Prospective Randomized Comparative Evaluation of Proximal Valve Polyurethane and Distal Valve Silicone Peripherally Inserted Central Catheters

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PURPOSE: The objective of this study was to evaluate and compare the relative durability and complications between the proximal valve polyurethane and distal valve silicone peripherally inserted central catheters (PICCs).

METHODS: Institutional review board approval was obtained. A total of 326 patients (mean age, 50.4 years) was assigned randomly to receive either a proximal valve polyurethane PICC (n = 198) or a distal valve silicone Groshong PICC (n = 194). All PICCs were inserted under radiologic guidance by interventional radiologists. Follow-up data were collected until catheter removal because of complications or treatment completion.

RESULTS: The mean catheter dwell time was 25.6 days (range, 1–245 days). Complications were encountered in 26.8% and 47.9% of the proximal valve polyurethane PICCs and distal valve silicone PICCs, respectively (P < .001). Significantly higher incidences of phlebitis (23.2% versus 11.6%, P = .003) and catheter-related infection (6.2% versus 2%, P = 0.043) were noted in the distal valve silicone PICCs. No significant differences in the incidence of catheter occlusion, fracture, or dislodgement were found. Multivariate logistic regression analysis showed a higher complication rate in the distal valve silicone PICCs corrected for patients' age, sex, underlying morbidity, indication, peripheral vein accessed, arm used, catheter tip placement, and the number of venepunctures attempted.

CONCLUSIONS: Proximal valve polyurethane PICCs were more durable than distal valve silicone PICCs, which were associated with a higher incidence of phlebitis and infection, probably related to the materials of the catheters and the designs and placements of the catheter valves.

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Abbreviations: DVSP = distal valve silicone PICCs, PICCs = peripherally inserted central catheter, CRBSI = catheter-related bloodstream infection

THE first documented peripherally inserted central catheter (PICC) was placed by Dr. Werner Forssmann, a German physician, through the left antecubital vein into his own heart in 1929 (1). However, it was not until silicone elastomer catheters were developed in the 1960s that PICCs began to be used widely (2). Over the last few decades, PICCs have been recognized gradually as a well-established way of providing reliable venous access, an essential element of modern health care (3–5). Because of their markedly superior efficacy over peripheral venous cannulas, PICCs are used extensively for patients needing intermediate to long-term peripheral venous access, particularly for prolonged antibiotic therapy (3).

Nevertheless, complications of PICCs and their subsequent implications continue to be significant issues. Various studies found that only 51%–69% of these catheters remained in use until successful completion of therapy (6–9). Notably, upper extremity venous thrombosis associated with PICCs was detected in up to approximately 40% of cases, the majority of which were complete occlusive thrombi (10,11). Valved PICCs were introduced and a significantly lower incidence of complications was found when compared with the open-ended catheters (12–14). However, evidence regarding the relative efficacy and complications between the proximal valve and distal valve PICCs was less conclusive (15).

We designed a prospective, randomized trial comparing PICCs with

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two distinctively different designs and materials: the proximal valve polyurethane PICCs (Vaxcel with PASV technology; Boston Scientific Corporation, Natick, Massachusetts) versus the distal valve silicone PICCs (Groshong, Groshong Peripherally Inserted Central Venous Catheter set; Bard, Salt Lake City, Utah). The objectives were to evaluate and compare the relative durability and complications between these two catheter groups as well as to assess if any patient- or procedure-related factors were associated with the complications.

MATERIALS AND METHODS

Subjects

Institutional review board approval was obtained for this prospective, randomized trial. Over a 20-month period between August 2005 and April 2007, 393 patients were recruited. All patients gave written informed consent for the trial. The 500 PICC insertions that were to be performed (250 for each of the two catheter groups) were randomized with the help of a statistician. Five hundred sealed envelopes labeled with consecutive numbers were prepared, each containing a name of the PICC to be used per the randomized list. An envelope was opened by an intervention nurse in consecutive order just before each procedure, and the corresponding PICC was inserted for that particular patient.

The 393 patients received a total of 459 PICC insertions. Proximal valve polyurethane PICCs were inserted on 228 occasions and distal valve silicone PICCs on 231 occasions. Sixty-seven patients, each receiving one PICC, were excluded from the study because of (i) death from underlying morbidity while the catheters were in situ (n = 38), (ii) no follow-up data due to transfer to other institutions (n = 21), and (iii) self-request of removal of catheters and discharge against medical advice (n = 8).

