The Art and Science of Infusion Nursing

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A Prospective Postmarket Study to Evaluate the Safety and Efficacy of a New Peripherally Inserted Central Catheter Stabilization System

ABSTRACT

An initial postmarket study of the SecurAcath used with 5 Fr peripherally inserted central catheters (PICCs) was conducted with 68 adult patients at 3 different institutions in the United States. PICCs were placed in both outpatients and inpatients, with patients in critical care and medical/surgical units, home care, and extended care facilities. Sixty-two (91.2%) of the patients completed therapy without a securement-related device malfunction or device-related adverse event associated with the securement system. The device was readily accepted by both patients and nursing staff. The SecurAcath represents a novel, safe, and effective method for catheter securement.

Key words: central venous catheters, peripherally inserted central catheter, SecurAcath

Peripherally inserted central catheters (PICCs) are widely used for a variety of intravenous (IV) therapies and, depending on the original indication for insertion, may remain in place for as short as a few days to as long as several months. Despite the substantial increase in the number of hospitals that have specialized teams specifically educated in the placement of central venous catheters and the important advances in maintenance protocols,[1] significant challenges for PICC use include bloodstream infections and inadvertent dislodgment. In patients in whom catheters migrate or become dislodged, PICC replacement is required. PICC replacement may include over-the-guidewire exchange, de novo placement, or placement of an alternative device. Complete inadvertent PICC removal may result in loss of a suitable vein for future vascular access device (VAD) placement. In addition, the costs related to the

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required weekly replacement of adhesive securement devices or treatment of a needlestick injury related to suturing are potentially significant.

Catheter dislodgment and bloodstream infections may be related to the movement of the catheter at the skin entry site, a problem that can be addressed with improved catheter securement methods.[2,3] Suturing PICCs into place can create additional potential entry points for bacteria and also can cause skin irritation. In addition, sutures are often uncomfortable and may not remain in place for the life of the device. Finally, suturing these catheters in place may expose the clinician to an additional risk of exposure to blood-borne pathogens. Adhesive securement devices such as StatLock (Bard Medical Division) are designed to hold the catheter hub to the skin. Cleansing the catheter site completely in the presence of these devices may, however, present a challenge. As a result, these devices require intermittent change, during which time the PICC is vulnerable to migration, particularly if the patient moves. Because adhesive securement devices adhere to the PICC hub or suture flange, a portion of the PICC can piston in and out of the PICC exit site. In addition, a subset of patients may have difficulty achieving adequate adherence of an adhesive device to the skin because of hair growth, skin lesions, allergy to the adhesive, or diaphoresis.

The Infusion Nurses Society's *Infusion Nursing Standards of Practice* (2011)[4] address VAD stabilization as an important component of clinical practice. Specifically, Standard 36[4(pS46)] states that "stabilization shall be used to preserve the integrity of the access device, minimize catheter movement at the hub, and prevent catheter dislodgment and loss of access." The *Standards* also note that alternative methods to sutures should be considered to mitigate the risk of needlestick injury. The SecurAcath was studied as an alternative device to provide secure VAD retention, requiring no replacement and eliminating the risk of sharps injury to clinicians.

STUDY PURPOSE

The SecurAcath (Interrad Medical, Inc) is a new catheter securement device that uses a small anchor placed just beneath the skin in the subcutaneous tissue. The purpose of this postmarket study was to evaluate the safety and effectiveness of this device in preventing catheter dislodgment and to use the data collected to (1) provide insight into enhancements to improve the safety and utility of the device, (2) provide a means for an early warning of any newly identified safety issues, and (3) allow clinicians to share their experiences and clinical advice for further device development.

