organisms from the Klebsiella-Enterobacter group were identified in 18 patients, all of whom were receiving broad spectrum antibiotics, although there was no other information about their clinical condition. Gram negative bacilli accounted for 21% of catheter-associated bacteremia in Eykyn's (1984) study. He stated that these organisms frequently colonize the skin of very sick patients, particularly those receiving antibiotics, following which they contaminate the catheter as it is pushed through the skin. Johnson et al. (1986) noted the correlation between the isolation of enteric organisms and patients with underlying abdominal pathology. They suggested that hematogenous seeding was responsible for 57% of the suppurative thrombophlebitis cases identified. The risk of acquiring a bacteremia following catheter infection is highest in the gram negative group (25%), giving rise to concern since gram negative bacteremias also have a very high rate of mortality (Hamory, 1987). Mylotte and McDermott (1987), found that catheter associated S. aureus bacteremia occurred more commonly on the medical service, compared to the surgical service (71% versus 21%), although the sample was too small to achieve statistical significance.

There is evidence to suggest that the incidence of fungemia (a bloodstream infection caused by fungi as opposed to bacteria) is also increasing. A recent study by Komshian (1989) which reviewed 135 cases of fungemia at a tertiary care hospital, found 39% to be probably associated with cannulas. In 44/53 of these episodes, semiquantitative cultures revealed high titers, although it was impossible to determine whether catheter infection was the cause or the result of fungemia. Almost all of these patients had been receiving systemic antibiotics, a finding mirrored by Walsh et al. (1986), who noted that those patients with candidal (infection caused specifically by the Candida species of yeast) suppurative thrombophlebitis, had a greater number of operative procedures, were more likely to receive systemic antibiotics and were hospitalized for a longer duration. Unfortunately this study had a sample size of 14, only half of which were candidal thrombophlebitis cases.

<u>Other Factors Affecting Catheter Infections</u>

All catheters have the potential to cause infection and the likelihood of infection increases with duration of time inserted. Some other factors which have been cited as affecting the probability of infection are: 1) the type of catheter used 2) the number of catheters inserted per patient 3) the insertion technique 4) the use of systemic antibiotic therapy, and 5) local care of the catheter site.

Many studies have reported an increased risk of infection with increased duration of time in situ. However, the issue of appropriate maximal duration for a catheter to stay in place, remains contentious. Early studies indicated that plastic catheters left in place for longer than 48 hours were associated with higher bacteremia rates than those changed more often (Collins et al. 1968; Banks et al., 1970), leading to the institution of guidelines requiring that catheters be changed at least every 2 days. Later studies (Tully et al., 1981; Tager et al., 1983; Maki and Ringer, 1987) continued to observe an increase in the day specific risk of acquiring phlebitis as duration lengthened, but found that the rate of infection was low enough to warrant leaving catheters in place for 72 hours if they were carefully monitored. The risk of phlebitis increased from .2% for catheters in place for one day, to 5.9% for catheters in place up to 6 days. Although there was some increase in the day specific risk, Tager suggested that much of the risk of infection may be due to a cumulation of relatively constant day specific risk, rather than due to progressively increasing risk. Maki and Ringer (1987) found the prevalence of local infection increased from 0% after 1 day to about 20% at >5 days, in all four dressing groups they studies. No catheter-related bacteremias were encountered in 2088 episodes, even though 25% had been in for over 72 hours. Other studies have supported a 72 hour tubing change policy (Josephson et al., 1985; Jacobsen et al., 1986) with no compromise in patient safety.

Small Teflon catheters which are used in increasing number have proven to be far safer than the polyvinylchloride or polyethylene catheters used previously. Some reports indicated that short plastic catheters were associated with bacterial colonization rates of 3.8 to 49%, septicemia rates of 0 to 3.4%, and phlebitis rates of 9 to 56% (Collin et al., 1975; Banks et al., 1970). Tully et al. (1981) found 1.4% colonization and 18.8% phlebitis with no septicemia, when investigating Teflon catheters. One group (Franson et al., 1984) using electron scanning microscopy found that bacteria attached preferentially to polyvinyl chloride catheters. Sheth et al. (1983) confirmed these findings by analyzing 787 catheters submitted to the lab. Twenty five percent of PVC catheters yielded positive semiquantitative cultures, while only 6.9% of Teflon catheters did so. It appears that attachment of bacteria is facilitated by irregularities in the surface of the plastic which allows organisms to colonize.

A few studies have documented the effect that the catheter order (ie. whether the catheter in question is the first, second or subsequent IV for this patient' hospital stay) has on the risk of catheter infection. Armstrong et al. (1986) investigated 169 hyperalimentation catheters using the semiquantitative culture technique. A proportional hazards model indicated a relative risk of 2.6 for followup insertions when compared to first insertions. However it was not significant at the 0.05 level. The study by Tager et al. (1983) did find a relationship between order and probability of infection. First order episodes had a phlebitis rate of 1.7%, with subsequent followup insertions increasing to 5%, a trend which was significant ($p<.001$). It is difficult to compare results however, because the former study used a culture criterion while the latter used a clinical one.

The difficulty of the catheter insertion can be assessed by documentation in the clinical progress notes, or estimated by judging the experience of the operator performing the insertion. A couple of studies have investigated this variable in central line catheters. However, there is no reason to suppose that the results would not be applicable to peripheral IV's. Although Conly et al. (1989) found the difficulty of insertion to be significant at the $p=0.05$ level, the confidence level is extremely wide and includes one (RR=5.39, 95% C.I. 0.9-30.6), leading to the questionability of true statistical significance. Armstrong et al. (1986) looked at physician experience as an indicator of difficulty of insertion and found that it was significant ($p<0.02$ in a chi-square test for trend). Additional evidence suggesting physician experience may play a role in predicting infection was noted; infection rates were highest during the months of July-September, a period when new residents were initiating their training.

Prevention

The debate over the role of antimicrobial therapy, either systemic or topical, is still in progress. One theory suggests that it is beneficial; however another suggests that antibiotic therapy contributes to the emergence of increased microorganism resistance patterns. Some controlled trials (Moran, 1965; Maki and Band, 1981) have shown that the application of a topical antimicrobial to the insertion site may help in prevention of some catheter-related infections. However it has been equally demonstrated that antimicrobials can disturb the local commensal flora and lead to organism resistance (Elliot, 1988). Maki and Ringer (1987) found that systemic antimicrobial therapy was associated with a decrease in local infection (RR=0.47, 95% C.I. 0.31-0.73), however they too caution against the use of prophylactic therapy aimed at catheter infection, and encourage more studies of cutaneous antisepsis. Eykyn (1984) surveyed patients in a London hospital over a several year period and ascertained that at least 50% of the patients infected with S. epidermidis and Gram negatives, were or had recently been on antibiotic therapy, and a large majority of these organisms isolated were resistant to the drug used.

Local care of the catheter site involves such factors as the skin disinfectant used prior to insertion, the type of dressing covering the insertion area, and the hospital policy surrounding maintenance of the catheter. Since skin flora has been implicated as a major source of infection, the antiseptic preparation of the site is extremely important. Results of clinical trials have indicated that iodine-containing disinfectants are effective in eliminating bacteria and fungi. However they may induce some patient sensitivity (Maki, 1973). Aqueous benzalkonium chloride, and antiseptic used previously in American hospitals, has been reported to have caused epidemics of Gram negative septicemia, when organisms were found proliferating in the solution. Maki and Band did a later study (1981) evaluating the efficacy of povidone iodine in reducing the rate of IV associated infections, but found no significant difference between the treatment and control groups. The use of 70% isopropyl alcohol is acceptable, and is the antiseptic used by Foothills Hospital staff.

Previously, gauze dressings were used exclusively to protect the insertion site, but the advent of transparent polyurethane dressings has allowed for improved surveillance. Two groups (Maki and Ringer, 1987; Craven et al., 1985) have conducted clinical trials comparing gauze to the newer dressing. Craven et al. (1985) compared dry gauze (N=421) and transparent dressings (N=316) in a randomized study and found that catheter tip colonization (>15 colonies) was associated with use of a transparent dressing (RR=1.8, 95% C.I. 1.1-3.2). There was no association of site colonization with a transparent dressing, and the tip colonization finding only held true in the summertime. Neither type of colonization was associated with signs of local infection, a finding supported by the later study of Maki and Ringer (1987), who found no difference between the two dressing groups, although moisture was accumulated more readily under the transparent dressing (26-28% versus 20-21% for the gauze). A higher moisture content could theoretically facilitate colonization, however they found no significant difference in colonization or local infection. Maki and Ringer also suggested that it would be cost effective to leave dressings on until the catheter is removed (usually no more then 72 hours), rather than replacing them every 48 hours. It has been reported that a new breathable transparent dressing will be available soon, which may eliminate any problem due to the accumulation of moisture.

Summary

The body of literature relating to IV-associated infections focuses on several issues pertaining to cause, susceptibility, pathogenesis and prevention. Unfortunately, due to the lack of consensus among studies, it is difficult to get a clear understanding of some of the risk factors associated with increased rates of infection, risks that may be in fact preventable. Although the peripheral IV infections per se may not be a large cause of nosocomial mortality, any hospital induced illness is unnecessary causing pain and suffering for the patient and increased health care costs for the system.

The current study attempted to address the question of peripheral IV related infections by combining both surveillance and microbiological data. Due to laboratory constraints it was necessary to use the semiquantitative method of culture, but it was felt that the addition of daily surveillance would increase the likelihood of identifying all infections. Use of the semiquantitative method also allowed for comparison with other studies. By investigating catheter-related infection in two general wards (medical and surgical), the profile of catheter-related disease in a "low risk" population was evaluated.

CHAPTER 3

METHODS

Study Rationale and Objectives

There has been a great deal of literature studying the risk factors for peripheral intravenous-associated infections. However, there is a lack of consistency between the use of standard definitions and methods. In addition, the majority of current research pertains to the risks of infection in "high risk" or "mixed risk" patient groups. "Low risk" groups have been virtually ignored, due to a decreased rate of nosocomial infection when compared to patients in the burn unit or ICU.

In 1989, the Infection Prevention Department of Foothills Hospital established a new mandate whereby further research projects would be directed towards "management by objective". This entailed the identification of specific targets for prevention of infection, rather than the broad management scheme formerly adopted. Peripheral intravenous catheters were selected as one of the targeted areas.

This study was designed to address issues relating to the risk factors involved in predicting catheter-associated infection by focusing on a sample of general medical and surgical patients, which were observed on two separate hospital units. It was also created to act as an exploratory, pilot study which would establish, with some degree of precision, the rate of infections in this sample of the hospital population. As well, the project enabled testing of the data collection procedure on a small scale, determining the feasibility of its future application in a larger study. As an addendum to the initial study, a fourth objective focused on surveying certain procedures designed to decrease the rate of IV related complications.

Research Questions

Several research questions were specifically addressed:

1) What is the true rate of peripheral intravenous-associated infections on general medical and surgical wards at Foothills Hospital, including local infection and bacteremia?

2) What risk factors make subjects more susceptible to a peripheral intravenous infection?

3) Are the monitoring policies associated with peripheral catheters being practiced by staff?

As a corollary to the initial questions, a fourth question was addressed:

4) Is there a difference between the two units with respect to infection rates, or microbiological profiles?

Study Design

It was decided that a prospective study of all the catheter episodes on two general medical/surgical units would be the most appropriate method with which to address the research questions. The SENIC study in the United States, used an elaborate medical record review to determine the rate of nosocomial infections in several hospitals. However this method found only 76% of total infections (Tager et al., 1981). Later studies indicated that a prospective daily surveillance of patients, including bedside visits, chart reviews, and correlation with laboratory reports would have identified the majority of infections (Tager et al., 1981).

The current study incorporated these suggestions, and had one researcher follow all catheter episodes on a daily basis. Approval for the study was obtained from the Foothills Centre for Advancement of Health and subsequently from the Research and Development Committee. Ethical approval was obtained from the Conjoint Medical Ethics Committee.

A two month period of surveillance, March-April 1989, was selected because it met two major requirements: 1) it allowed for the collection of an adequate sample size for estimating the rate of infection, and 2) it was felt to be manageable, with respect to the time commitment necessary for a single researcher to survey both wards every day. The head nurses on each unit were also contacted, and the study objectives and methodology were discussed to ensure that the project was feasible. In service meetings were also staged on both units to allow explanation of the project to the general floor staff.

Definitions

Since a major source of conflict between studies arises from contradictory definitions, this study followed those suggested by Plit, et. al. (1988). These guidelines showed evidence of being established in a standardized framework grounded by the most consistent of the previous literature. These definitions also concur with the Centre for Disease Control recommendations, which are the generally accepted convention for health care institutions in North America.

Phlebitis - area at the catheter entry exhibiting two or more of the following: redness, pain, heat, swelling or loss of function.

Infectious phlebitis - same as above, however also presenting with pus.

Semiquantitative culture - method of culturing catheter tips whereby the distal tip is rolled on a culture plate and incubated for growth.

Local infection - the growth of 15 or more colonies after semiquantitative culture.

Colonization - the growth of less than 15 but more than 0 colonies after semiquantitative culture.

Catheter-associated septicemia - isolation of the same species of microorganism in significant numbers from cultures of the catheter, and from blood cultures obtained by separate venepuncture when clinical and microbiological data disclose no other apparent source of infection and clinical features are consistent with bloodstream infection.

Phlebitis alone is not considered to be indicative of catheter-associated infection since it has several different etiologies, however infectious phlebitis is considered an appropriate alternate measure for establishing local infection.

Selection of subjects

The sample included all patients admitted to one general medical unit (Unit 61) and one general surgical unit (Unit 71) over a two month period of time, who during their stay acquired a peripheral intravenous catheter. These units were chosen with the assistance of the Infection Prevention Department on the basis of having a good representation of general hospital patients, and having helpful and cooperative staff. Each catheter episode was recorded individually; therefore it was possible for one patient to have several episodes. Those patients with a central venous catheter in addition to a peripheral line were excluded. Patients transferred onto the unit without a clear indication of when their catheter was inserted were also excluded from the study, as were patients transferred off the unit unless the transfer was related to an IV-associated complication, i.e. transfer to ICU due to catheter-associated septicemia.