The final study group thus comprised 326 patients with a mean age of 50.4 years (**Table 1**). A total of 392 PICC insertions were performed in these patients. A patient with prior catheter insertion who received a new catheter again during the study period was considered as a new patient for the study. Two hundred eighty-six patients had one PICC insertion each, 34 patients had two, six patients had three, and five patients had four.

Table 1
Patient Demographics, Underlying Morbidity, and Primary Indications for PICC Insertion

Catheter	PVPP	DVSP	*P* Value
Number	198	194	
Age (y)			.09
Mean ± SD	49.0 ± 15.8	51.9 ± 17.9	
Range	18–84	18–89	
Sex			.25
Male	119 (60.1%)	128 (66.0%)	
Female	79 (39.9%)	66 (34.0%)	
Underlying morbidity			.06
Infection	159 (80.3%)	139 (71.6%)	
Neoplasm	37 (18.6%)	51 (26.2%)	
Other*	2 (0.01%)	4 (0.02%)	
Indications for PICCs			.07
Antibiotic	159 (80.3%)	139 (71.7%)	
Chemotherapy	34 (17.2%)	40 (20.6%)	
TPN	5 (2.5%)	14 (7.2%)	
Fresh Frozen Plasma	0	1 (0.5%)	

Note.—DVSP = distal valve slicone PICC; PVPP = proximal valve polyurethane PICC; TPN = total parentheral nutrition. Numbers in parentheses are percentages within each catheter group.
*Includes bowel obstruction (n = 3), pancreatitis (n = 1), and hepatic failure (n = 1).

Catheters

In this trial, we compared the proximal valve polyurethane Vaxcel PICC® with Pressure Activated Safety Valve (PASV) with the distal valve silicone Groshong PICCs.

Both catheters were 4 F in diameter and 60 cm in length, with 17-gauge and 18-gauge lumens for the proximal valve polyurethane and distal valve silicone PICCs, respectively.

In addition to the catheter materials, the critical differences between the two catheters were the designs and placements of the catheter valves. The proximal valve polyurethane (Vaxcel) PICCs had the patented PASV built proximally within the hubs. The distal valve silicone (Groshong) PICCs incorporated their patented Groshong valves distally near the rounded, closed catheter tips. Both were pressure-sensitive valves that remained closed when subjected to normal central venous pressure. When positive pressure was applied into the catheters, the valves would open to allow infusion. With negative pressure, the valves would open the other way, allowing aspiration.

PICC Insertion Procedure

All the PICCs were inserted by interventional radiologists in the angiography suite under radiologic guidance (16). The patient was positioned with the arm extended and abducted at 90° or as tolerated. The arm was cleaned and draped with a tourniquet applied over the upper arm. Under direct sonographic guidance, a suitable vein in the mid arm was identified and entered using a 22-gauge venous cannula after subcutaneous administration of 1% lidocaine for local anesthesia (17). Venograms were not routinely performed. A 0.018-inch guide wire was then passed through the cannula into the vein, and the cannula was exchanged for a 4.5 F peel-away sheath. With a proximal valve catheter, the guide wire was advanced under fluoroscopic screening until the tip was located in the region of the superior cavoatrial junction, and the distance to the venepuncture site was measured. The catheter was cut to the appropriate length by trimming its distal end and inserted through the sheath. With a distal valve catheter, the catheter was advanced through the peel-away sheath under fluoroscopic guidance until the tip was located in the region of the superior cavoatrial junction. The catheter was trimmed to the appropriate length by cutting its

proximal end, which was then connected to the assembled hub.

The final position of the catheter tip was confirmed and documented radiographically (18). The sheath was peeled away, and the catheter was sutured through the suture wing onto the skin, close to the entry site. The catheter was aspirated until adequate blood return was noted and flushed with 20 mL of normal saline to ensure patency. The venepuncture site was cleaned and covered with a clear sterile dressing.

In a patient whose existing catheter failed from an inflammatory or infective cause, a new PICC would be inserted through the contralateral arm. In a patient whose existing PICC failed from a noninflammatory or infective cause, a new catheter was inserted through a different vein of the same arm or through a vein in the opposite arm.

The catheter care was in accordance with the hospital nursing protocol and as recommended by the manufacturers. Blood draws through the PICCs were allowed. The lines were flushed thoroughly with 20 mL of normal saline after each use or at least every 7 days. The dressings were changed after the first 24 hours and then at least every 7 days or earlier if needed.