METHODS

Study Design

This was a multicenter, prospective study designed to monitor the safety and performance of the SecurAcath device. The primary end point was device-securement success, defined as the percentage of SecurAcath devices inserted and explanted without (1) securement-related device malfunctions (ie, securement anchor breakage/fracture, catheter slippage within securement device, catheter lumen constricted/reduced by securement device, or catheter dislodgment) or (2) device-related complications/adverse events attributed to the subcutaneous securement system (ie, inability to remove device anchor as designed at explants, cellulitis at the securement site, persistent pain at the anchor securement site that required medical intervention, and erosion at the anchor securement site). Secondary end points included acute procedural success, securement time, securement device indwelling time, catheter and securement device complication rate, patient comfort, and ease of maintenance.

The study was performed at 3 different sites: Albany Medical Center in Albany, New York; St Joseph's Hospital in St Paul, Minnesota; and St Luke's Hospital in Kansas City, Missouri. Approval to conduct the study was granted by the institutional review board at each investigational site. Patients were recruited for this study during a 4-month period extending from August 19, 2010, through December 24, 2010. Each subject provided written informed consent prior to enrollment. The site coordinators carried out enrollment of patients and all data collection. All treating health care personnel were required to be proficient in inserting a PICC using ultrasound guidance. Before study initiation, all study personnel received on-site training on proper insertion and removal of the securement device as well as accurate documentation of all study-related information. All patients were treated according to the institutional standard of care and according to the instructions contained in the SecurAcath device instructions for use. Study supplies were provided by the study sponsor, Interrad Medical Inc.

Patient Selection

The study coordinator at each site was notified when a request for PICC placement was received, and each patient was assessed for eligibility based on the inclusion and exclusion criteria listed in Table 1. Patients were eligible regardless of their history of previous central venous catheter placement. Both inpatients and outpatients were eligible for inclusion. Patients exited from the study on PICC removal, whether scheduled or unscheduled.

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TABLE 1

Study Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Age 18 or older	Inability to understand the study or a history of noncompliance with medical advice
Requires a PICC to be placed	Unwilling or unable to sign ICF
	Known upper extremity venous thrombosis, occlusion, or flow-limiting stenosis within the desired catheter course with no other viable site for access in either arm
	Known hypersensitivity to nickel (the securement anchor is composed of nitinol, a nickel-titanium alloy)
	Previous mastectomy or axillary lymph-node dissection on the same side as catheter placement
	Skin integrity deemed unfavorable by the operator, eg, friable skin due to chronic steroid use, presence of cellulitis or rashes at the desired site of catheter insertion with no other viable site for access

Abbreviations: PICC, peripherally inserted central catheter; ICF, informed consent form.

Study Procedures

Before PICC insertion, a preprocedure ultrasound of the target access site was carried out in all patients. Upper extremity veins were assessed for patency and diameter. Patients were deemed ineligible if target veins were thrombosed or of inadequate size to allow PICC placement. Standard skin preparation and draping with full barrier precautions per each institution's protocol were performed. There were no restrictions regarding the brand or model of catheter used. Following PICC placement, the SecurAcath device was folded and deployed beneath the skin through the preexisting dermatotomy or puncture site. Once deployed, the securing anchors were stable. The catheter was then placed into the tract, and the lid was secured. Sites were then dressed per standard institutional protocol. PICCs were placed in the interventional radiology suite with immediate fluoroscopic verification of tip placement, and at the bedside, with chest x-ray confirmation of tip placement. No changes in PICC placement procedure, maintenance, or tip confirmation were required. The ease of SecurAcath deployment and deployment time were recorded. Subsequent dressing changes were performed according to each site's standard procedure and were performed by staff nurses from inpatient units, extended care facilities, and home care settings. Researchers placed no limitation on prospective PICC dwell time; therefore, the expected duration of each patient's participation in the study ranged from only immediate postoperative fluid administration, nutritional support, and/or monitoring, up to long-term needs in a home care setting.

