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Bard PowerPICC Solo2 vs Cook Turbo-Ject: A Tale of Two PICCs

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Abstract

Purpose: To compare the complications experienced for 2 different brands of peripherally inserted central venous catheters (PICC), Cook Turbo-Ject and the Bard PowerPICC Solo2. The rationale for this project revolved around concern that one of the PICCs in question had high rates of complications.

Methods: A prospective clinical trial was conducted after obtaining approval from the University of Saskatchewan Human Research Ethics Committee. All PICCs were implanted at the Royal University Hospital Medical Imaging Department by an interventional radiologist. Patient randomization was achieved by alternating the brand of PICC implanted in sequential patients. All the subjects were inpatients from a single surgical ward. Patients were excluded from the study if they had a known uncorrected coagulopathy, or if they were being treated for venous thrombosis. This project was financially supported by the Summer Student Research Fund, College of Medicine, University of Saskatchewan.

Results: A total of 53 PICCs (25 Bard and 28 Cook) were inserted over the study period. The mean PICC dwell time was 23.3 days for both the Bard and Cook PICCs, respectively. No statistically significant differences were detected in study group demographics, technical placement of the PICCs, or in the complications encountered.

Discussion: Both the Cook Turbo-Ject and the Bard PowerPicc Solo2 PICCs provided acceptable venous access for a wide variety of clinical indications.

Résumé

Objectif : Comparer les complications observées pour deux marques de cathéters centraux insérés par voie périphérique (CCIP), soit le Turbo-Ject de Cook et le PowerPICC Solo2 de Bard. Le projet avait pour objet de vérifier les allégations selon lesquelles un de ces CCIP présentait des taux supérieurs de complications.

Méthodes : Un essai clinique prospectif a été réalisé après approbation du Comité d'éthique en recherche sur l'humain de l'Université de la Saskatchewan. Tous les CCIP ont été insérés par un radiologiste spécialisé en intervention au service d'imagerie médicale du Royal University Hospital. La randomisation des patients a été obtenue en alternant la marque de CCIP insérée chez les patients de façon séquentielle. Tous les sujets étaient des patients hospitalisés dans une même unité de chirurgie. Les patients qui présentaient une coagulopathie connue non corrigée, ou qui étaient traités pour une thrombose veineuse ont été exclus de l'étude. Le projet a été financé par le Summer Student Research Fund, du Collège de médecine de l'Université de la Saskatchewan.

Résultats : Au total, 53 CCIP (25 Bard et 28 Cook) ont été insérés pendant la période d'étude. La durée moyenne pendant laquelle les CCIP ont été en place était de 23,3 jours pour les deux marques. Aucune différence statistiquement significative n'a été décelée concernant les caractéristiques démographiques du groupe étudié, l'insertion technique des CCIP ou les complications observées.

Discussion : Le Turbo-Ject de Cook et le PowerPicc Solo2 de Bard offrent tous deux un accès veineux acceptable pour un large éventail d'indications cliniques.

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Key Words: Interventional radiology; Venous access; Peripherally inserted central venous catheter; Complications

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One of the great advances in medicine was the ability to gain intravenous (IV) access, which has allowed safe and effective administration of nutrition, blood products, fluids and drugs, as well as the ability to withdraw blood samples. Safe IV access is invaluable to the health care system and is a vital component to patient care. The development of the modern IV needles and catheters has a long and complex history. Much of the impetus for the development of IV technology revolved around the need for reliable venous access for the delivery of blood transfusions and fluid replacement. Although physicians have been experimenting with IV access for the past 500 years, modern IV access, therapies, and equipment have only been in practice for about 25 years [1].