The Department of Medical Records at Foothills Hospital estimated patient turnover on the two selected units, based on discharge information recorded over a 3 month period of time (January-March, 1989). On Unit 61 (medical), there were 306 discharges with each patient staying an average of 10.7 days. Occupancy rates were recorded at 94%. By reducing these figures to a monthly rate, 102 patients could be expected/month. If we assume that 90% of these patients would receive an IV, a feasible sample from this unit could total approximately 184 patients over a 2 month period. Unit 71 (surgical), had a higher turnover rate and discharged 374 patients over a 3 month period, with each patient staying an average of 6.7 days. Therefore a sample of 224 patients was expected in 2 months. The actual unit of analysis was decided to be the catheter episode and not the patient, and since the majority of patients who receive catheters have more than one episode, the total of 400 patients expected in the two units could theoretically have 800 catheter episodes over the two month period.

One of the primary objectives of this study was to acquire a sample large enough to determine a baseline rate of infection precise to within plus or minus 2% that of the true rate. The sample size required to determine an infection rate of 10% within a 2% error margin at 80% power was 161 catheter episodes, and at 90% power was 369. The sample size required to determine an infection rate of 5%, within a 2% error margin, at 80% power was 85, and at 90% power was 195. Thus a 2 month period of investigation of 400 patients would allow for a precise determination of the infection rate at 90% power even if each patient had only one catheter episode.

Data Collection

Patients were added into the study on a cumulative basis when they received their first peripheral catheter. Each morning the Kardex was consulted for a listing of patients receiving intravenous therapy. Following this each eligible patient was approached, informed about the purpose of the study, and asked if they were willing to participate. After receiving patient consent, the catheter site was observed for signs of phlebitis, and the chart was consulted for details surrounding the catheter insertion. Information recorded on the first information sheet included: 1) hospital number 2) sex 3) age 4) diagnosis 5) date of insertion 6) order of insertion (first, second, third, etc.) 7) anatomical site of the catheter 8) type of cannula 9) use of antibiotics 10) who inserted the catheter and 11) date and reason for removal. (See Appendix A) Although it was known that certain infusion fluids are capable of causing chemical phlebitis, the type of solution being administered was not recorded since it was felt that the microbiological data would adequately delineate infectious phlebitis from other causes.

Daily observation of the site was continuously recorded on a second log sheet (see Appendix B) which was representative of all the patient's catheter episodes during their entire stay in hospital. As well as observing the catheter sites, the patient's chart was consulted on a daily basis to ensure that episodes occurring in the researcher's absence, were included. This was particularly important for patients who were not available at the time of surveillance for one or more days.

Every effort was made to observe each patient daily. However many were frequently absent or unavailable due to surgery, tests or visitors. The amount of information lost when surveillance was not carried out, appeared to be minimal, since nursing and intravenous records in the chart usually supplied the necessary missing information. However, the intravenous record alone was not sufficient in supplying adequate data on the catheter-associated history. It was necessary to go through the nursing notes, the emergency room reports, and the operating room records for validation. Observation was discontinued when the final catheter was removed, or the patient left the unit or died.

The collection of microbiological data was paramount in determining the true peripheral I.V. infection rate. It was understood that nursing policy dictated that all phlebitic I.V.'s should be sent to the lab for microbiological confirmation. However, it became evident that this was not standard procedure. To remind the floor staff that it was imperative to send catheters for culture, large posters were placed in strategic areas of the unit and continuous mention was made about the project. All plastic catheters which showed at least two of the signs of phlebitis were to be sent for culture. Butterflies (steel needles) were to be excluded from the study; however no use of this type of catheter was observed on the two units under study. In addition, as a control measure several catheters removed from patients showing no signs of phlebitis were sent to the lab for microbiological culture to determine whether any colonization occurred asymptomatically.

The procedure of sending plastic catheters required the distal 3 cm of the catheter tip to be removed and sent in a sterile tube accompanied by a green requisition identifying it as part of the "Peripheral I.V. Study". Any catheter tip sent improperly was discarded by the lab personnel, and the nursing staff was notified. All IV tips sent were cultured via the semiquantitative roll plate method on chocolate agar and RCM broth media. All cultures which grew any colonies after incubation were identified. However only those with >15 cfu's/plate had antibiotic sensitivities done on them. Sensitivities done included: 1) erythromycin 2) cloxacillin 3) Penicillin G 4) ampicillin 5) cephalothin 6) tetracycline 7) gentamycin 8) vancomycin 9) trimethoprim/sulphamethoxazole and 10) ciprofloxacin. There were no suspected catheter-associated bacteremias; therefore, it was not necessary to have blood cultures drawn for that purpose. Skin swabs were done on those patients expressing pus from the catheter entry wound during or following catheter removal, and these swabs were cultured on blood, chocolate, MacConkey and RCM broth media.

The severity of underlying patient illness is a potential confounder and one that does not receive much attention among "low risk" hospital populations. This study attempted to address the issue by categorizing the patients according to a scale devised by Horn et al. (1980). It was felt that this index would be appropriate for classifying "low risk" populations with some degree of sensitivity, although there are definite limitations surrounding the ambiguity of scoring procedures. The AS-SCORE system divides patients into four classes based on the body systems involved, the stage of illness, any complications incurred, and the response to therapy.

During the initial data collection, information was collected on the admission diagnosis. However when the time came to categorize patients according to severity of illness it was felt that there was a lack of information necessary to make a confirmatory diagnosis for many of the cases. It became necessary to perform a secondary chart review for the ambiguous cases which abstracted more definitive information, and allowed the classification of cases.

Validity Testing of Patient Severity of Illness Rating

To ensure that the rating was valid, 32 cases were simultaneously rated by the researcher and a clinician in a blinded manner. A high rate of concordance would indicate the researcher's judgement to be valid, despite the lack of clinical experience.

Although the overall concordance was relatively high (75%), the highest percentage of disagreement occurred between the rating of classes 3 and 4, with the researcher tending to rate 20.0% of the cases as more severe than the clinician.. The Kappa statistic for the agreement between the two raters for Classes 3 and 4 was 0.2.

To confirm validity, it was agreed that reexamination of the contentious cases by both raters would be necessary to ensure the maximum validity attainable, bearing in mind the limitations of the scoring procedure. There were approximately 43 charts rated as Class 4 by the researcher. Since 26 of these patients died it was only necessary to reexamine 17 charts. Another eight Class 3 charts were also reexamined since the researcher felt uncertain about their true status. Rating of the other cases by the researcher alone was considered to be acceptable, since the majority of cases (70%) fell into the Class 1 or 2 categories. The Kappa statistics for the agreement between Classes 1 and 2 and between Classes 2 and 3, were 0.71 and 0.82 respectively.

Data Entry and Analysis

Forty variables were set up and the coded information for each variable was entered into a data entry system. All but three variables were categorical. Days in hospital before catheterization and days in situ were collected and entered as continuous variables. Hospital number was also entered to allow the number of catheter episodes/patient to be quantified.

It is possible to set up ranges within the data entry system which only allow certain values of each variable to be entered. This cleaning process was set up for most variables to reduce the number of entry mistakes made. Collection of data for the severity of illness variable occurred following the initial study period, therefore at the time of later entry, all data was reentered to ensure further reduction of entry error.

Following entry of the data, analysis was undertaken. Initially, explorations of the data distribution were undertaken using frequencies and histograms. For those variables which were continuous, means were also calculated. Some variables were stratified before frequencies were tallied. Box plots of some distributions were also performed.

Following the initial exploration of the data certain variables were analyzed to detect the presence of associations. The chi-square or Fisher exact test was used to determine which associations deviated from the expected distribution. It was understood that the use of p values in an exploratory study was not meaningful, however it was thought that the p value would be useful for descriptive purposes. Where the chi-square was not appropriate, the data was presented in aggregate form.

When statistical significance was determined for differences between means, the t-test was used.

Following the determination of significant associations between variables, relative risk estimates and 95% confidence intervals were calculated for those associations thought to be meaningful (Kleinbaum, Kupper, and Morgenstern, 1982).

Survival analysis was performed to determine the day-specific or catheter-specific risk of infection (Lee, 1980).

Stratified analysis was carried out according to the method of Mantel and Haenszel (Hennekens and Buring, 1987).

CHAPTER 4

RESULTS

Sample

The final sample consisted of 476 catheter episodes in 285 patients on two hospital units. There were some variables, such as type of catheter, for which information was not always collected. In these instances, the analysis was performed with the available number of cases. Unless specifically noted, the unit of analysis will be the catheter episode and not the patient. Unit 61 (the medical unit) supplied 252 (53%) of the episodes, with Unit 71 (the surgical unit) supplying the remaining 224 episodes.

Demographics

Age

The age of the total studied population was concentrated most heavily in the 60-69 age range (19.1%) and 70-79 age range (21.0%), with 50% of those studied over age 59 (Table 1). The age category next highest in frequency was that of 30-39 (15%). Both units were fairly similar with respect to age distribution. Unit 71 had a slightly higher percentage of people less than 50. This could be due to a large proportion of acute surgeries.

Sex

The percentage of males in the total population was 53.6% (Table 1). This was consistent on both units. The age

TABLE 1 - DESCRIPTION OF THE POPULATION

	Unit 61	Unit 71	Total
Age			
<20	12 (4.8)	13 (5.8)	25 (5.2)
20-29	18 (7.1)	25 (11.2)	43 (9.0)
30-39	40 (15.9)	31 (13.9)	71(14.9)
40-49	23 (9.5)	21 (9.0)	44 (9.2)
50-59	24 (9.1)	32 (14.3)	56(11.7)
60-69	37 (14.7)	54 (24.2)	91(19.1)
70-79	63 (25.0)	37 (16.6)	100(21.0)
80-90	23 (8.7)	9 (4.1)	31 (6.5)
>90	12 (5.2)	2 (0.9)	14 (2.9)
Total	252 (100.0)	224 (100.0)	476(100.0)
Sex			
Male	137 (54.9)	117 (52.0)	254 (53.4)
Female	115 (45.1)	107 (48.0)	222 (46.6)
Total	252 (100.0)	224 (100.0)	476(100.0)
Severity of Illness			
Class 1	43 (17.1)	129 (57.6)	172 (36.1)
Class 2	72 (28.6)	29 (12.9)	101 (21.2)
Class 3	60 (30.6)	38 (17.0)	98 (20.6)
Class 4	77 (30.6)	28 (12.5)	105 (22.1)
Total	252(100.0)	224(100.0)	476(100.0)

breakdown of males and females was similar.

Severity of Illness

Severity of illness for each episode was determined through the use of a scoring system which separated patients into four classes. Those in Class 1 were least ill, with successive classes indicative of more severe illness. Class 4 patients often had illness serious enough to result death on the index admission.

Class 1 illness was found to be the most predominant in the studied population at 172/476 cases or 36.1% (see Table 1). The three other classes were about equal in frequency between 20-22%.

Unit 61 had a much higher frequency of Class 4 patients which was expected (30.6% versus 12.5% on Unit 71) since this unit is designed to deal with long-term, chronically ill patients. Unit 71, which handles elective and emergency surgery, had a very high rate of Class 1 illnesses (57.6%). Only 17.1% of the episodes on Unit 61 were rated as Class 1.

The age distribution associated with each illness category is described in Figure 1. The modal age associated with being in Class 1 was 30-39, while the most frequent age categories associated with the other classes were 60-69 and 70-79. It was expected that the older age categories would be associated with more severe illness.

Sex was not associated with severity of illness, except on Unit 71 ($p<0.02$) where there were more males and less

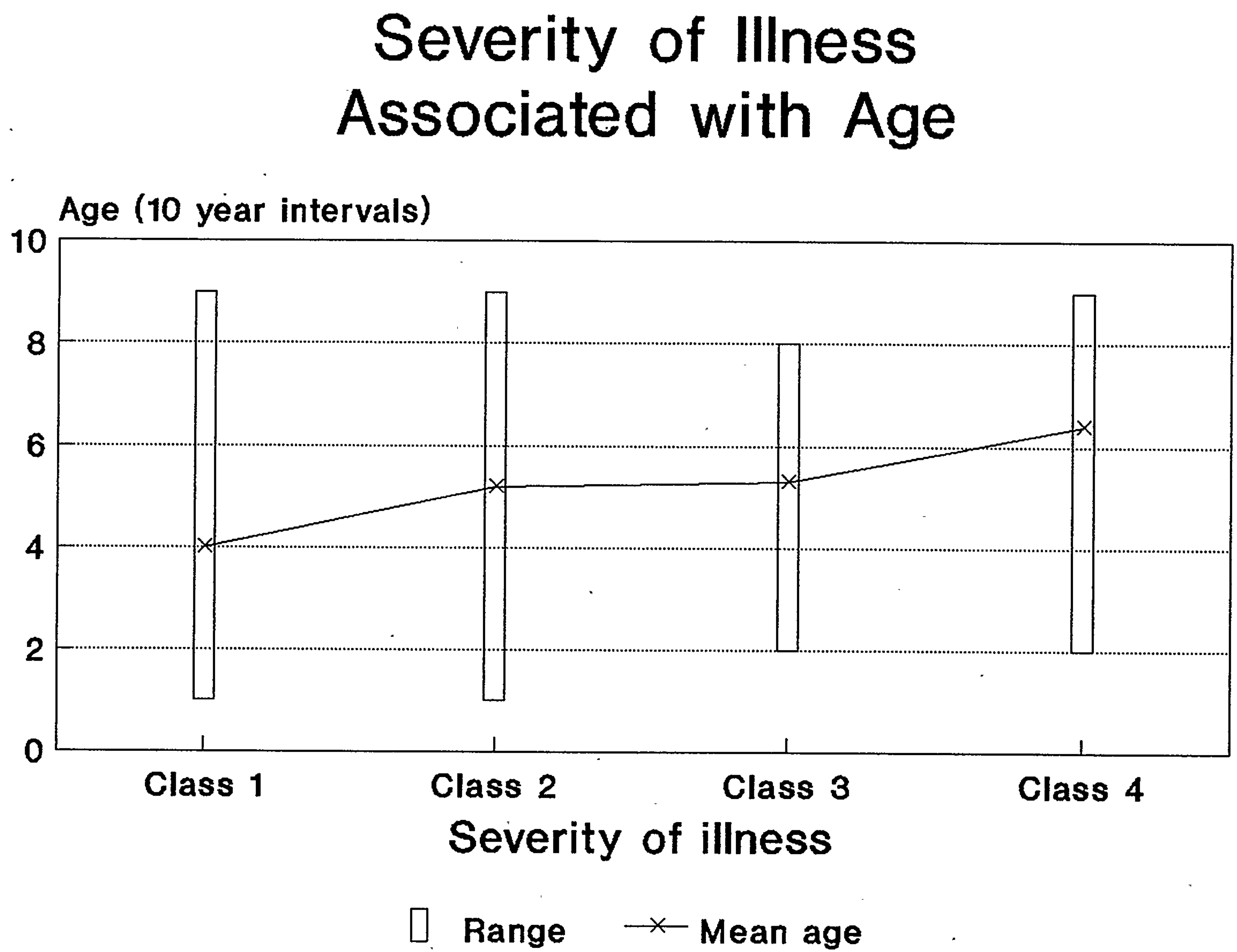
Severity of Illness
Associated with Age
Age (10 year intervals)
10
8
6
4
2
0
Class 1
Class 2
Class 3
Class 4
Severity of illness
Range
Mean age

Fig. 1

females than expected in Class 3. However there was no strong trend of one sex being progressively associated with more severe illness, so it was not considered to be of further importance.