The baseline data collected for all patients included gender, age, indication for PICC insertion, and significant past medical history, including previous IV access. The procedural data collected for all patients included the brand and model of the PICC used, the locations of PICC entry site and catheter tip placement, the securement device placement method (using the SecurAcath placement tool or manual method), the approximate time required for placement of each SecurAcath device, and the type of dressing used. An assessment of catheter stabilization and patency, performance of the securement device, and any complications were completed on a weekly basis. The primary end point, defined as device securement success, was assessed by measures including the absence of (1) securement-related device malfunctions (securement anchor breakage/fracture, catheter slippage within the securement device, catheter lumen constricted/reduced by securement device, and catheter dislodgment) and (2) device-associated complications/adverse events that were securement related (inability to remove the anchor as designed at time of explantation, cellulitis at securement site, persistent pain at anchor securement site that required medical intervention, and erosion at the anchor securement site). Acute procedural success was defined as the number of successful securements of the catheter without malfunction or placement failure of the SecurAcath device.

The study coordinator or investigators were notified if the catheter required removal or if the patient experienced any PICC-related complications or securement-related device malfunctions. When the SecurAcath device was removed, if the removal was unscheduled, the reason for removal was queried (eg, unintentional removal, kinking, pain at anchor securement site, or "other" complication). All patients were also asked to rate their levels of discomfort during dwell time and at removal on a scale of 0 to 10, with 0 indicating "no discomfort" and 10 indicating "worst possible pain."

Definitions

Catheter slippage was defined as catheter movement as a direct result of mechanical malfunction of the SecurAcath device and is specific to the study protocol. *Unscheduled* (ie, unplanned) *removal* was defined as unexpected removal for any reason, with no restrictions applied. Other terms are common to the use of central catheters, and the following definitions were derived from Yamamoto et al.[5] *Scheduled* (ie, planned) *catheter removal* was successful completion of the intended

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course of therapy for which the PICC was inserted. Accidental removal or movement that resulted in the loss of function was defined as *catheter dislodgment*, whereas *catheter migration* was defined as movement greater than 0.5 cm without loss of function, even if the catheter tip was no longer in a central position. *Cellulitis* was diagnosed if antibiotic treatment and/or catheter removal resolved skin tenderness, erythema, edema, and purulent exudates. A *confirmed catheter-related bloodstream infection (CR-BSI)* required isolation of identical organisms from both line and peripheral blood cultures or the loss or disappearance of fever after PICC removal. A *suspected PICC-related bloodstream infection* was defined as a bloodstream infection in which there was failure to meet the criteria for a confirmed line infection despite a strong suspicion by the primary medical team.

Data Analyses

All outcome data are summarized with descriptive statistics, without adjusting for missing data or outliers. Means and standard deviations are reported for quantitative measurements. Minimum and maximum values are also reported to indicate data ranges. Qualitative measurements are reported in frequency counts and percentages. Percentage is always computed by using available data only, with missing values and those reported as not available excluded from the denominator.

RESULTS

Patient and PICC Characteristics

The study population consisted of 68 patients who met inclusion/exclusion criteria and had an inserted PICC secured using a SecurAcath device. Medical and surgical inpatients accounted for 61.3% (42) and 26.5% (18), respectively, with an additional 4.4% (3) either in an intensive care unit or transplant unit. Outpatients accounted for the final 7.3% (5) of patients. Patient characteristics and comorbid conditions are presented in Tables 2 and 3, respectively.

All 68 PICCs inserted were 5 Fr power-injectable catheters and included the Morpheus Smart PICC (n = 4; AngioDynamics), MedCOMP Pro-PICC (n = 26; Medical Components, Inc), PowerPICC Solo*[2] (n = 13; Bard Access Systems, Inc), and PowerPICC (n = 25; Bard Access Systems, Inc).

Insertion Data

The median time to place the 68 SecurAcath devices was 15 seconds (range, 10-180 seconds) (Figure 1). Whereas the mean time for securement was 31 ± 38 seconds, 89.7% (61) were placed in ≤75 seconds (2 standard deviations, σ).