Today, PICCs are used to administer nutrition, blood products, fluids, or medications (ie, chemotherapy or antibiotics). PICCs have gained popularity because they are safe and effective for patients who require long-term venous access [2,3]. PICCs have a lower risk of infection and intraprocedural complications, and overall are less expensive compared with central venous catheters [4–6]. A complication of central venous catheters is catheter fracture and embolization that results from the “pinch-off syndrome,” that is, compression of the catheter between the clavicle and first rib [5]. The PICC is inserted into a peripheral vein, thus avoiding the “pinch-off syndrome” [5]. In addition, PICC design allows for ease of maintenance and can facilitate patient mobilization and earlier patient discharge.

PICCs have definite advantages, but complications exist. Early events include catheter-related problems, such as incorrect tip position; catheter migration; line fracture; and procedure-related events, such as bleeding and insertion site trauma [7]. Late events include infection, catheter fracture and migration, venous thrombosis, and catheter dysfunction [7]. Catheter occlusion and infection are common complications, with an incidence of 7%–25% [4–6,8–11].

A wide variety of PICCs are available from various manufacturers, each designed with unique properties. In this study, we compared the complication rates of 2 PICC designs from 2 different vendors: the Cook Turbo-Ject (Cook Medical, Stouffville, ON) and the Bard PowerPICC Solo2 (Bard Canada Inc, Mississauga, ON). The impetus for this project centred around the concern that one of the PICCs in question had an increased rate of complications.

Methods

A prospective clinical trial was conducted at the Royal University Hospital (RUH) for inpatients from a single surgical ward, after obtaining approval from the University of Saskatchewan Ethics in Human Research Board. Informed consent was obtained from all patients. All PICCs were placed in the RUH Medical Imaging Department by an interventional radiologist. Randomization was achieved by alternating the brand of PICC implanted in the patients. A patient with a prior PICC was considered a new patient if he or she required another PICC in the contralateral or

ipsilateral arm. Patients were excluded from the study if they had a known uncorrected coagulopathy or if they were being treated for a known venous thrombosis. Pregnant women also were excluded.

Patients were followed-up by using a standardized data collection form. The nursing team on the surgical ward were involved in the design of the project and agreed to document PICC-related problems during the study period on the form. The nurses were not permitted to flush any PICC from which blood could not be aspirated. Therefore, if the nurses were unable to restore the function of a PICC by replacing the injection cap, adjusting the PICC dressing, or repositioning the patient when they could not aspirate blood, then they were instructed to contact the interventional radiology suite for an imaging examination of the PICC.

All PICCs that could not be aspirated by the nursing team were assessed in the interventional radiology suite by injecting a water-soluble contrast agent during fluoroscopy. The presence of a fibrin sheath was defined as the accumulation of contrast agent in a confined space that surrounded the distal tip of the PICC, which restricted the flow of the injected contrast. The clinical team and the nursing team also were to report all PICC complications to the interventional radiology suite for assessment. All PICCs were followed-up until they were no longer in situ due to the discontinuation of care or the termination of the PICC related to a complication.

In addition to the prospective data collection, a retrospective chart review was performed for all study group subjects to document any clinical or nursing notes that pertained to PICC-related complications. This project was financially supported by the Summer Student Research Fund, College of Medicine, University of Saskatchewan.

PICC Description

The Bard PowerPICC Solo2 is indicated for long-term (more than 30 days) or short-term (fewer than 30 days) venous access, IV therapy, power injection of contrast media, and central venous pressure monitoring. The Bard PowerPICC Solo was developed in 2007 and was enhanced in 2008 as the Bard PowerPICC Solo2. It is designed with a kink-resistant polyurethane reversed-tapered design for over-the-wire placement. It contains 3 internal valves, all located within the hub. The larger valve is opened by a positive pressure created by gravity, a pump, or a syringe to allow for fluid infusion. The 2 smaller valves are opened when a negative pressure is applied, which allows for blood withdrawal. The valve system controls the flow of fluids and provides for a clamp-free strategy. The 2008 improvements allowed the PICC valves to operate in a wider range of aspiration pressures, with lower pressures required to open the valves for aspiration and infusion. Otherwise, the Bard PowerPICC Solo2 design is the same as the original Bard PowerPICC Solo. The 5F double-lumen catheter was used for this study. Both lumens of the PICC were identical in internal diameter. The maximum power injection rate was 5 mL/s, with a maximum pressure rate of 300 psi.