Days in Hospital Before Catheter Episode

The number of days in hospital prior to catheterization was recorded as a possible copredictor of severity of illness. The mean number of days in hospital was 4.77 with a range of 0 to 117. The data was skewed to the left, with 57% of cases receiving a catheter on the day of admission or the day following (see Fig. 2). The median day of catheterization was 1.00. Unit 61 had a higher proportion of older, sicker patients who tended to be in hospital for a longer time period before catheterization (5.8 days versus 3.6 days on Unit 71). Receiving a catheter 15 or more days after admission could be an indication of a longer stay and/or deterioration, hence a more severe illness. The days in hospital before catheterization appeared to be closely correlated with the severity of illness (see Fig. 3). The mean days progressively increased with increasing severity of illness from 1.7 in Class 1 to 9.1 in Class 4. When tested by chi-square, this was found to be significant ($p<0.0001$) on both units. Those patients in Class 4 were often in hospital for many days, thus their episodes of catheterization occurred after several days in hospital.

Cases on the surgical unit tended to have a catheter

Days in Hospital Before Catheterization

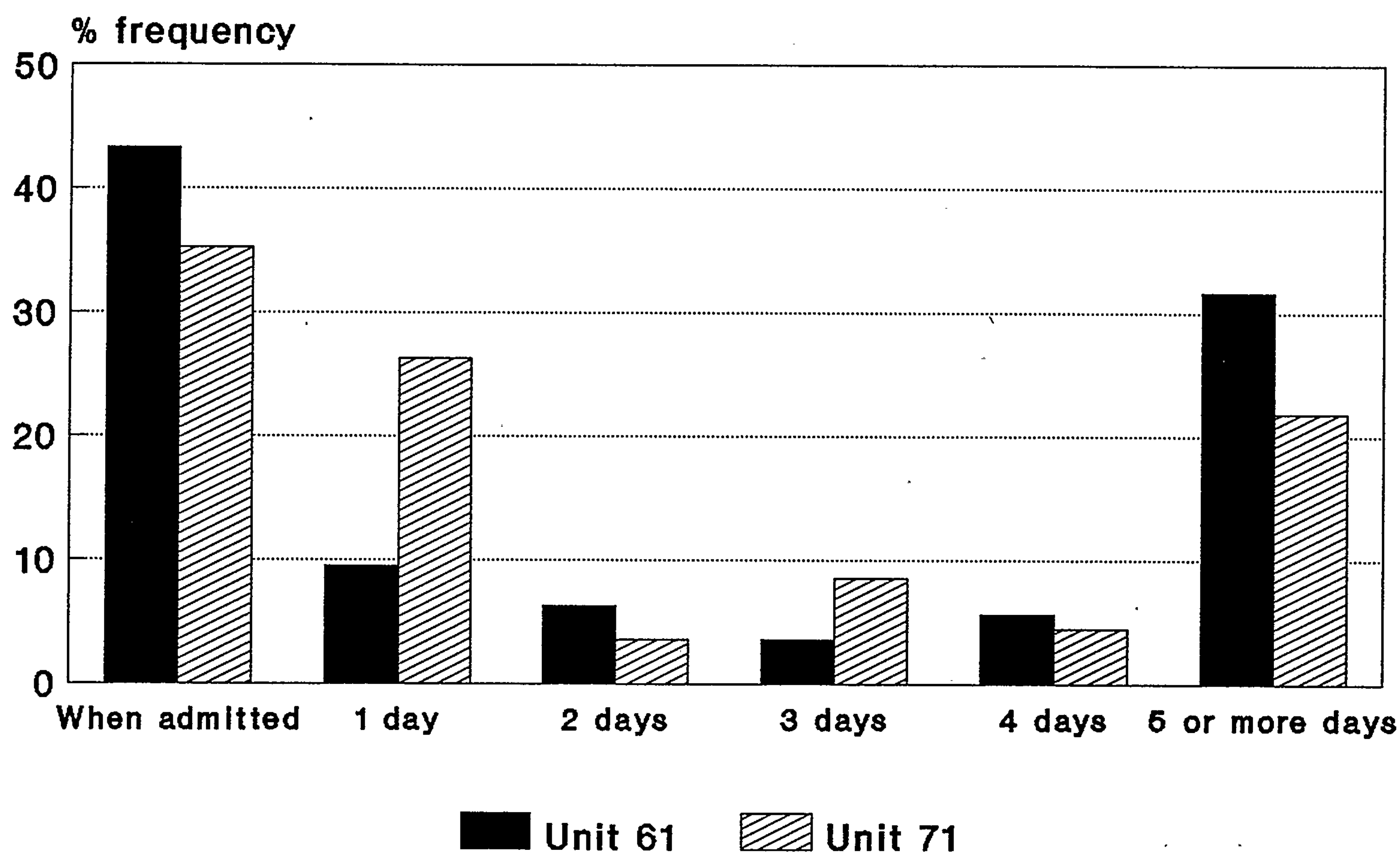

Fig. 2

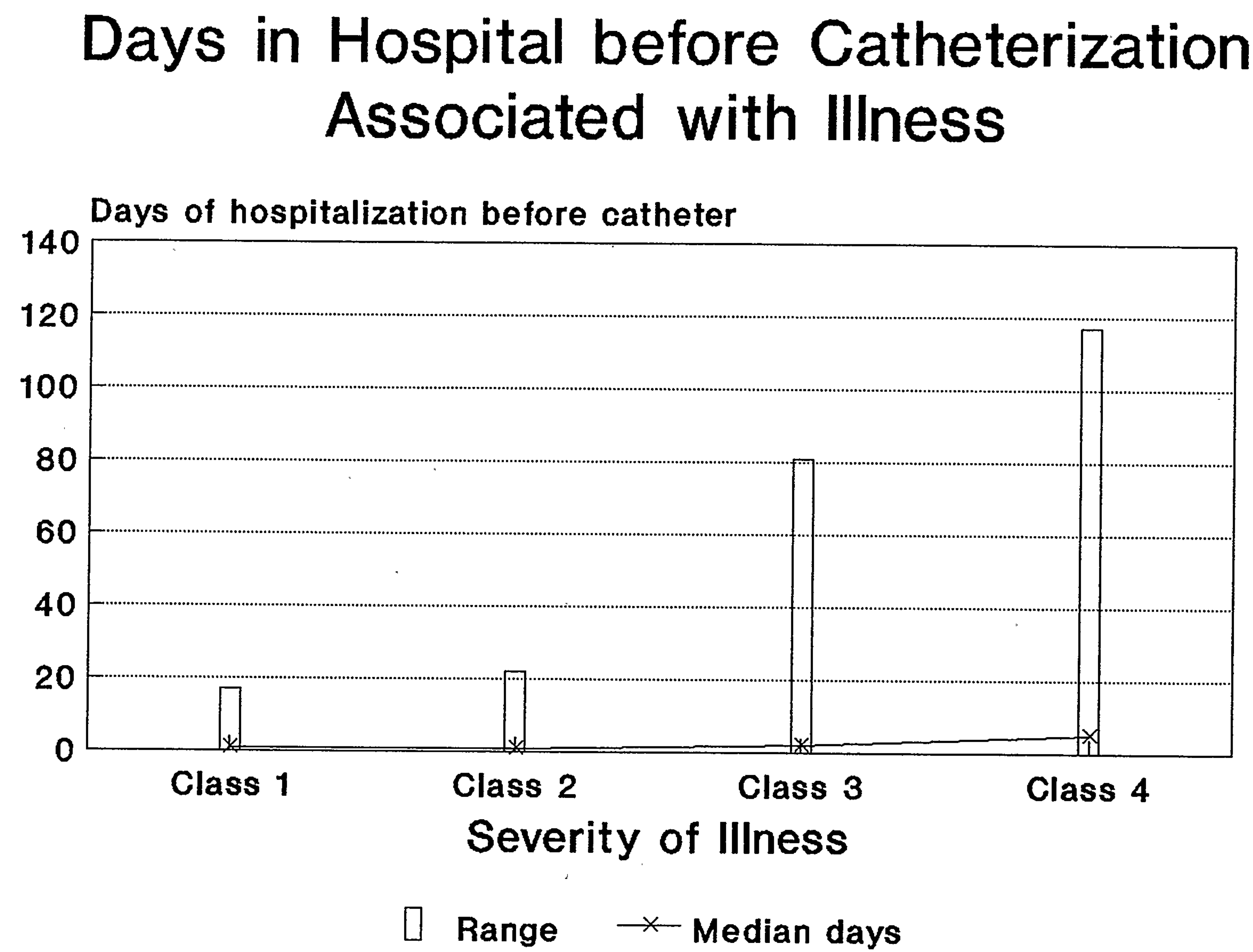
Days in Hospital before Catheterization
Associated with Illness
Days of hospitalization before catheter
140
120
100
80
60
40
20
0
Class 1
Class 2
Class 3
Class 4
Severity of Illness
Range
Median days

Fig. 3

episode after fewer days. Only 1 case was in for longer than 24 days before receiving a catheter, versus 14 cases on the medical unit. It should be noted that this variable is not only an indicator of days in hospital before first catheter episode, since many of the cases were on their third or fourth episode.

Antibiotic Use

Forty three percent (203/476) of the patients observed had been given antibiotic therapy, with 51.2% of these using one antibiotic only. There was no significant association between the hospital unit and the use of antibiotics (Table 2). There was an association between antibiotic use and both age ($p<0.001$) and days in hospital ($p<0.01$) before catheterization episode (Tables 3 and 4). Older cases and cases in hospital at least 5 days before catheterization were more likely to receive an antibiotic.

Antibiotic use was strongly associated with increasing severity of illness ($p<0.01$), indicating that sicker individuals are more likely to receive antibiotics.

Catheter Related Factors

Number of Days Inserted

The number of days a catheter is inserted has been found to be a major factor influencing the probability of infection. A catheter is supposed to remain in place no longer than 72 hours, unless there are extenuating circumstances and the site

TABLE 2 - ANTIBIOTIC USE ASSOCIATED WITH UNIT

	Unit 61	Unit 71	Total
Used antibiotics	108/252 (42.9)	95/224 (42.4)	203/476 (42.6)
Of antibiotic users, only used one antibiotic	54/108 (50.0)	50/95 (52.6)	104/203 (51.2)

TABLE 3 - TOTAL AND UNIT USE OF ANTIBIOTICS ASSOCIATED WITH AGE

	# used antibiotics on Unit 61 (%)	# used antibiotics on Unit 71 (%)	total use (%)
Age			
<40	35/70 (50.0)	22/69 (31.8)	57/139 (41.0)
40-69	48/84 (57.1)	49/107 (45.8)	97/191 (50.8)
70 >	25/98 (25.5)	24/48 (50.0)	49/146 (33.6)
	108/252 (42.9%)	95/224 (42.4%)	203/476 (42.6%)

TABLE 4 - TOTAL AND UNIT USE OF ANTIBIOTICS (AB) ASSOCIATED WITH THE NUMBER OF DAYS HOSPITALIZATION BEFORE CATHETERIZATION

Days of stay before catheterization	Use of Ab on Unit 61 (%)	Use of Ab on Unit 71 (%)	Total use of antibiotics (%)
0	36/109 (33.0)	29/79 (36.7)	65/188 (34.6)
1-2	11/40 (27.5)	28/67 (41.8)	39/107 (36.4)
3-4	14/23 (60.9)	16/29 (55.2)	30/52 (57.7)
>/= 5	47/80 (58.8)	22/49 (44.9)	69/129 (53.5)
	108/252	95/224	203/476

is monitored very carefully. In this study, 20.0% of catheters were in place longer than 72 hours. The mean number of days in place was 2.45 with the longest episode lasting 11 days. When analyzed by unit, 26.0% of catheters on Unit 61 were in situ 72 hours or more, while only 13.0% were in place that long on Unit 71 ($p<0.001$)(Fig.4). Again this may be some reflection of the type of patient present on Unit 61. Older, sicker patients tend to have poor venous access, therefore changing catheters every 72 hours may not always be feasible.