TABLE 2
Patient Characteristics (N = 68)

Characteristic	
Mean age ± SD (y), (range)	**58.7 ± 19.4 (20.5-87.8)**
Sex, n (%)	
Male	30 (44.1)
Female	38 (55.9)
Race, n (%)	
Caucasian	56 (82.4)
Black	9 (13.2)
Other	3 (4.4)
Vein used, n (%)	
Basilic	52 (76.5)
Brachial	15 (22.1)
Axillary	1 (1.5)
Indication for PICC,* n	
Antibiotics	40
Blood draws	34
Intravenous fluids	26
Lack of peripheral access	20
Parenteral nutrition	15
Blood products	7
Chemotherapy	3
Other	11

Abbreviations: PICC, peripherally inserted central catheter; SD; standard deviation.
**Some patients had more than one indication for use.*

Acute procedural success, defined as the number of successful securements of the catheter without malfunction or placement failure of the SecurAcath device, was 100% (68). Successful securement included any securement that did not require the subject to use a securement method other than the study device. (*Note:* the use of a transparent occlusive dressing or equivalent was not considered an additional securement method.)

All clinicians participating in the study used standard power-injectable PICCs, ultrasound guidance for insertion, and chest x-ray or fluoroscopy for tip confirmation. Use of the SecurAcath device did not require any change in PICC measurement, length, placement procedure, cleansing, or dressing techniques.

Outcome Data

The mean (± SD) catheter dwell time (defined as the time from catheter insertion/securement to securement

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TABLE 3

Patient Comorbid Conditions (N = 68)

Condition*	n (%)
Active infection	26 (38.2)
Diabetes	14 (20.6)
Cancer	12 (17.6)
HIV	1 (1.5)
Cystic fibrosis	1 (1.5)

Abbreviation: HIV, human immunodeficiency virus.
**Some patients had more than 1 comorbid condition.*

device removal) for all 68 patients was 22.6 ± 36.0 days (range, 0-228 days); 3 patients had their SecurAcath device removed while the PICC remained in place. Fifty-three (77.9%) of these patients had a dwell time of <30 days, 7 (10.3%) had a dwell time of 30 to 44 days, 4 (5.9%) had a dwell time of 45 to 89 days, and 4 (5.9%) had a dwell time of ≥90 days. For 79.4% (54) of patients (including 1 who died with the catheter and device in place), dwell time reflected successful completion of the intended course of therapy for which the PICC was inserted. Unscheduled removal of the SecurAcath device for any reason occurred in 20.6% (14) of patients because of suspected or confirmed bloodstream infections (n = 4), patient removal of own catheter (n = 4), pain (n = 2), dislodgment (n = 1), catheter kinking (n = 1), a 7 Fr SecurAcath used in error with a 5 Fr catheter (n = 1), and SecurAcath lid lost during home dressing change on the 140th day (the remaining SecurAcath base was later removed, but the catheter stayed in place; n = 1).

This study was designed to evaluate securement success and device safety in general use, specifically allowing all interim follow-up data to be gathered using each investigator's standard of care. Because each hospital had a different standard of care/protocol for PICC maintenance, there was no specified interval mandated in the protocol for gathering interim follow-up data. Floor nurses and home infusion nurses, rather than SecurAcath study nurses, carried out the majority of dressing changes. Therefore, the time for dressing change and cleaning was not always reported, which is a limitation inherent in the study design. Study nurses, however, monitored all patient charts regularly for any indication of adverse events (AEs).

The primary end point of this study—the percentage of the 68 patients with SecurAcath devices implanted and explanted without (1) securement-related device malfunctions or (2) device-related complications/AEs attributed to the subcutaneous securement system—was 91.2% (62), as shown in Table 4.