The Cook Turbo-Ject is a polyurethane, over-the-wire PICC intended for short- or long-term use. Indications for use include venous pressure monitoring, blood withdrawal, administration of drugs or fluids, and power injection of contrast and other fluids. The design used for this study was the 5F double-lumen catheter. Both lumens of the PICC are identical in internal diameter. The maximum flow rate was 5 mL/s, with a maximum pressure of 325 psi. The Cook Turbo-Ject PICC has no intrinsic valve technology and each lumen has an external plastic clamp to control lumen flow. In addition to the intrinsic valves or the external clamp technology of the PICCs, an external, needleless valve was attached to each lumen of the catheter by the ward nursing team. This was a single lumen, needleless valve (ICU Medical Inc, San Clemente, CA).

After informed consent was obtained, all PICCs were implanted by an interventional radiologist in the vascular/interventional suite by using the aseptic Seldinger technique. All PICCs were 5F dual-lumen design. All PICCs were inserted in the same fashion, no unusual techniques were used for a particular PICC. Each PICC was implanted by using a peel-away sheath.

The method used for venipuncture was left to the discretion of the interventional radiologist who was inserting the PICC by using ultrasound or venography. If the basilic vein was identified, then it was preferentially used for venous access. Local anesthesia was administered at the puncture site by using 1% lidocaine. Venous access was achieved with a Cook micropuncture set that consisted of a 21-gauge access needle and a 0.18-inch-diameter, platinum-tipped, guidewire (Cook Canada Inc, Mississauga, ON). The needle and guidewire were replaced with a 6F peel-away sheath. By using fluoroscopy, a guidewire was positioned in the distal superior vena cava (SVC). The length of the guidewire was marked. The PICC was cut to match the guidewire length (from the skin surface to the distal SVC). The wire was inserted into the PICC, and the combination was introduced via the peel-away sheath. The PICC was advanced, by using fluoroscopy, into the SVC. The guidewire and the peel-away sheath then were removed. Each catheter lumen was flushed with sterile saline solution and dead end caps were placed on each lumen. Both PICCs had suture wings incorporated into the design of the catheter. The PICCs were affixed to the patient's skin by using 2–0 Prolene suture material (Johnson & Johnson Inc, Markham, ON) in both suture wings of the catheter. Chest fluoroscopy was used to ensure proper PICC tip placement at the SVC–right atrial junction. A sterile dressing was applied at the insertion site. External needleless valves were placed on each lumen of the PICC when the patient reached Surgical Ward 5000. All PICCs were managed identically from the perspective of aspiration, flushing, and dressing strategies.

Maintenance of PICCs

The nursing team on Surgical Ward 5000 was responsible for the general maintenance of the PICCs. If any

complications arose, such as those involving blood withdrawal, or flushing, then vascular/interventional radiology was contacted for evaluation. The nursing staff was required to follow a standard flushing and blood withdrawal protocol, which was identical for both PICCs. Nonheparinized saline solution was used as the flushing solution for all patients.

The PICC lumen flushing protocol was as follows:

1. Aspirate until blood return into the syringe is achieved to ensure clearance of the PICC lumen.
2. With a 10-mL syringe, flush the PICC lumen with 10 mL 0.9% NaCl by using the stop-start technique.

The PICC blood withdrawal protocol was as follows:

1. Aspirate until blood return into the syringe is achieved to ensure clearance of the PICC lumen.
2. Draw 5 mL of blood into same syringe by slowly pulling and holding the plunger and allowing the valve to open. Discard the syringe.
3. Attach a Vacutainer (BD Canada, Mississauga, ON) or syringe and slowly aspirate the blood sample.
4. Flush the PICC lumen with 10 mL of 0.9% NaCl by using the stop-start technique.