Since it would be expected that older patients would have longer durations of catheterization, the data was explored to determine whether there was a difference in this variable between younger and older age categories. However, there was no significant difference in the duration of catheterization between younger and older age groups (Fig. 5). Approximately 24.0% of those <60 had a catheter episode of 4 days or more. Those 60 or older had 26.7% of their catheters in place longer than 4 days. The mean duration of catheter placement for each age group did not follow any significant pattern, although the mean was slightly lower for those <60 years of age (2.44 days versus 2.76 days). The youngest age group (<20) and the oldest (90 or more) both had average durations of catheter placements of 3.25 days. It is possible that staff assumed the younger group had less susceptibility to infection due to their relative good health. This could explain the increased duration of catheterization in this population. Older people

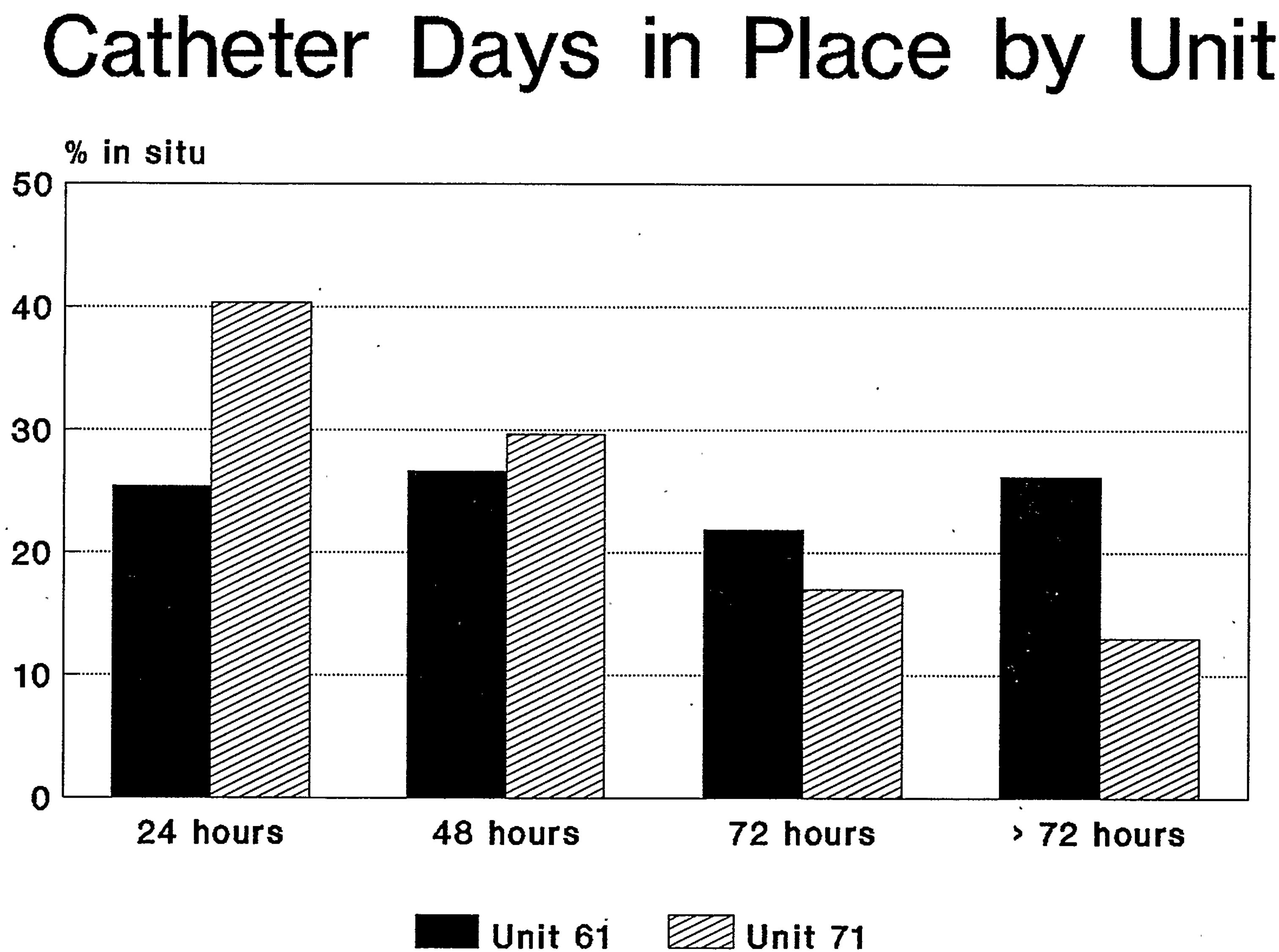
Catheter Days in Place by Unit
% in situ
50
40
30
20
10
0
24 hours
48 hours
72 hours
› 72 hours
Unit 61
Unit 71

Fig. 4

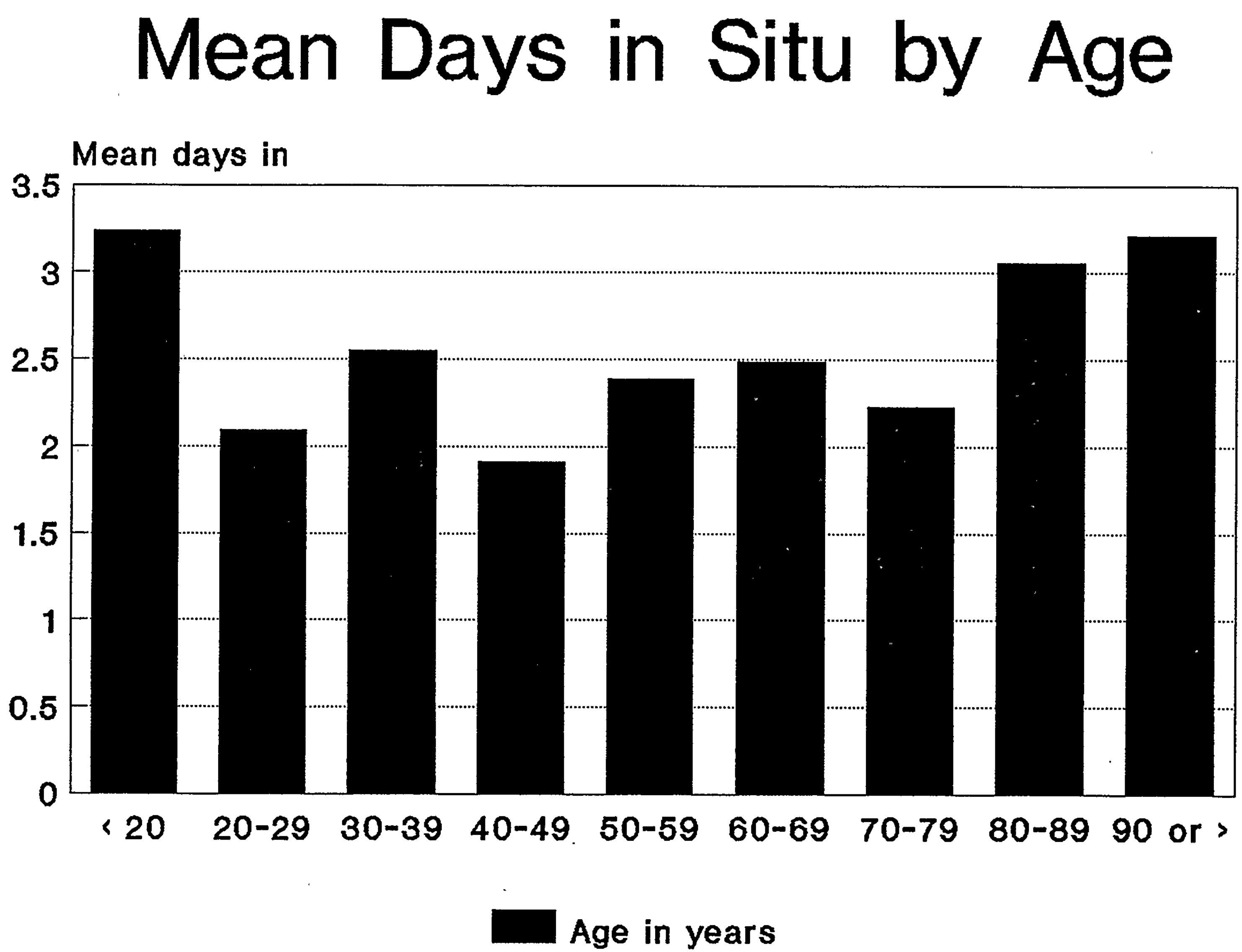
Mean Days in Situ by Age
Mean days in
3.5
3
2.5
2
1.5
1
0.5
0
‹ 20
20-29
30-39
40-49
50-59
60-69
70-79
80-89
90 or ›
Age in years

Fig. 5

also tended to have longer durations of catheterization due to the problems incurred by poor venous access.

The number of days a catheter was left in situ was associated with the severity of illness. Catheters which were in place for 4 or more days were more likely to be in patients who were in Classes 3 or 4. Consequently, there were fewer long duration catheterizations than expected in those episodes rated as Class 1 (Fig. 6).

Anatomical Site

The anatomical site in which the catheter was placed was available for 454/476 patients. The most frequently used site was the hand or wrist (48.6%) with the forearm next in popularity (46%). The left hand or arm was used most frequently, presumably since most people are right handed, and catheterization of that site may impede mobility to a greater degree. The remainder of sites accessed were: the antecubital fossa, the upper arm and the foot.

Type of Catheter

The type of catheter used was recorded since there is some evidence that gauge may affect the incidence of phlebitis. Generally, as the gauge number of the catheter increases, the size of the cannula bore decreases. Therefore a 22G catheter is very small and would be used in patients with very small or hard to access veins. It was also of interest to observe the rate of infection in heparin locks. Heparin locks are different from the standard catheters in

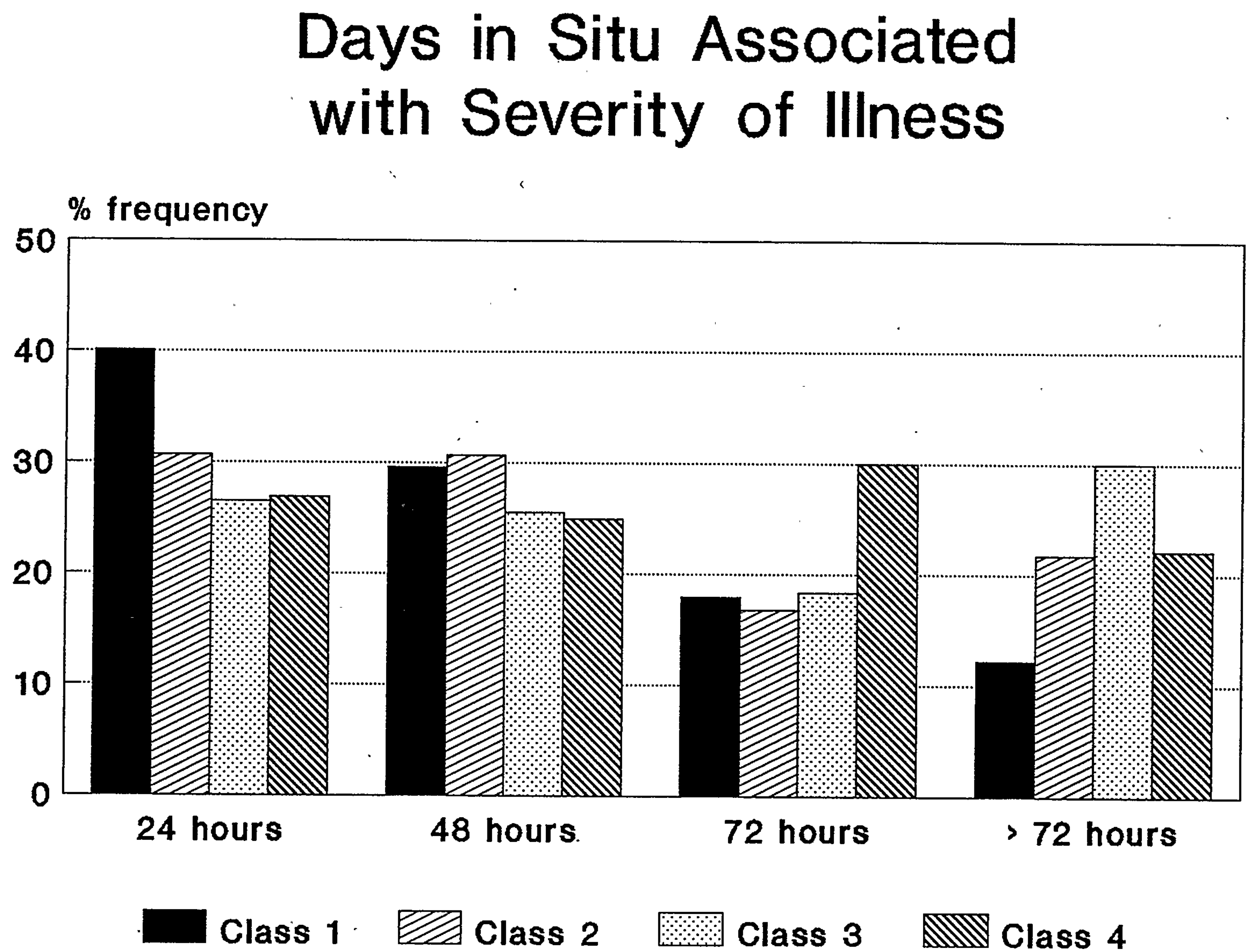
Days in Situ Associated
with Severity of Illness
% frequency
50
40
30
20
10
0
24 hours
48 hours
72 hours
› 72 hours
Class 1
Class 2
Class 3
Class 4

Fig. 6

that they are not constantly joined to the administration sets, allowing the patient greater mobility. Information on catheter type was only available for 365 episodes. This was due to the fact that it was rarely recorded in the I.V. record. When direct patient surveillance was not possible, this variable was often excluded.

Of the cases recorded, 18.6% were heparin locks with the rest ranging from 14G to 24G (Table 5). The most frequently used gauge of catheter was the 20G (36.4%). There was a significant association between the number of days in place and the type of catheter used. Thirty five percent of heparin locks were left in place 4 or more days while only 19.7% of the standard catheters remained in place for that length of time (See Fig. 7).

Because heparin locks are not infusing for much of the time, they are not monitored as stringently, therefore they are left in place longer. However there is no evidence to suggest that they are less likely to cause infection, with the risk of infection increasing the longer they are left in place. Unit 61 was more likely to use heparin locks than Unit 71 (26.1% versus 10.2%, $p<0.001$). Patients who are in hospital for longer periods of time might be more likely to receive a heparin lock since it provides venous access with an increase in patient mobility, a type of care more desirable to the patient.