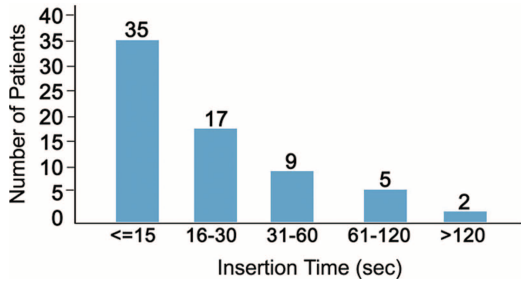

Figure 1. Placement insertion time of SecurAcath devices (N = 68).

TABLE 4

Primary End Point: SecurAcath Device Securement Success in Patients With a Peripherally Inserted Central Catheter (PICC) (N = 68)

Primary End Point Securement Criteria	n (%)
Securement-related device malfunctions	
Securement anchor breakage/fracture	0
Catheter slippage within the securement device*	2 (2.9)
Catheter lumen constricted/reduced by securement device	0
Catheter dislodgment**	0
Device-related securement complications/adverse experiences (AEs)***	
Unable to remove the anchor as designed at explants	1 (1.5)
Cellulitis (infection) at the securement site	1 (1.5)
Persistent pain at anchor securement site that requires medical intervention	2 (2.9)
Erosion at the anchor securement site	0
Subjects with securement-related malfunctions or device-related AEs	6 (8.8)
Subjects with no securement-related malfunctions or device-related AEs	62 (91.2)

**Catheter slippage (migration) defined as movement greater than 0.5 cm without loss of function due to device malfunction, even though the catheter tip may have no longer remained in a central position.*
***Only catheter dislodgment (defined as accidental removal or movement that resulted in the loss of function) due to device malfunction is included in the primary end point.*
****AEs were included as device-related for this end point if the site categorized the AE as either "probably" or "definitely" device-related.*

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AE report forms specifically queried about the occurrence of catheter thrombosis, bloodstream infection, cellulitis (infection) at the securement site, deep vein thrombosis, edema, erosion at the anchor securement site, extrusion at the anchor securement site, pain at the anchor securement site, thrombophlebitis/phlebitis, any other thrombosis, tissue growth around the anchor, and vessel occlusion, as well as any other AEs that may have occurred. A total of 20 AEs occurred in 22.1% (15) of the 68 patients during the course of this study (Table 5).

Twelve of these 20 AEs were classified as either possibly, probably, or definitely related to the SecurAcath device by the site. For 1 patient, "fevers—possible line infection" was stated as the reason for unscheduled device and catheter removal. A minor site infection was noted in 1 patient the day after she removed her own PICC for unknown reasons. Of the 5 patients who reported pain at the device securement site, none experienced any residual problems following device removal. In 2 of those 5 patients, the level of pain was sufficient to prompt an unscheduled removal of the device only, with the PICC remaining in place and subsequently being secured using standard methods. The first event began after device placement when the SecurAcath was manipulated, and the second began after the device was rotated 90° during the dressing change. The remaining 3 of those 5 patients reported intermittent pain either with movement of the involved arm, if the site was touched, or when lying on the device, respectively; no treatment was necessary, and all had a scheduled removal of device and catheter. One subject, who was African American, experienced excessive tissue growth around the anchor, described as "a 'keloid-like' growth of skin over device." The 4 "other" AEs reported to be possibly (n = 3) or definitely (n = 1) related to the SecurAcath device include 1 patient who removed her PICC at home (the SecurAcath was removed the next day at the hospital), 2 patients who experienced catheter migration in spite of intact SecurAcath devices and properly applied dressings, and 1 catheter dislodgment due to a device lid not snapped on securely over the catheter.

Three events listed in Table 5 (death, cerebral hemorrhage, and methicillin-resistant *staphylococcus aureus* meningitis) were recorded as serious adverse events and were all felt to be unrelated to the procedure, device, or catheter. No event in Table 5 was an unanticipated adverse device effect.

The level of patient comfort was defined in the protocol as the rating of each subject's pain level after device removal, using a scale of 0 to 10, with 0 indicating "no pain" and 10 indicating "worst possible pain."