The procedural data collected were the information on the arm used, peripheral vein accessed, catheter tip position, number of attempts required, and any procedural complications, such as resistance encountered during catheter placement and hematoma at the site of venepuncture (**Table 2**).

Table 2
Procedural Data

Catheter	PVPP (n = 198)	DVSP (n = 194)	P Value
Arm used			.57
Right	161 (81.3%)	162 (83.5%)	
Left	37 (18.7%)	32 (16.5%)	
Vein accessed			.59
Basilic	153 (77.3%)	152 (78.3%)	
Cephalic	23 (11.6%)	17 (8.8%)	
Venae commitantes	22 (11.1%)	25 (12.9%)	
Catheter tip placement			.88
Cavoatrial junction	95 (48.0%)	95 (49.0%)	
Superior vena cava	74 (37.4%)	74 (38.1%)	
Right atrium	29 (14.6%)	25 (12.9%)	
Attempts			.73
1	163 (82.3%)	153 (78.9%)	
2	25 (12.7%)	31 (16.0%)	
3	5 (2.5%)	7 (3.6%)	
4	2 (1.0%)	2 (1.0%)	
5	0	0	
6	3 (1.5%)	1 (0.5%)	
Mean	1.29 ± 1.04	1.29 ± 1.02	
Procedural complications			.75
Resistance	5 (2.5%)	4 (2.1%)	
Hematoma	1 (0.5%)	1 (0.5%)	

Note.—PVPP = proximal valve polyurethane PICC; DVSP = distal valve slicone PICC.

Follow-up

The catheter maintenance was performed by the ward nurses for the inpatients and the oncology or antibiotic clinic nurses for the outpatients. The catheter status, with or without any complications, was documented daily or at each visit to the clinic by the nurses. The follow-up parameters recorded were the date and reasons for catheter removal.

A PICC was considered a success when it was removed only after completion of the patient's therapy, for which the catheter was inserted.

Phlebitis was diagnosed if erythema or induration, warmth, pain, or tenderness existed around the catheter exit site (19). Exit-site infection was diagnosed when erythema, induration, or tenderness was noted around the catheter exit site, associated with other signs and symptoms of infection, such as fever or pus emerging from the exit site, with or without concomitant bloodstream infection (19). Definite catheter-related bloodstream infection (CRBSI) was defined as isolation of the same organism (identical species and antibiogram) from the catheter segment and the peripheral blood culture in a patient with clinical symptoms of bloodstream infection and no other apparent source of infection (20). Probable CRBSI was defined as positive culture either from catheter segment or peripheral blood in a patient with clinical symptoms of bloodstream infection and no other apparent source of infection, defervescence within 48 hours of catheter removal, and initiation of appropriate antibiotic therapy (20).

A catheter was occluded when resistance, which significantly compromised the use of the catheter for infusion of its assigned therapy, was encountered. Inability to draw blood through the catheter by itself was not considered as occlusion.

Statistical Analysis

Statistical analysis was performed with commercially available software (SPSS, version 16, SPSS, Chicago, Illinois). Continuous variables were expressed as mean ± standard deviation or range when appropriate. The differences between the two catheter groups for patient demographics, indication, underlying morbidity, procedural data, and outcome were investigated with χ^2 test for categorical variables and student t test for continuous variables. Univariate and multivariate logistic regression analyses were carried out to investigate the association of patient's age, sex, underlying morbidity, indication, arm used, peripheral vein accessed, catheter tip placement, number of venepuncture attempts, and the type of catheter used with the incidence of complications.

RESULTS

PICC insertions were successful in all patients, with 94.9% of the venepunctures achieved with no more than two attempts and 80.6% on first attempts. Resistance was encountered during catheter placements in nine pa-

tients; these required the use of 0.018-inch guide wires (Terumo, Somerset, New Jersey) to negotiate stenotic or partially occluded veins to reach the superior vena cava. Hematoma developed at the venepuncture sites in two patients during the procedures (**Table 2**).

The most common underlying morbidity and indication was infection requiring long-term intravenous antibiotics, accounting for 76.0% of our total study population (**Table 1**). There were no statistically significant differences in the patient demographics, underlying morbidity, and primary indication for insertion of PICCs between the two catheter groups (**Table 1**). Similarly, no significant differences in the arm used, vein accessed, catheter tip placement, number of attempts required to gain venous access, and procedural complication were noted between the two catheter groups (**Table 2**).