TABLE 5 - TYPE OF CATHETER USED (%)

Catheter Type	Unit 61	Unit 71	Total
Heparin lock	49 (26.1)	18 (10.2)	67 (18.4)
#14G	1 (0.5)	0 (0.0)	1 (0.3)
#16G	3 (1.6)	11 (6.2)	14 (3.8)
#18G	38 (20.2)	51 (28.8)	89 (24.4)
#20G	58 (30.9)	75 (42.4)	133 (36.4)
#22G	39 (20.7)	21 (11.9)	60 (16.4)
#24G	0 (0.0)	1 (0.6)	1 (0.3)
	188(100.0)	177(100.0)	365(100.0)

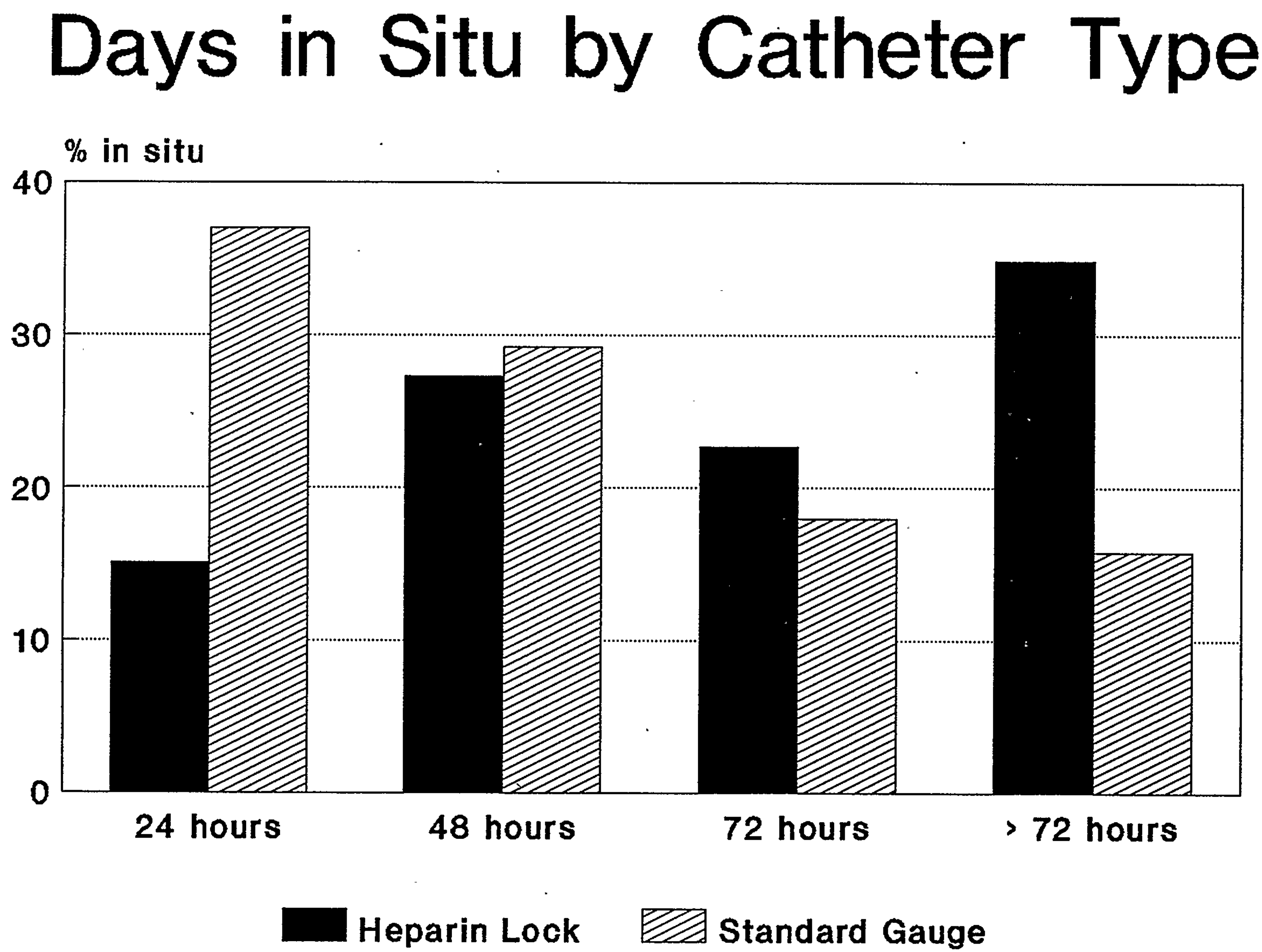
Days in Situ by Catheter Type
% in situ
40
30
20
10
0
24 hours
48 hours
72 hours
› 72 hours
Heparin Lock
Standard Gauge

Fig. 7

Manner of Insertion

Although it was impossible to determine the difficulty of insertion, it was feasible to collect information on the person or department inserting the catheter. This was important, particularly since there is no I.V. team at the Foothills Hospital and different staff members are responsible for catheter care. When the catheter is inserted on the unit, it is done by a unit nurse, certified in the procedure. Catheters inserted in the operating room are the responsibility of the anaesthetists, while in the emergency room either nursing staff,residents or physicians may be responsible for insertion. A catheter inserted in the Emergency Room may be started under pressured conditions where less attention is applied to aseptic technique. Some patients enter hospital with catheters already in place, inserted by paramedics or before transfer from another hospital. Each group has its own protocol for the procedure. Of the cases studied, 54% (257/476) had catheter insertions performed by the unit nursing staff, 12.4% (59/476) had catheters inserted by Anaesthesia, 29.6% (141/476) had catheters inserted by Emergency and the remainder had them inserted in transit or at another hospital (Table 6). Insertions on Unit 61 were done primarily by the unit staff (60.3%) and secondarily by the Emergency Room (34.9%). Unit staff were also responsible for the majority of insertions on Unit 71 (46.9%), with anaesthesia (26.3%) and the emergency room (23.7%) in second

TABLE 6 - OPERATOR INSERTING THE CATHETER ASSOCIATED WITH UNIT (%)

	Unit 61	Unit 71	Total
Unit/RN	152 (61.0)	105 (46.9)	257 (54.3)
Anaesthesia	0 (0.00)	59 (26.3)	59 (12.5)
Emergency	88 (35.3)	53 (23.7)	141 (29.8)
Paramedics	7 (2.8)	4 (1.8)	11 (2.3)
Other hospital	2 (0.8)	3 (1.3)	5 (1.0)
Total	249 (100.0)	224 (100.0)	273 (100.0)

* 3 cases missing from Unit 61

and third position respectively.

Number of Catheter Episodes

The number of catheter episodes a patient endures may increase the probability of acquiring an infection. It may be an indicator of severity of illness, i.e. sicker patients are more likely to have more than one catheter per hospital stay, and also more susceptibility to infection. Conversely an increased number of catheters also increases the opportunity for microorganisms to gain access to the intravascular portion of the catheter.

Fifty three percent of the catheter episodes observed were first order insertions (Table 7). Of these, 120 or 48.0% went on to acquire a second catheter. Twenty five percent of episodes studied were second episodes, 11.0% were third episodes, and 9.9% were fourth or greater. The frequency of higher order catheters was greater on Unit 61, although the association was not statistically significant. This was expected since patients on Unit 71 coming in for elective and emergency surgeries generally did not have more than one catheter episode during their hospital stay.

It would be expected that as the severity of illness increased, the number of catheter episodes per patient would also increase. This expectation was supported by the data. Class 1 patients only had more than 2 episodes of catheterization 9.7% of the time, while Class 4 patients had

TABLE 7 - ORDER OF CATHETER EPISODE ASSOCIATED WITH UNIT (%)

	Unit 61	Unit 71	Total
First order	122 (49.2)	127 (56.7)	249 (52.9)
Second order	67 (27.2)	52 (23.2)	120 (25.5)
Third order	32 (13.0)	21 (9.4)	53 (11.2)
Fourth order	15 (6.1)	11 (4.9)	25 (5.3)
Fifth order	5 (2.0)	5 (2.2)	10 (2.1)
Sixth order or more	6 (2.4)	8 (3.0)	14 (3.0)
Total	247 (100.0)	224 (100.0)	471 (100.0)

more than 2 episodes 39.8% of the time.

Removal of Catheters

Catheters were generally removed on the order of the physician once the patient was drinking well, no longer required the IV, or was about to be discharged (261/476 or 54.8%). The other reasons for removal of catheters included: 1) being pulled out by the patient (6.1%) 2) becoming interstitial (14.1%) 3) becoming leaky or plugged (5.9%) 4) in at least 72 hours (8.0%) 5) patient died (2.1%) 6) painful and/or warm, red, swollen (8.4%). There was no information on three catheter episodes.

Incidence of Complications

Of the 476 catheter episodes followed, there were 39 (8.2%) cases of clinically defined phlebitis. The rate of phlebitis according to the number of catheter days in, was 39/1161 or 3/100 catheter days. Catheters were considered to be infected if they cultured >15 cfu's/plate, or if they showed signs of phlebitis accompanied by the presence of exudate. Of all the episodes studied, 1.5% (7/476) cultured positive and an additional 1.1% (5/476) exhibited signs of phlebitis with pus, although the latter were not sent to the lab for verification. The rate of probable infections was therefore 2.5% (12/476). One catheter was colonized with less than 15 cfu's/plate. The rate of catheter infections by catheter days in was 1/100 catheter days.

When phlebitis was analyzed by unit, there were 21/252 cases or 8.3% found on Unit 61, and 18/224 or 8.0% found on Unit 71. This difference was neither clinically nor statistically significant. There was no difference in infection rates between units; 2.9% on Unit 61 and 2.3% on Unit 71 (Table 8).

There were a large number of catheters exhibiting phlebitis which were not sent to the lab for culture (Table 9). Approximately 59.0% (23/39) of the catheters which were recorded as being phlebitic in the chart, were not sent for culture and sensitivity. Of those which were recorded as being phlebitic and sent for culture, 43.8% (7/16) were found to be infected according to Maki's definition. Fifty percent of the phlebitic catheters (8/16) which were sent for culture did not grow any microorganisms and one grew less than 15 cfu's, so it was recorded as being colonized and not infected (Table 10).

Seven catheters showing no signs of phlebitis were also sent for culture to determine whether asymptomatic catheter sites could be harboring infection. None of the catheters from asymptomatic sites cultured positive. It was originally planned to collect every fifteenth uninfected catheter that was removed. However, it was very diffecult to get phlebitic catheters sent for culture, and therefore almost impossible to get catheters sent which showed no signs of infection.

TABLE 8 - RATE OF COMPLICATIONS ASSOCIATED WITH PERIPHERAL IV CATHETERS

	Unit 61	Unit 71	Total
Phlebitis	21/252 (8.3%)	18/224 (8.0%)	39/476 (8.2%)
Local infection	7/252 (2.8%)	5/224 (2.2%)	12/476 (2.5%)

TABLE 9 - ASSOCIATION OF COMPLICATIONS WITH MICROBIOLOGICAL CULTURE

	No signs of phlebitis	Phlebitis	Total
Catheters sent for culture	7	16	23
Catheters not sent for culture	430	23	453
Total	437	39	476

TABLE 10 - ASSOCIATION OF INFECTION WITH CATHETERS

Of catheters sent for culture (n=23)

	Phlebitis	No signs of phlebitis
Positive cultures		
< 15 cfu's/plate	1	0
>/= 15 cfu's/plate	6	0
Swab of exudate	1	0
Negative cultures	8	7
Total	16	7

Of catheters not sent for culture (n=453)

	Phlebitis	No signs of phlebitis
Exudate present	5	18
No exudate present	0	430
Total	5	448

Control catheters were only sent when the researcher was lucky enough to be present at the time of catheter removal.

It might be thought that older, sicker patients would have a higher incidence of phlebitis. However there was no significant statistical association between age (9 categories) or sex and phlebitis, even when analyzed by hospital unit. When age categories were collapsed into those less than or equal to 59 years of age and those greater than 59 years, there was a higher frequency of older people who acquired clinically defined phlebitis ($p<0.04$).

As with phlebitis, there was no statistical association between infection and age or sex; although there were more infections in those over 59 (3.5% versus 1.7%) (Table 11).

Severity of illness or the days in hospital before catheterization were not significantly associated with phlebitis when analyzed in whole or by hospital unit. Of the phlebitis identified, an equivalent number of cases were found in Class 1 and Class 4, 28.2% and 33.3% respectively. However according to the proportions in each illness category, those in Class 4 were almost twice as likely to have phlebitis as those in Classes 1, 2 and 3 (12.4% versus 6.4%, 7.9% and 7.1%). This might indicate that neither variable is a good predictor of the true patient physiological condition. It is also feasible that severity of illness does not increase the risk of phlebitis, particularly that which is caused by chemical or mechanical sources (Fig. 8).

TABLE 11 - ASSOCIATION OF COMPLICATIONS WITH AGE

	Phlebitis	Local Infection	Total
Age			
59 or less	13 (5.8%)	4 (1.6%)	239
60 or greater	26 (10.9%)	8 (3.5%)	237

% Frequency of Complications Associated with Class of Illness

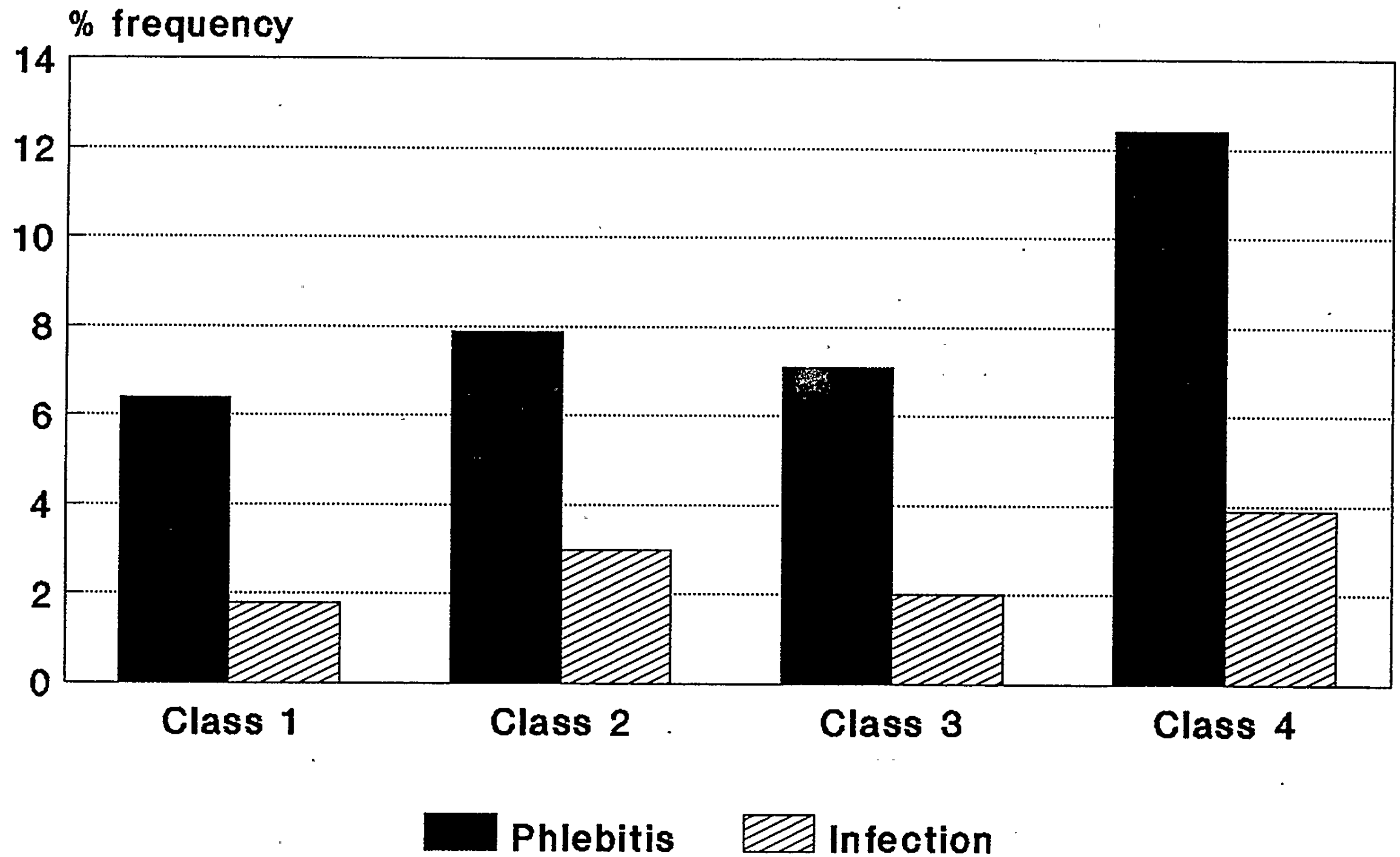

Fig. 8

Similarly, local catheter infections were not associated with either severity of illness or days in hospital before catheterization, although there were double the number of infections in those of greater acuity when compared those least ill (3.9% versus 1.8%). However the numbers are too small to determine whether this is a significant trend. When the illness categories were collapsed into two categories, there were still more infections in the group categorized as sickest (3.1% compared to 2.3%). Infected episodes were more likely to be found in patients with less days in hospital before catheterization (3.5 days for those with infection versus 4.8 days for those not infected).

