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Performance and safety of PowerPICC catheters and accessories: a prospective observational study

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ABSTRACT

Objective This study aimed to evaluate the safety and performance of PowerPICC catheters in a real-world setting.
Design Prospective, observational, multicentre study.
Setting Nine European countries, involving 14 centres.
Participants General patient population.
Intervention PowerPICC catheter inserted by the clinician as standard of care with routinely collected outcomes followed through device removal or 180 days postinsertion.
Primary and secondary outcomes measures Safety and performance outcomes were assessed for PowerPICC, PowerPICC SOLO 2 and PowerGroshong PICC. The primary safety endpoint was the incidence of symptomatic venous thrombosis (VT), and secondary safety endpoints included phlebitis, extravasation, vessel laceration, vessel perforation local infection, accidental dislodgment and catheter-related bloodstream infection (CRBSI). The primary performance endpoint was the percentage of patients whose PowerPICC device remained in place through the completion of therapy. The secondary performance endpoints included catheter patency, placement success in a single attempt and usability.
Results The enrolled patients (N=451) received either PowerPICC, PowerPICC SOLO 2 or PowerGroshong PICC catheters. Across all devices, 1.6% of patients developed symptomatic VT, and CRBSI occurred in 1.6% of patients. There were no cases of phlebitis or extravasation and only three cases of vein laceration or vein perforation. The catheters showed high success rates in completing therapy (81.8%), maintaining patency (93.9%) and achieving successful placement in a single attempt (90.4%). Clinicians overwhelmingly agreed that both the guidewire and stylet (93.3% and 94.4%, respectively) were easy or very easy to use.
Conclusions This study demonstrates the safety and performance of PowerPICC catheters across diverse settings and patient cohorts in real-world hospital settings across Europe. The findings indicate that these catheters are safe and can be effectively used in the general patient setting and when inserted by a variety of clinicians. The low incidence of complications and high success rates further support the clinical utility of these catheters.
Trial registration number NCT04263649.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study provides real-world evidence assessment on the safety and efficacy of PowerPICC catheters.
⇒ Observations across 9 European countries and 14 centres revealed high safety and performance, despite potential variations in clinical practice across hospitals.
⇒ The study population was diverse, including patients admitted for various health diagnoses such as oncology, infection, surgical, cardiac, gastrointestinal and neurological conditions.
⇒ Patients were not randomised and underlying conditions, as well as clinical practices at the specific site, may have impacted the findings.

INTRODUCTION

Vascular access is a critical component for developing and delivering healthcare plans for hospitalised patients. Approximately 90% of patients require vascular access during hospitalisation[1] and millions of vascular access devices (VADs) are placed across Europe every year for the administration of medications, fluids, and blood products as well as for blood sampling, haemodynamic monitoring, and power injection of contrast media.[2–5] These VADs include peripheral intravenous catheters (PIVCs), peripherally inserted central catheters (PICCs), femorally inserted central catheters (FICCs), and centrally inserted central catheters (CICCs).

The selection of a particular VAD should be tailored to the needs of the patient by considering a combination of clinical factors, including the duration of therapy, infusion requirements (eg, need for multiple lumens), and risk of complications.[6] For patients requiring central access, PICCs are often preferred over CICCs and FICCs due to a reduced risk of complications associated with placement via subclavian, jugular, and femoral veins.[7] Notably, hospital systems with dedicated PICC placement teams have been shown to confer additional advantages with PICC utilisation by optimising PICC placement; these benefits include decreased patient wait times, improved patient care, and decreased costs associated with PICC

placement.[8 9] PICCs may also be employed to decrease the frequency of venipunctures required for the replacement of PIVCs in patients who require therapy for prolonged durations and for administration of infusates with certain osmolarity, pH, or cytotoxicity profiles.