The mean catheter dwell time was 27.8 days (range, 2–245 days) for the proximal valve polyurethane PICCs and 23.3 days (range, 1–168 days) for the distal valve silicone PICCs. The total catheter days were 5,494 and 4,524 for the proximal valve polyurethane PICCs and the distal valve silicone PICCs, respectively.

A statistically significant difference in the total complication rate between the proximal valve polyurethane PICCs (26.8%) and the distal valve silicone PICCs (47.9%) was found ($P < .001$) (**Table 3**). The use of proximal valve polyurethane PICCs was associated with an absolute complication risk reduction of 21.1% or a relative complication risk reduction of 44.1% when compared with the use of distal valve silicone PICCs.

This difference was a result of significantly higher incidence of phlebitis ($P = .003$) and infection ($P = .043$) associated with the distal valve silicone PICCs (**Table 3**). Although the incidences of catheter occlusion, fracture, and dislodgement were also more common in the distal valve silicone PICCs, the difference was not statistically significant (**Table 3**).

A total of 16 cases of catheter-related infections (1.6 infections per 1,000 catheter days) were encountered, four in the proximal valve polyurethane PICCs (0.7 infection per 1,000 catheter days) and 12 in the distal valve silicone PICCs (2.7 infections per 1,000 catheter days). Seven cases of definite CRBSI, with *Klebsiella pneumoniae* ($n = 3$), methicillin-resistant *Staphylococcus aureus* ($n = 2$), *Escherichia coli* ($n = 1$), and coagulase-negative *Staphylococcus* ($n = 1$) were isolated from the catheter tips and peripheral blood cultures. Nine cases of probable CRBSI were identified with all the organisms, which included *Pseudomonas aeruginosa* ($n = 5$), *Acinetobacter baumannii* ($n = 2$), *Pseudomonas aeruginosa* plus methicillin-resistant *S aureus* ($n = 1$), and *A baumannii* plus coagulase-negative *Staphylococcus* ($n = 1$), grown from the catheter tips and none from the peripheral blood cultures.

A univariate logistic regression analysis of the data showed no statistically significant association between the incidence of complications and the patient's age, sex, underlying morbidity, primary indication, arm used, vein accessed, catheter tip placement, or number of venepunctures attempted (**Table 4**). The catheter type was the only variable in our study that showed a significant correlation with the complication rate ($P < .001$). Multivariate regression analysis also showed that distal valve silicone PICCs (DVSPs) were associated with a significantly higher complication rate corrected for all other factors.

Table 3
Completion of Therapy and Complications

Catheter	PVPP ($n = 198$)	DVSP ($n = 194$)	P Value
Completion of therapy	145 (73.2%)	101 (52.1%)	<.001
Total complications	53 (26.8%)	93 (47.9%)	<.001
Phlebitis	23 (11.6%)	45 (23.2%)	.003
Infection	4 (2.0%)	12 (6.2%)	.043
Exit site infection*	2 (1.0%)	4 (2.1%)	
Definite CRBSI	2 (1.0%)	5 (2.6%)	
Probable CRBSI	2 (1.0%)	7 (3.6%)	
Catheter occlusion	19 (9.6%)	23 (11.9%)	.516
Catheter fracture/leakage	2 (1.0%)	7 (3.6%)	.102
Catheter dislodgement	5 (2.5%)	6 (3.1%)	.769

*All the six cases of exit site infection had concomitant blood stream infection.

Table 4
Univariate Logistic Regression Analysis for Complications

Variable	Odds Ratio	95% Confidence interval	P Value
Age	1.01	0.99–1.02	.31
Sex	1.05	0.68–1.60	.83
Underlying morbidity	1.19	0.77–1.82	.42
Primary indication	1.27	0.89–1.81	.18
Arm used	0.73	0.43–1.23	.24
Vein accessed	1.15	0.86–1.55	.35
Catheter tip placement	0.93	0.75–1.11	.54
Number of venepuncture attempt	1.22	0.98–1.51	.15
Catheter	2.52	1.61–3.80	<.001

DISCUSSION

Our study found a significant difference in the complication rates between the two catheter types. The DVSPs were associated with a significantly higher incidence of complications, particularly phlebitis and catheter-related infection.

The two catheter groups that were compared in this study differed primarily in the designs and locations of the valves as well as the materials from which they were made.