TABLE 5

All Adverse Events (AEs) in Patients Implanted With a Peripherally Inserted Central Catheter (PICC) Secured by a SecurAcath Device (N = 68)

Adverse Event (AE)	Subjects, n (%)	Events, n	Related* to Device, n
Catheter thrombosis	1 (1.5)	1	0
Bloodstream infection**	3 (4.4)**	3**	1**
Cellulitis	1 (1.5)***	1***	1***
Pain at anchor securement site	5 (7.4)	5	5
Tissue growth around the anchor	1 (1.5)	1	1
"Other" adverse event****	8 (11.8)	9	4
Subjects with ≥1 AE	15 (22.1)		
Subjects with ≥1 device-related AE	10 (14.7)		

**Includes all events reported to be definitely, probably, or possibly related to the SecurAcath device.*

*** Includes 1 patient with methicillin-resistant* staphylococcus aureus *(MRSA) catheter-related bloodstream infection (CRBSI) (001-103); 1 with a positive culture for both blood and urine but no information if they were the same microorganism and only a "possible" relationship to the catheter (001-109); and a patient with unexplained fevers for whom the only information provided was that a possible line infection may exist (001-106).*

****One patient (005-112) came into clinic 1 day after removing her own peripherally inserted central catheter (PICC) at home to have a new PICC inserted and so that staff could remove the SecurAcath device which was still in place. She was noted to have a 2- to 3-cm erythema at the securement site and also reported some purulent discharge from site at home but was afebrile. She was treated with cephalexin and hot packs. No reason was given for removing the PICC, and at removal of the SecurAcath she stated that she was "very satisfied" with the SecurAcath and that it was "much better" than previous attachment systems she had experienced.*

*****Includes 2 patients who removed their own PICCs (securement devices remained in place until removed later), 2 patients with catheter migration, 1 catheter dislodgment, 1 death, 1 amputation wound infection, and 1 patient who experienced both a cerebral hemorrhage and MRSA meningitis.*

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TABLE 6

Patient Comfort Measured Immediately After SecurAcath Removal

Pain Score After SecurAcath Removal	Subjects (N = 68) [57],* n (%)
0 = no pain	30 (52.6)
1	9 (15.8)
2	4 (7.0)
3	6 (10.5)
4	2 (3.5)
5	1 (1.8)
6	2 (3.5)
7	0 (0)
8	1 (1.8)
9	0 (0)
10 = worst pain possible	2 (3.5)
Mean ± SD (range)	1.5 ± 2.5 (0-10)

**Number of patients with responses.*
Abbreviation: SD, standard deviation.

As shown in Table 6, the mean pain score immediately after device removal in 57 patients was 1.5 ± 2.5 (range, 0-10). Eleven patients had no pain score recorded: 1 died with the device and catheter in place, 1 was leaving the hospital and did not answer the questionnaire, 2 had no reason given for lack of response, 3 were described as unavailable to answer the questionnaire, and 4 were clinically unable to respond. Pain scores during SecurAcath use were also recorded. The mean pain score during device dwell time in the 57 patients available for responses was 0.7 ± 1.6 (range, 0-7). In terms of their overall satisfaction with SecurAcath, 91.2% (52) of 57 patients responding were either neutral, satisfied, or very satisfied, and 84.2% (48) were either satisfied or very satisfied.

DISCUSSION

The incidence of catheter-related complications can be significantly affected by inadequately secured PICCs. This prospective, multicenter, postmarket study was designed to capture information on the performance and safety of the SecurAcath stabilization device in general use. In this study, each institution used standard, commercially available PICCs and followed individual site protocols for maintenance.

Sixty-two (91.2%) of the 68 patients enrolled in this study met the goal measured by the study's primary end point of SecurAcath device implant and explant without (1) securement-related device malfunctions or (2) device-related complications/AEs attributed to the subcutaneous securement system. Of the 20 AEs that occurred in 15 (22.1%) of the 68 patients during the course of this study, only 12 of these events were classified as either possibly, probably, or definitely related to the SecurAcath device.