Patients who receive PICCs may also require infusion of contrast media for enhanced CT. Contrast media can enhance the opacity of a target tissue or anatomical structure in order to diagnose and monitor certain diseases, including cancer, arterial stenosis, and pulmonary embolism.[10 11] However, injection of high-pressure contrast media requires delivery of these agents at well-controlled flow rates with reinforced lumens capable of withstanding the pressures associated with timed contrast infusions.[12] The need for high-pressure contrast media injection-compatible VADs has led to the development of VADs with 'power injection' capabilities. A range of power injectable-compatible PICCs are now available with multipurpose functions that provide vascular access for injection of contrast media in addition to standard uses such as intravenous therapy, blood sampling, parenteral nutrition, and venous pressure measurements.

In particular, the PowerPICC line of devices (BD, Franklin Lakes, New Jersey, USA) was introduced to the European market in 2008 and has been successfully used in hospital systems for over a decade. Therefore, it is important to fully understand the safety and performance of these devices. This is the first prospective study to further evaluate the overall safety and performance of PowerPICC catheters in a real-world setting using an observational, multicentre approach.

METHODS

Study overview and oversight

This prospective, observational, multicentre, single-arm study assessed the safety and performance of the PowerPICC catheters; the studied catheters included PowerPICC, PowerPICC SOLO 2, and PowerGroshong PICC. This study was conducted from 18 June 2020 to 5 January 2022, at 14 centres in 9 European countries (Austria, Belgium, Czech Republic, Denmark, Germany, Italy, Netherlands, Spain, and Switzerland). Good clinical practice principles were adhered to for the design, conduct, recording, and reporting of clinical investigations that assess the safety and performance of medical devices as described by the International Organization for Standardization (ISO 14155:2011), the principles of the Declaration of Helsinki, applicable sections of national laws and regulations, and EU Medical Device Regulation (Council Regulation 2017/745 of 5 April 2017). This study was registered with the National Institutes of Health clinical trial registry (NCT04263649) (online supplemental table S1). The PowerPICC devices were used for therapy as medically required. Catheter selection for patients, anatomical placement and vessel assessment were performed at the discretion of the clinician. Hence, patients were enrolled non-consecutively. Particular equipment (eg, ultrasound) or assessment protocols (eg, RaPeVa) were used as deemed necessary by the providing clinician during standard of care practice.

Patient population and study devices

Patients were considered for enrolment if they required the use of one of the study devices (PowerPICC, PowerPICC SOLO 2, and PowerGroshong PICC) for either short-term (<30 days) or long-term (≥30 days) vascular access. A key distinction between these devices is their valve-related properties; PowerPICC catheters are open-ended, PowerPICC SOLO 2 catheters have a pressure-activated proximal hub valve, and PowerGroshong catheters are closed-ended (figure 1). Additionally, PowerPICC and PowerPICC SOLO 2 are made of thermoplastic polyurethane, and PowerGroshong PICCs are made of silicone. To be eligible to participate in this study, the PowerPICC catheter selected by the clinician for patient use had to be inserted as standard of care, and the patients were expected to be available for observation through the duration of PICC therapy. Patients were excluded from the study if any of the following criteria applied: (1) the presence of any device-related infection, bacteraemia or septicaemia was known or suspected; (2) insufficient body size to accommodate the size of the implanted device; (3) known or suspected allergic reactions to materials contained in the device; (4) a history of irradiation of the prospective insertion site; (5) previous episodes of venous thrombosis (VT) or vascular surgical procedures occurred at the prospective placement site and (6) presentation of local tissue factors that would have prevented proper device stabilisation and/or