Statistical Analyses

The PICC brand (Bard or Cook) was the independent variable. PICC complications were the primary dependent variable. Age, sex, insertion vein, PICC tip position, reason for PICC insertion, primary and secondary diagnoses, diabetes, and method of insertion (ultrasound vs fluoroscopy) were evaluated as potential confounders. Descriptive statistics were used to summarize data. Means (standard deviations) were calculated for continuous data, and frequencies were calculated for categorical data. Between-group comparisons of categorical data were performed with χ^2 testing. Two group comparisons of continuous data were tested with Student *t* test (2 tailed). Any analysis that demonstrated a $P < .05$ was considered statistically significant. Analysis was carried out with SAS statistical software version 9.2 (The SAS Institute Inc, Cary, NC).

Results

A total of 53 PICCs were inserted (Bard, $n = 25$; Cook, $n = 28$). Each variable in patient demographics, technical placement of the PICC, complications were analysed independently for statistical differences. There were no statistically significant differences for age, sex, diabetes, and primary or secondary medical diagnosis between the 2 PICC groups ($P > .05$) (Table 1). There were no significant differences detected between the groups regarding method of insertion, PICC insertion location, tip position, reason for insertion, or duration of PICC insertion ($P > .05$) (Table 2). The average number of days the PICCs were inserted per patient was 23.3 (range, 7–55 days) and 23.3 (range, 2–92 days) for the

Table 1
Patient demographics and disease parameters

Patients	PICC brand ^a		P value
	Bard (n = 25)	Cook (n = 28)	
Women	15 (65.2%)	18 (66.7%)	.914
Age (y)	56.2 ± 4.7	61.7 ± 3.7	.358
Diabetes			
Yes	7 (28%)	5 (17.8%)	.331
No	15 (60%)	22 (78.6%)	
Unknown	3 (12%)	1 (3.6%)	
Primary diagnosis			No P value <.346
Neoplastic	4 (18.2%)	11 (42.3%)	
Gastrointestinal	8 (36.4%)	7 (26.9%)	
Infection	8 (36.4%)	6 (23.1%)	
Other ^b	2 (9.1%)	2 (7.7%)	
Unknown	3	2	

n = number of patients; PICC = peripherally inserted central venous catheter.

^a The numbers in parentheses indicate the percentage for each brand of PICC.

^b Includes respiratory (n = 1), genitourinary (n = 2), and metabolic (n = 1).

Bard and Cook groups, respectively. The total indwelling catheter days for the Bard PICC was 898 and for the Cook PICC was 658.

There were no unique complications encountered in this cohort, all complications encountered were recognized complications of PICCs that have previously been documented in the literature. The total number of patients who experienced complications for both catheter types was 19 of 53 (35.8%), a complication rate of 12.2/1000 catheter days. There were no statistically significant differences in

Table 2
PICC implantation parameters

PICC placement ^a	PICC brand		P value
	Bard (n = 25)	Cook (n = 28)	
Reason for insertion			
Total parenteral nutrition	21 (84.0%)	20 (71.4%)	.275
Others ^b	4 (16.0%)	8 (28.6%)	
Method of insertion			
Ultrasound	0 (0.0%)	2 (7.4%)	.225
Fluoroscopy	19 (100.0%)	25 (92.6%)	
PICC location			
Arm			
Right	12 (48.0%)	16 (57.1%)	.506
Left	13 (52.0%)	12 (42.9%)	
Vein			No P value <.322
Basilic	22 (88.0%)	20 (71.4%)	
Brachial	2 (8.0%)	6 (21.4%)	
Cephalic	1 (4.0%)	2 (7.1%)	
Tip position			
SVC	20 (87.0%)	21 (75.0%)	.480
Cavoatrial junction	3 (13.0%)	7 (25.0%)	
No. days inserted (mean ± SE)	23.3 ± 3.1	23.3 ± 3.3	.986

n = number of patients; PICC = peripherally inserted central venous catheter; SE = standard error; SVC = superior vena cava.