Previous literature has always alluded to the increased risk of catheter related infection in patients classified as critically ill, particularly those in ICU. The data from this study did not support that finding. Infections occurred in all illness categories in similar proportions. If the scoring system for classifying patients into illness categories is valid, then the results imply that sicker individuals on general wards are not necessarily at greatest risk of catheter infection.

The final host factor examined was the use of antibiotics. Antibiotic use has been reported to increase the incidence of infectious phlebitis by allowing resistant bacteria to colonize and multiply. It could also be that patients who are sicker and more likely to receive prophylactic antibiotics, are also more prone to infection. Antibiotic use may also lead to the occurrence of chemically induced phlebitis, particularly use of some of the cephalosporins which are known to have irritating side effects. Phlebitis was associated with antibiotic use, with those who used them having a higher incidence of phlebitis (12.3% versus 5.1%). There was no difference in the use of antibiotics between units. Of those who used antibiotics on both units, there was no difference as to the number of antibiotics used. The relative risk of acquiring phlebitis when antibiotics were used was 2.46 (95% C.I. 1.32-4.63) (Table 12).

Use of antibiotics was not associated with an increased risk of catheter-related infection. The incidence of infection was similar in both groups, with those using antimicrobials having a 2.5% rate of infection and those not using them having a 2.6% rate of infection, bearing in mind the small numbers identified in each group. The relative risk of acquiring an infection was 0.96 compared to those not on antibiotic therapy. The confidence interval is very wide and crosses the null, therefore the effect is not significant in this study.

It might be anticipated that length of time on antibiotic therapy would be associated with the incidence of catheter-related infections. There was a strong association between days in hospital before catheterization and antibiotic use,

TABLE 12 - USE OF ANTIBIOTICS ASSOCIATED WITH COMPLICATIONS

	Used antibiotics	Did not use antibiotics	RR (95% C.I.)
Phlebitis	25 (12.3%)	14 (5.1%)	2.46 (1.32 - 4.63)
Infection	5 (2.5%)	7 (2.6%)	0.96 (0.31 - 2.98)
Total	203	273	

with those in hospital for at least 5 days more likely to be on antibiotic therapy. However, from the data collected, it is unknown whether patients who were hospitalized longer, received a lengthier course of therapy. Long term use could select for the emergence of resistant organisms, or conversely, eliminate possible pathogens from the site. The data from this study did not show any association between the days of hospital stay prior to catheterization and catheter related infection, but this may be a problem of inadequate sample size, rather than a lack of effect.

The most frequently used antibiotics in those episodes which became infected were: 1)metronidazole 2)ampicillin and 3) penicillin. These drugs are not generally known for inducing chemical phlebitis (Sanford, 1988). Of the eight specimens (7 catheter tips, 1 swab of the infected site) which were sent for culture and sensitivity, only one tip grew 2 organisms. The most frequently cultured organism was coagulase negative staphylococcus species (6/8 or 75%) followed by <u>Staphylococcus</u> <u>aureus</u> (2/8 or 25%) and Group D enterococcus (1/8 or 12.5%). There was no dominant species of organism associated with either unit. When the organisms cultured were susceptibility tested, both <u>S</u>. <u>aureus</u> species were resistant to penicillin but sensitive to a wide variety of other antibiotics. All the coagulase negative staphylococci species were sensitive to vancomycin and ciprofloxacin, although they were resistant to most of the other antibiotics tested. None of the organisms persisted after appropriate treatment and removal of the catheter.

Previous research has indicated that the risk of phlebitis increases with the length of time in situ. The risk of phlebitis increased from 3.25% after 1 day, to 15.8% for those in place at least 4 days. The risk appeared to decrease after 4 days. However, the total number of catheter episodes inserted for 5 or more days was very small, making the rates unstable (Table 13). There was an association between phlebitis and the length of time the catheter was in situ, with the frequency of phlebitis greater when the catheter was in for 4 or more days ($p<0.01$).

When the day specific risk is calculated there appears to be a steady increase through days 1 to 4 of catheterization (Table 14). When confidence intervals are observed , the risk remains constant through days 1 to 3, with a sharp increase occurring on day 4. Because of the small numbers in the subsequent categories, it is not possible to determine whether the day specific risk continues to rise.

The relative risk of acquiring phlebitis when a catheter remained in place 4 days or more was 2.42 (95% C.I. 1.32-4.44) times higher than a catheter in place 3 days or less.

The risk of infection increased from 0.8% for catheters in place up to three days to 9.5% for those in place longer than 72 hours. This was a very strong association at $p<0.0001$, since no infections were identified in catheters

TABLE 13 - DURATION OF CATHETERIZATION ASSOCIATED WITH PHLEBITIS

	Phlebitis	Total	RR (95% C.I.)
Days in place			
1	5 (3.2)	154	-
2	11 (8.3)	133	2.59 (0.91-7.15)
3	8 (8.6)	93	2.69 (0.89-7.83)
4	11(21.6)	51	6.74(2.46-18.48)
5 or more	4 (8.9)	45	2.78 (0.77-9.92)

* 1 case missing

TABLE 14 - DAY SPECIFIC RISK ASSOCIATED WITH DURATION OF CATHETERIZATION

Day	Episodes at risk	# with phlebitis	Day specific risk (%)
1	475	5	1.06%
2	321	11	3.49%
3	188	8	4.35%
4	95	11	12.29%
5 or more	45	4	9.52%

Day specific risk = hazard function (Lee, 1980) which were in place less than 3 days (Table 15). This may have been due to selection bias, with tips that were in situ for greater than 72 hours more likely to be sent for culture. Tips left in place for one or two days were rarely sent for culture so their microbiological status was unknown.

When the day specific risk of infection is calculated, there is no progressive increase with increasing number of days in situ, although the hazard function peaks on the fourth day of catheterization. Confidence intervals calculated for each successive hazard function indicate that only the risk of becoming infected on the fourth day is significant. All other confidence intervals cross over the null value (Table 16).

The relative risk of acquiring a local catheter infection when the catheter was in place for more than 3 days was 12.0 (95% C.I. 3.34-43.16). Although the confidence interval is very wide due to the small numbers infected, the risk appears to be at least 3 times greater than the null hypothesis.

Phlebitis was not significantly associated with the number of catheters a patient had during the hospitalization. Twenty three percent of phlebitic episodes were third order or higher, while 21.3% of those without phlebitis also had more than 2 catheter episodes (Table 17).

Catheter-related infections did not appear to be associated with the number of catheters a patient had during the hospital stay (Table 18). No infections occurred in

TABLE 15 - DURATION OF CATHETERIZATION ASSOCIATED WITH LOCAL INFECTION

	# Infections	Total	RR (95% C.I.)
Days in			
1	0 (0%)	154	
2	0 (0%)	133	1.0
3	3 (3.2%)	93	
4	7(13.7%)	51}	
5	1 (3.8%)	26}	12.0 (3.34-43.16)
6 or more	1 (5.6%)	18}	

TABLE 16 - DAY SPECIFIC RISK OF LOCAL INFECTION

Day	Episodes at risk	# infected	Day specific risk (%)
1	475	0	-
2	321	0	-
3	188	3	1.6%
4	95	7	7.6%
5 or more	62	2	3.3%

TABLE 17 - THE ASSOCIATION OF PHLEBITIS WITH # CATHETER EPISODES/PATIENT

No. of catheters	No. phlebitic episodes	RR (95% CI)
1	18/249 (7.23%)	-
2	12/120 (10.0%)	1.38 (0.65-2.77)
3	5/53 (9.43%)	1.30 (0.51-3.35)
4	1/25 (4.00%)	0.55 (0.08-3.94)
5 or more	3/24 (12.50%)	1.73 (0.41-5.45)

* 5 cases missing

TABLE 18 - THE ASSOCIATION OF INFECTION WITH # CATHETER EPISODES/PATIENT

No. of catheters	No. infected	RR (95% CI)
1	5/249 (2.01%)	1.00
2	5/120 (4.17%)	1.57 (0.51-4.88)
3	2/53 (3.77%)	
4	0/25 (0.00%)	
5 or more	0/24 (0.00%)	

patients with more than 3 successive catheters. The rates of infection associated with having 1, 2, or 3 catheters during hospital stay, were 2.0%, 4.4% and 3.9% respectively. When the categories were collapsed into 1 catheter versus more than one, the rates were 2.0% and 3.3%; however, this was not statistically significant. The catheter-specific risk did not increase. It was thought that the number of catheters patients acquired during their hospital stays might be a reflection of the acuity of their illness, with sicker patients having many catheters. Since acuity was not associated with infection, it was not unexpected that order of catheter was similarly unassociated.

There was no relationship between the department of insertion (ER, OR, or unit) and the acquisition of phlebitis or catheter-related infection. Of those catheters inserted on the unit by nursing staff, 7/257 (2.7%) became infected. A similar number of catheters became infected when inserted by the Emergency Room staff, 4/141 (2.8%) None of the 59 catheters inserted by Anaesthesia became infected (Fig.9).

Heparin locks were no more likely to be associated with an increased rate of phlebitis than the standard catheters on either unit. Similarly there were no cases of infection associated with the intermittent catheterization devices.

The highest number of infections were found in the #20 gauge catheters (33.0%). However this was no higher than expected given the larger proportion of catheters in this

Frequency of Complications Associated with Insertion

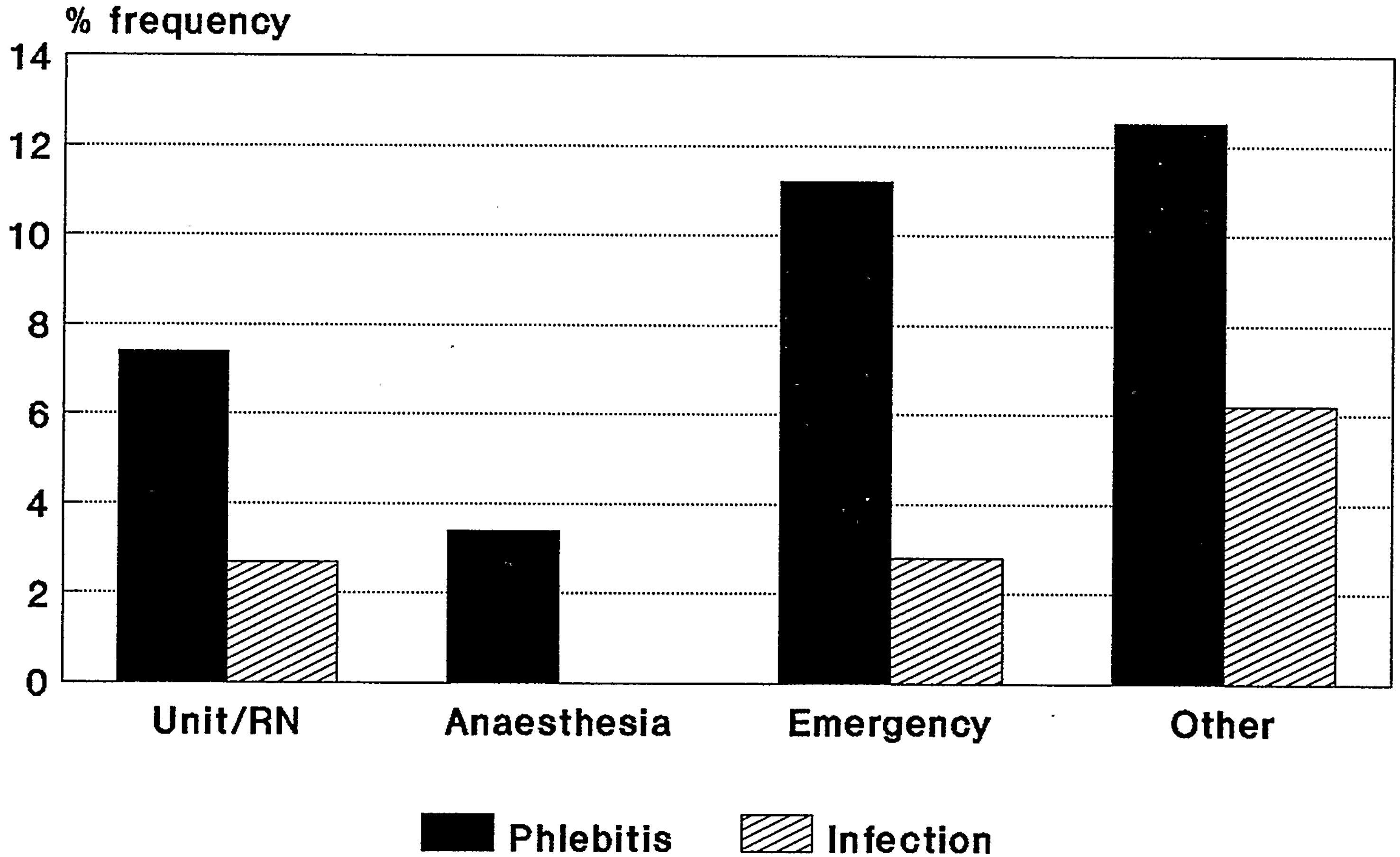

Fig. 9

group.

Stratified Analysis

It was felt that the duration of catheterization might confound the relationship between some variables and the rate of complications. Therefore a stratified analysis was performed following the method of Mantel and Haenszel.

The first variable to be analyzed in this manner was the location or unit of hospital stay (medical versus surgical). It was thought that duration of catheterization might confound the effect of unit since catheters were in situ longer on Unit 61 and longer duration of catheterization appeared to increase the risk of IV-associated complications.