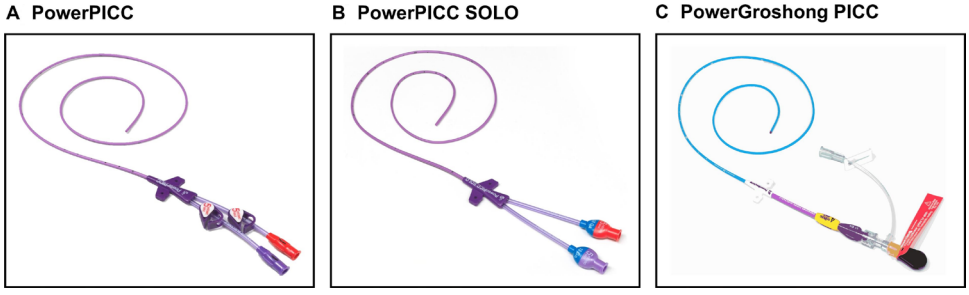

Figure 1 Example images of PowerPICC devices. (A) PowerPICC catheter with open-ended valves. (B) PowerPICC SOLO with pressure-activated proximal hub valve. (C) PowerGroshong PICC with closed-ended, three-position valve which allows fluids to flow in or out but remains closed when not in use. PICC, peripherally inserted central catheter.

access. At Austrian sites only, pregnant and breastfeeding women were excluded from the study, as requested by the Austrian Medical Device Law (MPG). Patients were followed through device removal or 180±14 days postinsertion, whichever came first, in accordance with previous studies.[13]

Clinical study endpoints

Two distinct primary endpoints were assessed in the current study in order to assess both safety and performance outcomes. The primary safety endpoint was the incidence of symptomatic VT with thrombus presence confirmed by ultrasonography or other imaging. The secondary safety endpoints were the incidence of phlebitis, extravasation, vessel laceration (vessel tissue tear), vessel perforation (hole in vessel tissue), local infection, accidental dislodgment, and catheter-related bloodstream infection (CRBSI).

The primary performance endpoint was the proportion of patients who received a PowerPICC device that was successfully used through the completion of therapy. Treatment success was defined as a device that was either still in place at the end of the 180-day observation or had been removed because the therapy was completed (end of useful medical use), changed, or cancelled. Patients who died during the study were considered as having completed the therapy. The secondary performance endpoints were the percent of catheters that were patent (ie, functional) through the completion of therapy, the percent of placement success in a single insertion attempt (based on proper tip location and patency after the first insertion attempt), and usability (based on a postinsertion survey on guidewire/stylet performance). As this was an observational study, no outcome measures were performed outside of what was considered routine practice.

Study design and procedures

The PowerPICC device was used for therapy as medically required, according to the device-specific instructions for use (IFU) and hospital protocols. Information was collected on the study patients and devices before, during, and after catheter insertion while the device was indwelling, and during device removal to assess both safety and performance endpoints. Clinical data for the primary and secondary endpoints were gathered from information collected as part of the patients' routine care, and no study-specific procedures were performed. Choice of the specific PowerPICC type, size, number of lumens, and length required for an individual patient was left to the discretion of the clinician. After the catheter was inserted and procedure data was recorded, the inserting clinician completed a short survey to assess the performance of the guidewire/stylet. The device maintenance (ie, flushing, fluid locking, cleansing) and insertion site maintenance (ie, cleansing, dressing) were performed according to the device-specific IFU, standard medical practice and hospital protocols. The study device was discontinued/removed when it was deemed medically appropriate by the patient's treating clinician (eg, no longer needed or no longer functioning). Removal of the device was also performed according to the device-specific IFU, standard medical practice, and hospital protocols.

For patients treated in an acute-care setting, the catheter/site was assessed daily until the device was removed or until they were discharged with the device in place (then treated as an outpatient). When the patient was treated in an outpatient setting, the catheter/site was assessed at each therapy visit until the device was removed, or until 180 days postinsertion (±14 days), whichever came first. For the purposes of endpoint calculations, PICCs remaining in place after 180 days were considered to have completed therapy.

Statistical methods

A sample size of 150 participants for each type of device (PowerPICC, PowerPICC SOLO 2 and PowerGroshong PICC) was chosen based on the precision of the point estimates of the primary endpoint (VT), as well as the ability to observe rare adverse events or complications. Assuming the primary endpoint of VT incidence is 10%,[14] the precision of the point estimate is 4.8% with a sample size of 150 (ie, the 95% CI is the point estimate ±4.8%). Additionally, with a sample size of 150, the probability of observing at least one rare complication with a 1% rate is 78%, and the probability of observing at least one rare complication with a 2% rate is 95%.