^a Unavailable data: method of insertion: Bard (n = 6), Cook (n = 1); tip position: Bard (n = 2).

^b Includes antibiotics (n = 2), intravenous access (n = 8), and chemotherapy (n = 2).

complications between the 2 PICC brands used in the project. Complications encountered are summarized in Table 3.

There were 12 patients (48%) in the Bard PICC group who experienced a total of 15 complications, an event rate of 16.7/1000 catheter days. The most common complication in this group was skin fixation failure, which occurred in 6 cases, for an event rate of 6.7/1000 catheter days. In 4 of the 6 cases, it was proven that this was the result of the skin suture working out of the skin anchor point. The second most common complication in this group was PICC occlusion, which occurred in 5 instances, all due to fibrin sheath formation. The event rate of fibrin sheath for the Bard PICC was 8.9/1000 catheter days.

There were 7 patients (25%) in the Cook group who experienced a total of 10 complications, an event rate of 15.2/1000 catheter days. Skin fixation failure was encountered in 3 cases, an event rate of 4.6/1000 catheter days. In one of these cases, it was proven that the sutures had worked their way out of the skin. Occlusion developed in 3 Cook PICCs, 2 of which were encased by fibrin sheath formation. The event rate of fibrin sheath formation for the Cook PICC was 3.0/1000 catheter days. The third catheter in this cohort was totally occluded and had to be removed. It was suspected that 3 of the Bard PICCs and 3 of the Cook PICCs became infected: event rates of 3.3/1000 and 4.6/1000 catheter days, respectively. All of these catheters were removed on the ward, and none of these cases had cultures performed. One of the subjects in the Cook group developed central venous thrombosis that terminated at the axillary-subclavian vein junction. This was diagnosed by Doppler ultrasound. The event rate for venous thrombosis was 1.5/1000 catheter days for the Cook PICC.

Discussion

PICCs have gained popularity over central venous catheters because they are safe; easy to insert; effective for administering nutrition, fluids, or medication; easy to maintain and remove; and can be used for prolonged periods of time. However, PICCs are still challenged, with complications and the costs associated with the additional care related to the management of these complications.

In discussing the overall complication rates for patients with PICCs, it is evident that the rate of complications is highly variable. A tabulation of PICC complications demonstrates that the percentage of PICCs with complications varies between 23.2% and 40.7% (6.8–16.7/1,000 catheter days) [2,4,9,11–15]. The compilation of this previous data is summarized in Table 4.

Ong et al [12] performed a side-by-side comparison of 2 different PICC brands and found complication rates that varied between 26.8% and 47.9% [12]. The complication rate for the Bard group (48%) falls at the upper end of this range, whereas the Cook group complication rate (25%) was at the lower end of this range.

Occlusion was one of our most common complications: 5.6/1000 catheter days for the Bard group and 4.6/1000 catheter days for the Cook group. To prevent PICC

Table 3
PICC complications

PICC type	Bard (n = 25)		Cook (n = 28)		P value
Total catheter days	898		658		
Patients complications					
No	13 (52%)		21 (75%)		.506
Yes	12 (48%)		7 (25%)		
Both catheters combined	19/53 (35.8%)				
Complications experienced	n	Events/1000 catheter days	n	Events/1000 catheter days	
PICC infection, suspected	3	3.3	3	4.6	
PICC occlusion	5	5.6	3	4.6	
Skin fixation failure	6	6.7	3	4.6	
Migration of PICC tip	1	1.1	0	0	
Thrombosis	0	0	1	1.5	
Total complications	15	16.7	10	15.2	

n = number of patients; PICC = peripherally inserted central venous catheter.

occlusion, positive pressure must be maintained throughout the line, which prevents blood reflux into the PICC lumen. To diminish the possibility of occlusion, different manufacturers have modified their PICC design, it is hoped, to prevent blood reflux. Previous studies have proven the benefit of a valved system in diminishing PICC occlusion [4,16]. Both Hoffer et al [4] and Hinson and Blough [16] found statistically significant reductions in catheter occlusion when a valved PICC was deployed. The Cook Turbo-Ject PICC is designed with external-line clamps, whereas the Bard PowerPICC Solo2 incorporated an internal valve system. However, because an external needleless valve was affixed to both PICCs, the net result was valve protection for the both PICCs in our study, which prevented any disparity between the 2 PICC designs.