One hypothesis of the advantage of placing the catheter valves proximally in the hubs rather than distally at the catheter tips was that the valves would not be in direct contact with the bloodstream. As a result, the valves

would not be affected by platelet aggregation or fibrin formation that might lead to their malfunctions and subsequent catheter occlusions. Our study found no significant difference in the occlusion rate between the two PICC groups ($P = .516$). However, as the lumen size (18-gauge) favored the distal valve silicone PICCs, the actual benefit of the 17-gauge proximal valve polyurethane PICCs in reducing occlusion might be underrepresented.

Our study found a relatively lower incidence of catheter fracture (2.3%) and catheter dislodgement (2.8%) when compared with a similar study evaluating proximal valve against distal valve PICCs, which showed 28.0% and 5.0% catheter fracture rates and dislodgement rates, respectively (15). We observed from previous experience (unpublished data) that leaving excessive and redundant catheter length external to the skin entry sites frequently resulted in catheter kinking and fractures as well as accidental dislodgements. We therefore sutured all our PICCs with the suture wings fixed fairly close to the skin entry sites. This might explain our relatively lower incidence of catheter fractures and dislodgements. A significantly higher rate of catheter fracture was noted by Hoffer et al (15) in the distal valve PICCs. Although we found more fractures in our distal valve silicone PICCs, the difference was not statistically significant ($P = .102$), largely because of an overall low incidence (**Table 3**).

Phlebitis ($P = .003$) and to a lesser extent, catheter-related infections ($P = .043$) were found in our study to be significantly more common in the distal valve silicone PICCs. To assemble the hubs of the distal valve silicone PICCs, extra catheter length external to the skin entry site was needed when compared with the proximal valve polyurethane PICCs. The extra catheter length resulted in more movement of the redundant catheters at the skin entry sites, particularly during handling of the catheters and changing of the dressings. This was noted by Mazzola et al (21) as a significant predisposing factor in the development of phlebitis. An in vivo study by Sherertz et al (22) found that silicone catheters had a greater risk of grossly apparent infection and harbored a larger number of organisms by quantitative culture than catheters made of other materials, including polyurethane. Similar findings, with regard to the adherence of *S aureus* to silicone and to polyurethane catheters, were noted by Balaban et al (23).

Our overall rate of phlebitis (17.3%) was higher when compared with several previous studies (12,15,24). However, the previous studies had stricter criteria for the definition of phlebitis, which was diagnosed if there was clinically palpable cord along the vein or positive sonographic evaluation (12,15). A study by Chlebicki et al (7), which used the same definition for phlebitis as our study, showed a similar rate of 21.3% for phlebitis. The tips of all the 68 PICCs removed because of underlying phlebitis in our study were sent for culture, and all results were negative.

Our catheter-related infection rate of 1.6 per 1,000 catheter-days was very comparable to the mean overall pooled rate of 2.1 PICC-related bloodstream infections per 1,000 catheter-days reported in the literature (25,26).

A few studies showed a higher complication rate in PICCs used for total parenteral nutrition (TPN) (4,9,27). However, we found no significant association between the incidence of complications and the infusates used ($P = .18$), although the number of catheters used for TPN was relatively small (**Table 4**).

No significant difference was noted in the occlusion rates between the two catheter groups ($P = .516$). Declotting of occluded PICCs was not performed, as we were uncertain of its cost effectiveness in the setting of our center. In addition, the cost of delay in patients' therapies during the declotting procedure could not be quantified, particularly for the majority of our patients who relied on uninterrupted administration of antibiotics to reach effective blood-antibiotic levels for their underlying infections (15). All PICCs deemed occluded in our center were removed and replaced.

In contrast to most of the other studies on PICCs, we excluded all our patients from our final data analysis who died with the catheters in situ, because the eventual outcomes of these catheters could not be ascertained per our definitions. We also included catheter dislodgement as one of our complications when most studies excluded it.

There were certain limitations to our study. The radiologists who performed the PICC insertions could not be blinded to the type of PICC used because of the different appearances of the PICCs. Second, operator-induced (radiologists and catheter nurses) bias could not be eliminated because of the large number of patients recruited for this study. By randomizing a relatively large study population, standardizing the insertion procedure and catheter care, and adhering to objective definitions of the complications and study endpoints, we aimed to minimize any potential bias.

Our prospective, randomized study found that the proximal valve polyurethane PICCs were more durable than the distal valve silicone PICCs, with a significantly lower incidence of complications, particularly phlebitis and catheter-related infections.

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