The incidence rates of symptomatic VT (primary safety endpoint) and of select complications (secondary safety endpoints) and their 95% CI were calculated. The percentage of PICCs remaining in place through the completion of therapy and a 95% CI was calculated based on the total number of PICCs where information about success or failure was documented. The percentage of patent PICCs and the percentage of placement success in a single insertion attempt were calculated together with 95% CIs. The results of the postinsertion user questionnaire were analysed descriptively. No missing value imputation methods were used.

Patient and public involvement

None.

RESULTS

Patient characteristics

A total of 451 patients signed the consent form, of which 1 patient did not meet the eligibility criteria, as illustrated in figure 2. The study device was attempted to be placed in 450 patients (150 patients each for PowerPICC, PowerPICC SOLO 2, and PowerGroshong PICC), and a total of 447 patients received treatment and were included in the evaluable set. PowerPICC SOLO 2 could not be placed in two patients and could not be used for the intended treatment in one patient. Of these patients, 335 were documented as having completed the therapy via

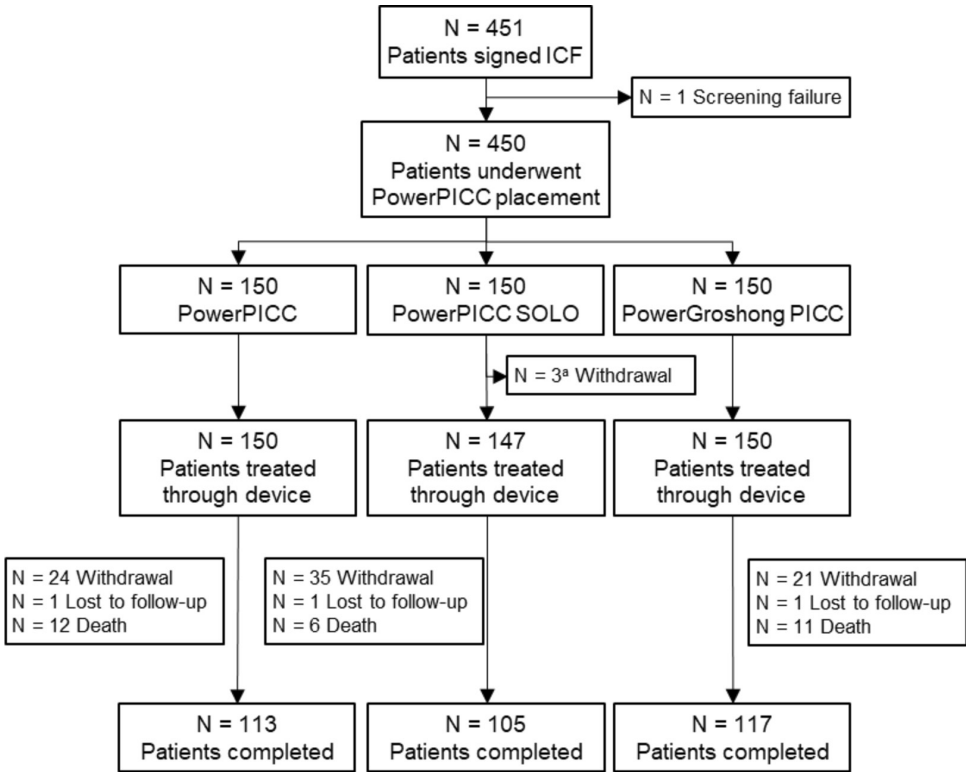

Figure 2 Patient and device disposition of the 29 patients who are documented as being withdrawn because of death, 28 patients had the study device still in place at the time of death and were considered as having completed the therapy for the assessment of the primary performance endpoint and 1 patient was lost to follow-up with no information available about the whereabouts of the device. [a]Unsuccessful placement of study device in two patients; one patient with successful placement of study treatment but could not be treated via the device. ICF, informed consent form; PICC, peripherally inserted central catheter.