With data from a single-arm study such as this, the usual course is to compare these data with data from the clinical literature for other securement methods. There is, however, a paucity of recent articles dealing with PICC securement. Although other papers on PICC securement using StatLock are available,[6-10] only the study by Yamamoto et al[5] presents the data with sufficient detail and definitions to allow comparisons between StatLock and SecurAcath.

Yamamoto et al[5] reported a total of 42 PICC complications (including catheter dislodgment, catheter migration, CR-BSI, cellulitis, leak, occlusion, and central venous thrombosis) among the 85 patients using StatLock, yielding an incidence rate of 15.0/1000 catheter-days. When the same categories are applied to SecurAcath data using the definitions from the paper by Yamamoto et al, only 6 AEs are included, giving an incidence rate of 3.9/1000 catheter-days. StatLock-secured catheter dislodgment occurred in 8 patients, with an incidence of 3.6/1000 catheter-days compared with 1 SecurAcath-secured patient, with an incidence of 0.7/1000 catheter-days. CR-BSI incidences for the 2 studies were more comparable, with 2.4 (n = 2) and 1.5 (n = 1) per 1000 catheter-days, for StatLock and SecurAcath, respectively. In addition, 23.5% (n = 20) of the StatLock-secured PICCs had an unplanned removal, defined as only those removals resulting from dislodgment, infection, phlebitis, thrombosis, catheter leakage, or occlusion. When only the same categories are applied to the SecurAcath data from this study, the unplanned removal rate is 2.9% (n = 2).

The SecurAcath device was managed successfully in a variety of care settings in this study, including inpatient units, extended care facilities, and the home. Routine maintenance was performed by staff nurses rather than study personnel or vascular access teams. There were 1 catheter dislodgment and 2 catheter migrations in this study, all 3 of which were related to failure of the cap to completely affix to the base of the SecurAcath device. The device has since been modified to feature an improved locking mechanism that provides positive feedback to the user when the cap is appropriately engaged.

There are several limitations to this study. Only 5 Fr PICCs were placed. Future evaluation of this device

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with catheters of different size and design is warranted. Device deployment times varied but improved once nursing staff became more familiar with the device and increased their proficiency with insertion. Although patients were asked to report their levels of satisfaction with the device, many had no prior experience with other securement mechanisms. Thus, their ability to compare comfort and satisfaction with standard securement methods was sometimes limited. Because this was a single-arm study, direct comparison could not be made with similar concurrent patients using adhesive devices or sutured catheters. Because no needle or blade is involved in the use of the SecurAcath, however, it can be reasonably assumed that potential exposure to blood-borne pathogens via needlestick injury will be eliminated. Lee et al[11] reported that the economic cost of managing needlestick injuries is substantial, ranging from $51 to $3766 (2002 US dollars)—amounts that do not include the cost of treating the long-term complications of needlestick injuries, eg, human immunodeficiency virus and hepatitis B and C infections, for which care is estimated to cost several hundreds of thousands of dollars for each case.

An analysis of the financial impact of the SecurAcath was not performed. The manufacturer's suggested retail price of 1 SecureAcath device is $25. This is a 1-time cost for a device that is expected to last for the duration of catheter use. In comparison, an adhesive securement device typically costs between $5 and $6, with replacement occurring weekly or more often, depending on the clinical needs of each patient. Evaluating the cost-effectiveness of SecurAcath versus adhesive devices and sutures, including material costs, time to securement, effectiveness of securement, and reduction in needlestick injury, is one area for future investigation.

On the basis of the initial trial of the SecurAcath device on 5 Fr PICCs in a variety of clinical settings, it is reasonable to conclude that SecurAcath, which was readily accepted by both patients and nursing staff, represents a novel, safe, and effective method for catheter securement.

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