The most common cause of obstruction in our study population was fibrin sheath formation, which prevented aspiration and blood withdrawal; this was the cause for all of the occlusions in the Bard group and two-thirds of the occlusions in the Cook group. Fibrin sheath formation is a complex, multifactorial complication for which there is no reliable preventative strategy [17,18].

A substantial number of PICCs demonstrated skin fixation failure, 6 in the Bard group and 3 in the Cook group. Four of the 6 skin fixation failures in the Bard group were proven to

be caused by the skin sutures pulling through the skin, which liberated the PICC from the skin fixation points. This failure could only be proven to be the cause in one of the subjects in the Cook group. The Bard PICC seemed to be more rigid in its construction, and this rigidity may have contributed to skin fixation failure. All of our subjects were inpatients, and the severity of their illnesses may have resulted in mobility and transfer issues that preferentially affected one group more than the other. The cause of this complication remains unresolved.

There are a variety of clinical parameters that can alter complication profiles for medical devices. For instance, it has been reported that PICC complications can be greater for oncology patients [2,7,15]. In particular, Haider et al [2] demonstrated that patients with hematologic malignancies were more likely to experience complications than those with solid tumours [2]. Having said this, it should also be noted that Cheong et al [14] demonstrated that patients with solid tumours had higher complication rates than patients without malignancies. Our study population included 18.2% and 42.3% of oncology patients for Bard and Cook groups, respectively.

All of our subjects were inpatients and often were quite ill and required a greater degree of nursing care. The mobility of this group was restricted and required more transfers to and from their beds. This patient population would certainly be expected to experience more complications than a mobile outpatient cohort.

Inpatients have a greater risk of device failure, infection, and occlusion based upon previous assessment of this patient population [19,20]. Both of these researchers found that inpatients had an enhanced risk of complications in general related to the use of a PICC but also demonstrated that those inpatients who received IV parenteral nutrition were particularly at risk for PICC complications. Our patient population was specifically from an inpatient surgical ward. A high percentage of the subjects had a PICC implanted for IV parenteral nutrition: 84% for the Bard group and 74% for the Cook group.

Both the Cook Turbo-Ject and the Bard PowerPicc Solo2 PICCs provide safe and effective venous access for a variety

Table 4
Compilation of PICC complications

Study	Year	No. PICCs	Overall PICC complication rates	
			No./1000 catheter days	%
Alport et al (current study)	2011	53	12.2	35.8
Ong et al ¹²	2010	392	14.6	37.2
Haider et al ²	2009	146	14.4	32.8
Van Winkle et al ¹³	2008	39	16.2	33.3
Cheong et al ¹⁴	2004	27	12.6	40.7
Walshe et al ¹⁵	2002	366	10.9	32.8
Hoffer et al ⁴	1999	535	6.8	23.2
Smith et al ⁹	1998	555	16.7	35
Merrell et al ¹¹	1994	389	10.2	28.3

PICC = peripherally inserted central venous catheter.

of clinical indications. Neither of the PICCs studied demonstrated a statistically significant complication profile. Nursing difficulties with one of the PICCS were perceived but were not statistically validated, despite the sense that one of the PICCs in question was particularly problematic. Complications encountered while using a PICC for therapy will vary considerably based upon PICC design, patient disease, and the treatment location, to name a few possible influential variables. These variables should be taken into consideration when planning patient treatment.

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