the study device (device either removed after therapy or still in place at 180 days), and 115 were documented as non-completers ('withdrawal'). The reasons given for the withdrawal included lost to follow-up in 3 patients, death in 29 patients, adverse events in 53 patients, device deficiency in 19 patients, and 'other' in 11 patients. Catheter to vessel ratio was assessed prior to insertion in 60.4% of all patients.

Of the total patient cohort, 50.2% of patients were women and 49.8% were men. Patient age ranged from 6 to 96 years, with a median of 62.0 years (table 1). The most frequent indication for device placement was the administration of chemotherapy (69.6%). In 78.4% of patients, the PICC was intended for long-term use (ie, for at least 30 days). Device placement was successful in 99.6% of patients.

Safety results

Symptomatic VT after device placement, the primary safety endpoint, was observed in 0.7% (PowerPICC), 1.4% (PowerPICC SOLO), and 2.7% (PowerGroshong PICC) of patients as shown in table 2. When stratified based on the number of lumens, symptomatic VT was observed in six patients (1.6%) among those who received single-lumen PowerPICC catheters and one patient (1.5%) among those who received double-lumen catheters. For secondary safety endpoints, the incidences of the preselected complications across all study devices were 0% for phlebitis, 0% for extravasation, 4.5% for local infections, 1.6% for CRBSI, and 3.8% for accidental dislodgment. The CRBSI rate per 1000 catheter days was 0.17 across all PowerPICC devices (online supplemental table S2). The device-specific incidence rates for these complications are listed in table 2.

Performance results

For the primary performance outcome, PowerPICC devices remained in place throughout the required therapy time in 81.8% of patients (table 3). For secondary performance outcomes, 93.9% of all PowerPICCs were patent through therapy, and 90.4% could be placed in a single insertion attempt with proper tip location and patency (table 3). When clinicians were asked if the guidewire or stylet facilitated placement of the PICC, the majority of clinicians 'agreed' or 'strongly agreed' that the guidewire and the stylet facilitated placement (94.6% and 94.9%, respectively, online supplemental tables S3 and S4). Use of the guidewire and stylet was reported to be 'easy' or 'very easy' by 93.3% and 94.4% of the clinicians, respectively.

DISCUSSION

This study provides the most robust evidence available on the safety and performance of PowerPICC catheters when used in real-world settings across nine European