When the data was analyzed without stratification, no statistically significant risk of phlebitis or infection was found to be associated with either unit. The crude relative risk of phlebitis associated with residing on Unit 71 was 0.97 (95% C.I. 0.53-1.77) when compared to Unit 61. When the analysis was adjusted for duration of catheterization, the risk increased to 1.13 (95% C.I. 0.63-2.04). However this was not statistically significant (Table 19).

The crude relative risk of infection on Unit 71 was 0.81 (95% C.I. 0.26-2.52). When the analysis was stratified by duration, the risk was still not significant even though the magnitude of the risk changed direction (RR = 1.33, 95% C.I. 0.34-5.18). Both strata (3 days or less and greater than 3 days) demonstrated a slight protective effect of being on Unit

TABLE 19 - COMPARISON OF RISK FACTORS FOR COMPLICATIONS UNADJUSTED AND ADJUSTED FOR DURATION OF CATHETERIZATION

Phlebitis

Risk factor	Crude RR (95% C.I.)	Adjusted RR (95% C.I.)
Unit 71	0.97 (0.53-1.77)	1.13 (0.63-2.04)
Class 3 and 4 Illness	1.56 (0.86-2.84)	1.27 (0.70-2.29)

Local Infection

Risk factor	Crude RR (95% C.I.)	Adjusted RR (95% C.I.)
Unit 71	0.81 (0.26-2.52)	1.33 (0.34-5.18)
Class 3 and 4 Illness	1.36 (0.45-4.12)	0.96 (0.25-3.64)

61. This was unexpected, however, as with phlebitis, the numbers are extremely small, making the estimates of risk unstable. Since there was no evidence of a difference, it was not necessary to interpret this phenomenom any further.

Class of illness could also be confounded by duration of catheterization since severely ill patients had catheters in situ for lengthier time periods. Illness was collapsed from four into two categories, to ensure enough cases per illness group. The crude relative risk for acquiring phlebitis when classed in a groups 3 or 4 illness category was 1.56 (95% C.I. 0.86-2.84). When risks were adjusted for duration, Class 3 and 4 groups were risk factors for phlebitis when the catheter was in situ for 3 days or less (RR = 1.81, 95% C.I. 0.83-3.93). Class 3 and 4 illness had a protective effect with respect to phlebitis, when the catheters were in place for longer than 3 days (RR=0.72). Due to the difference in direction of risk, it may not be appropriate to present a summary odds ratio. It may be that those patients who acquire phlebitis shortly after IV initiation are more susceptible to this complication because of the type of illness, poor venous access, type of IV medication or lack of antibiotic therapy. Patients who acquire phlebitis at this stage would probably have there catheters removed leaving an overrepresentation of those Class 3 or 4 patients on antibiotic therapy or less irritating IV medications, and therefore less likely to acquire phlebitis.

Being in group 3 or 4 was not a statistically significant risk factor for acquiring an IV-associated infection when the analysis was performed unadjusted for duration of catheterization (RR = 1.36, 95% C.I.0.45-4.12). When stratified by duration the RR dropped from 1.36 to 0.96 (95% C.I.0.25-3.64). However neither estimate was statistically significant.

Compliance with monitoring procedures

A major factor influencing the design of the study was the feeling of the Infection Control Department that IV monitoring practices were not being carried out appropriately by staff. During collection of the patient data, certain practices, such as recording on the IV sheet, and dating of the infusate bag, tubing and Opsite were observed. In 25.3% of all episodes, the IV record was filled out inadequately, i.e. date of insertion was missing, removal was not documented, etc (Table 20). This occurred fairly consistently on both units. Fifty eight percent of the time the IV tubing was not dated. It has been recommended that tubing be changed every 72 hours even if for some reason the catheter must be left in place longer. Without dating the tubing this would be impossible.

Dating of the infusate bag is especially important when the fluid is dispensed for the purpose of keeping the vein open. Frequently these solutions run very slowly and can be

TABLE 20 - RATE OF COMPLIANCE WITH MONITORING AND SAFETY PROCEDURES ASSOCIATED WITH PERIPHERAL CATHETERIZATION

	Unit 61(%)	Unit 71(%)	Total(%)
IV Sheet			
Not filled out appropriately	78/252 (31.0%)	42/224 (18.8%)	120/476 (25.2%)
IV Tubing			
Not dated	141/252 (56.2%)	135/224 (60.3%)	276/476 (57.7%)
Infusate Bags			
Not dated	54/252 (21.4%)	65/224 (29.0%)	119/476 (25.0%)
Op-site Dressing			
Not dated	4/252 (1.6%)	2/224 (0.9%)	6/476 (1.3%)

administered over a long period of time without change, unlike antibiotic therapy which is administered relatively quickly in smaller doses. Nursing policy states that bags should hang no longer than 24 hours, therefore dating is extremely important. Dating of the bag was only consistently maintained for 37.1% of all catheter episodes.

Opsite dressings were used for all catheter episodes, and were accurately dated 96.4% of the time.

The rate of infection in episodes where the IV record sheets were consistently filled out, was 1.4% (5/349) as opposed to the rate in sheets never or rarely filled out, 5.5% (7/126). This association was significant to $p<0.02$.

<u>Summary</u>

A sample of 476 catheters in 285 patients on two general hospital wards (one medical and one surgical) were followed to determine the rate of IV-related infection.

The sample consisted primarily of patients who were relatively healthy and admitted for minor problems and elective surgeries. However, there was a smaller proportion of episodes followed in patients with severe underlying conditions. There was a clear trend of greater acuity with increasing age.

Of all the episodes followed, phlebitis was found in 8.2% of cases. There was no difference in the rates of either complication between units. Catheters were found to be infected at a rate of 2.5% (1.5% verified by culture and 1.0% showing definate clinical signs of infection). Fifty-nine percent of the catheters classified as phlebitic were not sent for culture, leading to a probable underestimation of the true infection rate.

There was an increased frequency of phlebitis and infection those cases 60 years old or greater, and more severely ill. However, neither of these associations were statistically significant. Phlebitis was associated with the use of antibiotics; cases using them were 2.46 (1.32-4.63) times more likely to acquire phlebitis.

Duration of catheterization was associated with both an increased risk of phlebitis and infection, particularly after 3 days of placement. The increase in risk, however, was not day-specific but cumulative. Catheters in situ 4 or more days were 2.37 (1.29-4.30) times as likely to be associated with phlebitis and 12.0 times (3.34-43.47) as likely to be associated with local infection.

The rate of infection was also higher in patients receiving more than one catheter during their stay (3.2% versu 2.0%). This was probably a reflection of acuity; however, it was not significant.

No other factors were strongly associated with phlebitis or local infection.

Stratified analysis by duration of catheterization did not increase the number of risk factors associated with IV complications.

Compliance with monitoring practices, such as recording information on the IV sheet and dating IV tubing and bags, was also observed during the study period. These procedures were frequently not carried out appropriately on either unit. There was a significantly increased rate of infection in those episodes where the IV sheet was not adequately filled out when compared to those sheets which were.

CHAPTER 5

DISCUSSION

The following chapter will focus on some of the implications of the results through discussion of rates and risk factors associated with phlebitis and local IV site infections. Some of the factors to be discussed in the context of previous research, will include the severity of illness, order of insertion, duration of catheterization, and the use of antibiotics among others. Following the initial review, there will be a brief discussion of current IV monitoring policies. Limitations of the study will also be addressed, particularly those involving methodologies. Finally, areas of future research which might be applicable to this subject area will be elaborated on.

Implications of the Results

Associations between Independent Variables

The overall study population was concentrated in the older age categories (60-79), divided equally with respect to sex, and generally not suffering from life-threatening illness. Information obtained from Medical Records (FH) indicated that 44% of the patient population is concentrated in the 15-45 year old age range. There were however, enough subjects in each illness category to make the sample representative of all acuity levels.

It was expected that age would be strongly associated with severity of illness. There was a general trend for those patients in younger age groups to be less ill than older subjects. However, there was a large proportion of older patients (70-89) classified as belonging in Class 2. This may have been in part to a weakness of the scoring system which did not take age into account, ie. a 79 year old patient with duodenal ulcers and hypertension would be placed in the same category as a 30 year old patient with the same condition.

Antibiotic use was associated with age with those in the youngest age groups using less antibiotics than some older groups. However the pattern of antibiotic use did not follow this trend on Unit 61 and may have been due to a larger number of more severely ill young patients cared for on this unit.

The average number of days a catheter was in place was found to be 2.45 days which falls under the recommended number of days suggested by the CDC. However the two units differed markedly with respect to the duration of catheterization, with a much higher proportion of catheters on Unit 61 in place for longer than the recommended time. For many of these cases, it was likely that changing catheters was not feasible, due to poor venous access, although this was not always the case. The researcher observed several instances where poor documentation in the IV record led to prolonged catheterization of patients.

This claim was further substantiated by the finding that there was no significant difference in the duration of catheterization between older and younger age groups. Usually the problem of venous access occurs in young children and the elderly. The youngest cases in the current study were in their late teens, therefore venous access should not have been a problem. However both the youngest and oldest groups had the same average duration of catheterization. It may have been that the majority of the younger age group had catheters left in place longer because they were healthier and incurred no signs of complications. Conversely, a proportion of severely ill young cases with poor veins may have skewed the mean. There was a definite trend of longer catheterization in those cases of greater acuity.

As well as having longer periods of catheterization, sicker patients were more likely to have more catheter episodes. The requirement for IV therapy usually ceases when a patient is recovering promptly. Patients with more severe illness were more likely to have more than one catheter episode. Second or third order catheterizations may only be a marker for acuity. However, the rate of complications could be increased if the same vein was successively catheterized. Higher order insertions might also be confounded by duration if the patient is very ill.

The type of catheter used was of interest for two reasons: 1) to determine if the rate of complication was higher with heparin locks and 2) to determine if the gauge of catheter had any influence on the phlebitis/infection rate. Heparin locks allow for intermittent administration of IV fluids without the patient being joined to the IV apparatus on a continuous basis. Because heparin locks are not infusing constantly, the researcher felt that they would not be monitored as stringently and hence might be in place for longer periods of time. The data from this study confirmed this suspicion since 35% of heparin locks were in situ for longer than the recommended 72 hours, as compared to 19.7% of the standard catheters. There is no evidence to suggest that heparin locks can be safely left in place for longer than the standard catheter. In fact since the heparin locks in this study were found in patients who had been in hospital for a longer period of time, they could have been more likely to cause complications.

The study population was clearly differentiated between the two hospital units followed. The patient profile on Unit 61 was older and sicker with a subsequent lengthier hospital stay. Hence, these patients were likely to have more catheter episodes which were inserted for a longer period of time. They also had a higher frequency of heparin locks in situ. Although they were sicker, there was no increased use of antibiotics.

Unit 71 had a much higher frequency of younger, less ill patients who were admitted for elective and emergency surgeries. Many of these patients had a brief hospital stay resulting in a subsequent shorter duration of catheterization and fewer catheter episodes.

Phlebitis - Rates and Predictors

The rate of phlebitis was 8.2% for the current hospital population studied. This rate was much lower than the 32% incidence reported by Tomford et al. (1984) but comparable to that found by Maki and Ringer (1987) of 9.4%. It is possible that cases of phlebitis were missed since it has been reported that phlebitis often occurs >24 hours after removal of the catheter. Many patients were discharged relatively soon after removal of their catheters and therefore could not be followed. The diagnosis of phlebitis is also very subjective, a factor which could lead to the wide variation in reported rates.

There was no statistical association between age, severity of illness, or days in hospital before catheterization and the rate of phlebitis. Hershey et al. (1984) reported that some illness conditions (such as infections and immunosuppression) increased the severity of illness. Tager et al. (1983) indicated that patients with high risk diagnoses (hematological and disseminated malignancies and immunodeficiencies) had a 2.7 fold excess risk compared to low risk patients. They found age to be unrelated to an increased rate of phlebitis except as influenced by duration of catheterization. The lack of consistent results in the current study may be due to invalidity of the illness rating scale or could indicate a low proportion of "high risk" patients with similar illness profiles.

There was a 1.56 fold increase (not statistically significant) in phlebitis when a patient was classified as Class 3 or 4 illness as compared to healthier patients. Since the effect of illness could be confounded by duration of catheterization, a stratified analysis was performed. The adjusted risk was slightly lower, indicating that duration of catheterization might have caused an increased rate of phlebitis in sicker individuals. However neither risk estimate was statistically significant due to the small numbers in each stratum, and it is therefore impossible to determine the true relationship.

Use of antibiotic therapy was associated with the occurrence of phlebitis, a finding which might indicate that antibiotics themselves were responsible for inducing chemical phlebitis. Hershey et al. (1984) found a strong relationship between the development of phlebitis and the use of IV vancomycin. However the antibiotics used in the current phlebitic episodes (metronidazole, ampicillin, and penicillin) were not ones commonly known to produce that side-effect. It is unknown whether some other fluid which was infusing through the IV apparatus could have been responsible for the phlebitis.

Longer duration of catheterization was associated with an increased rate of phlebitis (3.2% after 1 day to 15.8% after 3 days). This finding agrees with previous literature. Tager et al. (1983) found that the risk of phlebitis rose with increasing duration of catheterization. Phlebitis which occurs after a longer period of catheterization may be more likely due to an infectious process, as opposed to a chemical or mechanical irritation which would occur within a short time of IV therapy initiation. The relative risk of acquiring phlebitis when a catheter remained in place longer than 3 days was 2.42 (95% C.I. 1.32-4.44). The day-specific risk increased significantly on Day 4. This finding, along with the high number of cases after 3 days in situ might indicate that a large proportion of phlebitic cases identified were truly of an infectious nature, even though few were actually cultured.

The type of catheter did not appear to influence the rate of phlebitis. It was thought that a larger bore could irritate the vein and cause venous spasms. The volume of infusate delivered to the vein would also be increased with a larger gauge of catheter thereby possibly causing chemical irritation. Infectious phlebitis could also be influenced by a larger bore catheter since the insertion wound could be larger and more invasive, allowing greater migration of colonizing microorganisms. However, in the current study, the catheter gauge did not affect the rate of phlebitis.

The number of catheter episodes a patient incurred while in hospital was considered important to follow since it could have been another predictor of acuity. Tager et al. (1983) found increasing chronological order of catheter to be associated with an increased rate of phlebitis. They postulated that this was due to a single vein being catheterized on multiple occasions. Phlebitis was not significantly associated with increased chronological order of catheter, although there was a slightly higher proportion of phlebitis in second or tertiary order episodes.