Table 1 Patient demographics and baseline characteristics

	PowerPICC N=150	PowerPICC SOLO N=150	PowerGroshong PICC N=150	Any PowerPICC N=450
Sex, N (%)				
Male	80 (53.3)	45 (30.0)	99 (66.0)	224 (49.8)
Female	70 (46.7)	105 (70.0)	51 (34.0)	226 (50.2)
Race, N (%)				
White	141 (94.0)	148 (98.7)	150 (100.0)	439 (97.6)
Asian	4 (2.7)	1 (0.7)	–	5 (1.1)
Black or African American	3 (2.0)	–	–	3 (0.7)
Other	2 (1.3)	1 (0.7)	–	3 (0.7)
Age, median years (min; max)	62.5 (6; 96)	57.5 (21; 92)	63.0 (33; 87)	62.0 (6; 96)
Body height, mean cm (SD)	169.83 (10.61)	169.29 (8.37)	168.62 (8.90)	169.25 (9.34)
Body weight, mean kg (SD)	75.22 (17.51)	77.56 (17.30)	73.45 (13.25)	75.41 (16.20)
BMI, mean (SD)	26.00 (5.54)	27.07 (5.79)	25.83 (4.29)	26.30 (5.27)
Primary diagnosis for current admission, N (%)				
Cardiac	12 (8.0)	–	–	12 (2.7)
Trauma	2 (1.3)	–	–	2 (0.4)
Neurological	7 (4.7)	–	1 (0.7)	8 (1.8)
Infection	33 (22.0)	8 (5.3)	1 (0.7)	42 (9.3)
Surgical	14 (9.3)	14 (9.3)	1 (0.7)	29 (6.4)
Oncological	67 (44.7)	120 (80.0)	141 (94.0)	328 (72.9)
Vascular	4 (2.7)	–	–	4 (0.9)
Gastrointestinal	8 (5.3)	5 (3.3)	5 (3.3)	18 (4.0)
Other	3 (2.0)	3 (2.0)	1 (0.7)	7 (1.6)
Reason for PICC placement, N (%)				
Central venous pressure monitoring	2 (1.3)	–	–	2 (0.4)
Hydration support	12 (8.0)	7 (4.7)	1 (0.7)	20 (4.4)
Intravenous therapy				
Immunoglobulins	1 (0.7)	–	1 (0.7)	2 (0.4)
Antimicrobial/antifungal	56 (37.3)	19 (12.7)	4 (2.7)	79 (17.6)
Blood product and transfusion	13 (8.7)	4 (2.7)	4 (2.7)	21 (4.7)
Chemotherapy	62 (41.3)	116 (77.3)	135 (90.0)	313 (69.6)
Pain management	12 (8.0)	11 (7.3)	7 (4.7)	30 (6.7)
Total parenteral nutrition	22 (14.7)	18 (12.0)	10 (6.7)	50 (11.1)
Vasopressors	4 (2.7)	–	–	4 (0.9)
Limited peripheral access	24 (16.0)	16 (10.7)	85 (56.7)	125 (27.8)
Nutritional support	5 (3.3)	6 (4.0)	4 (2.7)	15 (3.3)
Other	2 (1.3)	–	1 (0.7)	3 (0.7)
Serial blood sampling	29 (19.3)	10 (6.7)	22 (14.7)	61 (13.6)
Serial radiographic studies	1 (0.7)	–	2 (1.3)	3 (0.7)
Thrombocytopenia or coagulopathy	3 (2.0)	–	–	3 (0.7)
Intended access duration, N (%)				
Short term <30 days	67 (44.7)	28 (18.7)	2 (1.3)	97 (21.6)
Long term ≥30 days	83 (55.3)	122 (81.3)	148 (98.7)	353 (78.4)
Number of lumens, N (%)				
Single lumen	94 (62.7)	141 (94.0)	150 (100.0)	385 (85.6)
Double lumen	56 (37.3)	9 (6.0)	–	65 (14.4)

BMI, body mass index; max, maximum; min, minimum; n, number of patients; PICC, peripherally inserted central catheter.

Table 2 Incidence of complications (SAF, N=450, n=447; PowerPICC n=150, PowerPICC SOLO n=147, PowerGroshong n=150)