There were no differences in phlebitis rates between units. This was unexpected since duration of catheterization was found to be a major factor influencing the rate of phlebitis. Therefore, a stratified analysis was performed to determine whether duration was a confounder. If Unit 61 catheters were in situ for longer periods of time, being on Unit 71 might appear to be protective for phlebitis. As with the first stratified analysis, no statistical differences were noted. There was a slight increase in the risk associated with being on Unit 71. However the confidence interval crossed over the null.

Infection - Rates and Predictors

There was no statistical association between greater acuity and an increase in local IV site infections. This was an unexpected result since previous literature had always alluded to the strong association between acuity and nosocomial infection. If the scoring system for classifying patients into illness categories is valid, then the results imply that sicker individuals on general wards are not necessarily at greatest risk of catheter infection. Perhaps as Craven et al. (1987) suggested, patients on ICU's are more susceptible to catheter-associated infections because they have a greater number of invasive devices and not because of underlying illness. The sickest patients followed in this study did not acquire multiple invasive devices, and therefore may not have been at similar risk. Alternatively, the numbers may have been too small for any meaningful conclusions. A stratified analysis suggested that severity of illness may have actually been confounded by duration of catheterization. Although not statistically significant, the adjusted risk estimate was closer to the null, however the 95% C.I. was still very wide.

Antibiotic use was not associated with local infection. It might be anticipated that length of time on antibiotic therapy would be associated either positively or negatively with the incidence of catheter-related infection. Long term therapy might select for the emergence of resistant organisms, or conversely, eliminate possible pathogens from the site. If the latter occurred, it might not be surprising that a proportion of catheters did not grow anything. No data was collected on the duration of antibiotic therapy prior to culture of the catheter.

Many studies (Maki et al. 1979; Elliot, et al 1988; Maki and Ringer, 1987) have found an increased rate of infections with lengthier duration of catheterization. Although there are different theories explaining the source of infecting microorganisms, most researchers agree that a certain time element is necessary for the bacteria to migrate down from the hub or skin surface and colonize the intravascular portion of the catheter. There were no infections in those catheters which had been in place less than 3 days. This is consistent with pathogenesis theories which suggest that migration and colonization of microorganisms takes at least 2-3 days to occur. It might be thought that as exponential growth of the microorganisms occurs, the day specific risk of catheter-related infection might increase. In this study, the risk of infection appeared to be cumulative and not day-specific. Since the number of infectious episodes was very small for long durations of catheterization, it was impossible to determine whether this finding was valid. Tager et. al. (1983) suggested that much of the risk associated with complications occurs through cumulation of a constant day-specific risk, and not a daily increase of risk. This was in disagreement with Tully, et. al. (1981) who did note an increase in the day-specific risk.

The only size of catheter showing a high rate of infections was the one used most frequently, indicating that it is probably not a strong factor influencing infection. The effect of catheter size on infection has not been well documented in previous research. Although the bore size should not affect the rate of infection directly, those receiving smaller gauge catheters might have poor venous access due to age (either very young or old) or severity of illness, which in turn could make them more susceptible to complications. A large gauge catheter might directly facilitate phlebitis due to irritation and spasming of the vein.

There was no increased rate of infection noted with the use of heparin locks, even though they appeared to be in for longer periods of time without being changed. Although not verified, anecdotal evidence suggests that heparin locks were typically used in patients who were recovering but still needed some hospital care. These patients were generally healthier and perhaps more resistant to infection.

Armstrong, et al. (1986) did not find a significant association between the number of catheters a patient had and the rate of infection. Patients in the current study with several catheter episodes were more likely to have had a lengthier hospitalization and be suffering from a more severe illness. If these catheter episodes were also more likely to become infected, analyzing the data by this unit would not be appropriate, since several infections could be provided by one patient. In such a case it might be more appropriate to report the rate as infections/person-days at risk. Neither phlebitis nor local infection was significantly associated with an increased number of catheter episodes/patient, although there was a slightly higher proportion of both complications in second order or higher episodes. This finding was similar to that of Armstrong, et al. (1986) who found a trend of increased risk with successive catheters. Perhaps a larger sample would have provided more power to detect a significant trend.

Experience of the staff member inserting the catheter has been shown to be a factor influencing the risk of infection. When catheterization is difficult and requires multiple stabs and manipulation, the probability of infection increases due to microorganism access (Plit, 1988; Armstrong, et al. 1986). It has also been demonstrated that catheter-related complications were less frequent when catheters were inserted by an intravenous team as compared to the regular floor staff (Tomford et al., 1984; Hamory et al., 1984). Armstrong et al. (1986) found that physician experience was important in predicting infection. Both these findings seem to indicate that increased experience leads to decreased infection rates.

It was not feasible to collect this type of data in the present study. However it was possible to obtain information on the person or department inserting the catheter. It must be noted that this is not an indicator of experience per se, since different groups have their own protocols, and within each group there will be individuals of varying experience. Although there were no significant differences between inserters, catheters put in by the Department of Anaesthesia had no infectious complications when compared to the others. However this was not significant and no other group had an extraordinarily high rate of infections. It should be noted that residents begin their yearly rotation in July. Since the current study was carried out in February and March, it would not be as likely that their experience (or lack of) at inserting catheters would significantly influence the rate of complications on specific units.

Policies

Monitoring of compliance procedures indicated that there was a high frequency of procedures not being carried out by the staff. This was also very evident by the lack of catheters sent for culture and sensitivity, which although stated as a policy, was rarely carried out in practice. It is understood that the numerous responsibilities of nursing staff leave them very little time for additional practices and paperwork. However if current policies are unworkable, it makes very little sense to keep them place. Although the current study cannot provide evidence that lack of documentation causes an increase of catheter-related infections, there was an increased rate of infections in those episodes not adequately documented. Therefore it might be necessary to enforce current policies more stringently, or initiate new policies which are more acceptable to nursing staff, in order to provide maximum safety for the patient.

Limitations

A major concern encountered when doing active surveillance on a unit, is generation of the Hawthorne effect amongst the staff (Babbie, 1979). Daily visualization of the researcher by staff could trigger the staff to be more conscientious about IV maintenance. It was not feasible to do bedside surveillance and gain access to the charts without informing nursing personnel. Although the Hawthorne effect did not seem to occur in this study, as evidenced by the low numbers of catheters sent to the lab; there may have been some small effect generated since it was reported that no catheters were sent for culture prior to initiation of study.

Another limitation encountered when operationalizing the study was the lack of catheter tips from phlebitic patients, sent for culture and sensitivity. The Nursing Policy Manual states that peripheral IV catheters showing signs of phlebitis are to be sent to the lab for culture after removal. In reality, this practice was rarely carried out, and it was very difficult to implement a procedure which was not already routine, even though maximum effort was put forth to remind nursing staff to send catheters for culture. Although,it is understood that the diagnosis of phlebitis is very subjective, there were several cases where staff had recorded the catheter as being phlebitic, but still failed to send the tip. This could have led to an underestimation of the "true" infection rate.

Although the transport of too few catheters to the lab, could have resulted in underestimation of the infection rate, the subjective diagnosis of phlebitis may have led to a surplus of negative tips being cultured. Phlebitis in the current study and the nursing manual was defined as tow or more of the following signs: 1) redness 2) warmth 3) pain 4) swelling or induration. However most of these signs could be interpreted differently amongst separate observers, allowing a proportion of "false positives" to be sent for culture. Bryan et.al. (1983) suggested that occult IV site infection is a term which describes infections that do not produce pus or inflammation but can still lead to bacteremia. The findings of this study lend more evidence to suggest that phlebitis is not a sensitive marker for infection. Fifty percent of the phlebitic catheters sent for culture were not infected. This could imply that the cases were not really phlebitic or conversely, that phlebitis is a poor marker for infection.

As well as the vagueness associated with phlebitis as a diagnostic criterion, the semiquantitative method of culturing catheters has several shortcomings. Although Maki (1977) demonstrated an association between >/= 15 cfu's/plate after semiquantitative culture and bacteremia, there is evidence to suggest that this method lacks specificity. Several studies have found that an infected tip is often not predictive of the occurrence of clinically manifested catheter infection or bacteremia (Garland et al. 1987; Ducharme et al. 1988; Elliot, 1988). The semiquantitative method cultures only the outside surface of the catheter which by design must come into contact with the patients skin during insertion and removal. Therefore, this method of culture may be more prone to detect skin colonization picked during removal. Culture of the catheter lumen alone might be more appropriate since organisms colonizing this area would not be affected by removal of the catheter through the skin surface. Unfortunately there are no currently used laboratory methods which allow culture of the lumen only.

Another major weakness in this study was the scale used to categorize severity of illness. It was originally chosen because previous studies that stratified patients by illness used scales which were too broad or inappropriate for use in a general medical population. The scale chosen for this study classified patients by the number of systems involved, any complications incurred, and the completeness of recovery. However there was no apparent method of numerical scoring that could be consistently followed, so much of the evaluation was left up to the researcher who was not clinically oriented. To solve some problems of validity, a clinician randomly selected about 25 charts and blindly classified them to ascertain the level of agreement between herself and the researcher. It was noted at this time that the classification system was vague, especially when it came to distinguishing between the condition responsible for the patient's current hospitalization and any underlying chronic problems. It was particularly difficult to distinguish between the more severe classes of illness. Likewise the system did not delineate cases that were immunocompromised. All the Class 4 episodes were reevaluated by the clinician, however it is still likely that some episodes of illness were misclassified. The lack of association between severity of illness and complications may have been due to decreased validity of the classification system.

There were some variables for which it was not feasible to collect data, such as the number of attempts at insertion, the experience of the inserter, the length of antibiotic use and the total length of hospital stay. The last variable, in particular may have provided more valuable information with respect to severity of illness.

Although the small sample size allowed for relatively precise determination of the infection rate, the small numbers in subdivided risk categories did not allow for meaningful risk ratios to be calculated. The low power of the study may not have supplied sufficient evidence to reject the null hypothesis even if it were truly false, ie. a true risk may not have been detected (Kelsey et al., 1986). However, the study was designed to be exploratory and not confirmatory. Although it would have been desirable to collect a larger sample, it was not possible with the time and monetary constraints imposed.

Future Research Possibilities

Much of the impetus for further research arises from the limitations listed above. Further study, using similar but revised methods could be done on a much larger sample of the general hospital population. This could lend additional support to the findings of this current study. At the same time, it would be of interest to obtain information on other variables which have not been widely researched, such as the experience of the staff catheterizing the vein. In another study it might be preferable to initiate the methodology a month previous to actual data collection, to increase staff awareness of the project. Daily bedside surveillance could be reduced to every other day without a significant information loss. It might also be interesting to analyze the risk factors for infection with multiple logistic regression if the data warranted.

It would also be salient to conduct a similar type of study in different populations of patients, particularly pediatrics where little research has been done to date. Further studies must be undertaken in this population to determine if colonization of catheters in children occurs in the same time frame as that of adults. Garland et. al. (1987) implied that colonization (or infection) of catheters in children decreased after 3 days in situ when compared to less than 3 days. However, the status of antibiotic therapy in those catheters which remained in longer than 3 days was never clarified. Since staff are more hesitant about changing catheters frequently in children (and poking them more), studies in this area could have important ramifications for pediatric IV policies.

Another area of study which has not been well researched is the rate of complications associated with heparin locks. Although the current study did not implicate them as detrimental, the numbers were too small to make confirmatory statements.

There are two important methodology issues which would benefit from further research: 1) the microbiologic culture method and 2) the severity of illness scale.

A new method of culturing or identifying infected catheters would be useful. Although the semiquantitative method is relatively quick and acceptable to lab staff, intimations about the lack of specificity give rise to questions about its consistent use. Some ideas for alternate methods might include the use of new staining techniques, electron microscopy, or a quantitative method whereby only the lumen of the catheter is cultured. Perhaps other assays could be developed which measure the level of pathogenicity of bacteria which adhere to the catheter.

The other research tool which must be improved in the area of nosocomial infection, is the acuity or severity of illness index. An efficient and valid method of classifying patients according to their total physiological status and length of hospital stay would enable more significant associations to be detected in these types of studies. Devising a reliable and valid scale would be a challenging project in its own right.

Another area which has not been explored extensively is the frequency of asymptomatic or "occult" local site infections and the implications associated with this type of colonization. A high rate of "infected negatives" might be another indication that Maki's criterion for infection should be accompanied by more clinical manifestations.

Another new trend evolving in catheter-related infection research is the clinical testing of practices which might prevent or decrease the likelihood of colonization. Antibiotic impregnated catheters could be studied to determine whether inhibition of growth or proliferation of resistant organisms occurred. As well, new materials which do not allow adherence and colonization of microorganisms, would be extremely useful in catheter manufacture. Maki et al. (1988) tested a silver impregnated cuff which is implanted subcutaneously on a central line. The cuff acts as a barrier to microorganisms without inducing resistance phenotypes.

Finally with the emergence of new priorities directed at cost containment and environmental safety, there could be a resurgence of previously used methods and materials, i.e. gauze dressings, non-disposables, etc. A return to these procedures will require testing to ensure that patient safety is not compromised.

It is evident that although peripheral intravenous catheters have been around for several years, there will always be new avenues of research opportunities opening, particularly with the advent of new catheter materials and methods of preventing infections.

Implications of the Study

The current study has added to the body of knowledge surrounding peripheral catheter use, particularly in a general hospital population. Although the study lacked the power to make confirmatory statements, it appears that peripheral IV catheters are still responsible for a significant proportion of complication. However the study indicated that factors such as the severity of illness and the order of catheterization, among others, may not be as important as previously thought, once the effect of duration has been accounted for. Results from this study also implied that the semiquantitative method of culturing catheters may not be highly correlated with clinical illness, since no systemic infection occurred. From an infection control perspective, the study provided evidence that current IV care and monitoring policies are not always followed, and that lack of compliance might lead to an increase in local IV site infections.

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Appendix A - Risk Factors

Addressogram

Unit

Diagnosis

Class

Surgery

Date inserted

Anatomical Site

Type of catheter

Order

Person/Place Insert

Date removed

Systemic antibiotics

Reason for removal

Appendix B - Daily Log

Date																											
Initials																											
Site																											
-red																											
-pain																											
-warm																											
-swelling																											
Exudate																											
Tubing marked?																											
-changed?																											
-Opsite?																											
SQ culture																											
-infected?																											
Fever																											
WBC																											
Blood Culture -peripheral																											
-line																											
Bag marked?																											
Discontinued																											
IV sheet kept up to date?																											