Complication by device type	Number (%) of patients	95% CI (%)
Primary safety endpoint		
Symptomatic venous thrombosis		
PowerPICC	1 (0.7)	0.0; 3.7
PowerPICC SOLO	2 (1.4)	0.2; 4.8
PowerGroshong	4 (2.7)	0.7; 6.7
Any PowerPICC	7 (1.6)	0.6; 3.2
Secondary safety endpoints		
Phlebitis		
PowerPICC	0 (0.0)	0.0; 2.4
PowerPICC SOLO	0 (0.0)	0.0; 2.5
PowerGroshong	0 (0.0)	0.0; 2.4
Any PowerPICC	0 (0.0)	0.0; 0.8
Extravasation		
PowerPICC	0 (0.0)	0.0; 2.4
PowerPICC SOLO	0 (0.0)	0.0; 2.5
PowerGroshong	0 (0.0)	0.0; 2.4
Any PowerPICC	0 (0.0)	0.0; 0.8
Local infection		
PowerPICC	6 (4.0)	1.5; 8.5
PowerPICC SOLO	13 (8.8)	4.8; 14.6
PowerGroshong	1 (0.7)	0.0; 3.7
Any PowerPICC	20 (4.5)	2.8; 6.8
CRBSI		
PowerPICC	2 (1.3)	0.2; 4.7
PowerPICC SOLO	3 (2.0)	0.4; 5.8
PowerGroshong	2 (1.3)	0.2; 4.7
Any PowerPICC	7 (1.6)	0.6; 3.2
Accidental dislodgment		
PowerPICC	4 (2.7)	0.7; 6.7
PowerPICC SOLO	9 (6.1)	2.8; 11.3
PowerGroshong	4 (2.7)	0.7; 6.7
Any PowerPICC	17 (3.8)	2.2; 6.0
Vein laceration		
PowerPICC	1 (0.7)	0.0; 3.7
PowerPICC SOLO	1 (0.7)	0.0; 3.7
PowerGroshong	0 (0.0)	0.0; 2.4
Any PowerPICC	2 (0.4)	0.1; 1.6
Vein perforation		
PowerPICC	0 (0.0)	0.0; 2.4
PowerPICC SOLO	1 (0.7)	0.0; 3.7
PowerGroshong	0 (0.0)	0.0; 2.4
Any PowerPICC	1 (0.2)	0.0; 1.2

CRBSI, catheter-related bloodstream infection; PICC, peripherally inserted central catheter; SAF, safety analysis set.

Table 3 Performance and secondary performance endpoints (EVS, N=447, n=445; PowerPICC n=149, PowerPICC SOLO n=146, PowerGroshong PICC n=150)

Primary performance endpoint by catheter type	Number (%) of patients	95% CI (%)
PICCs that remained in place through the required therapy time		
PowerPICC	124 (83.2)	76.2; 88.8
PowerPICC SOLO	111 (76.0)	68.3; 82.7
PowerGroshong	129 (86.0)	79.4; 91.1
Any PowerPICC	364 (81.8)	77.9; 85.3
Secondary performance endpoint	**Number (%) of catheters**	**95% CI (%)**
Patent PICCs		
PowerPICC	139 (93.3)	88.0; 96.7
PowerPICC SOLO	135 (92.5)	86.9; 96.2
PowerGroshong	144 (96.0)	91.5; 98.5
Any PowerPICC	418 (93.9)	91.3; 96.0
Placement success in single insertion attempt		
PowerPICC	129 (86.0)	79.4; 91.1
PowerPICC SOLO	129 (86.0)	79.4; 91.1
PowerGroshong	149 (99.3)	96.3; 100.0
Any PowerPICC	407 (90.4)	87.3; 93.0

EVS, evaluable set; PICC, peripherally inserted central catheter.

countries. Importantly, our prospective, observational, multicentre study approach provides greater generalisability to our findings, as our findings reflect the health outcomes that occur when PowerPICC catheters are used in diverse patient populations across European countries with varying standard clinical practices. The patients included in this study ranged from 6 to 96 years of age, and patients were admitted for a variety of health indications, including cardiac, trauma, neurological, oncological, and gastrointestinal conditions. Based on the results of the current study, our findings demonstrate that PowerPICC catheters are safe for treating patients experiencing a variety of health conditions and that these catheters are effectively used by clinicians across Europe.

The incidence of complications was low when using PowerPICC catheters, highlighting the general safety of these devices. For instance, our findings showed that 1.6% of patients developed symptomatic VT across all PowerPICC catheters. This is nearly half that reported by Greene *et al*, which found that of 3790 patients who received a PICC during their hospital stay, ~3.1% of patients developed symptomatic VT.[15] A recent meta-analysis assessing the occurrence of symptomatic deep VT with PICCs revealed an even higher incidence rate of 4.58% for non-intensive care unit (ICU) patients and 5.08% for ICU patients.[16] This observation of higher VT incidence rates with other PICC devices depicts the relatively low incidence of VT that occurs in patients receiving a PowerPICC catheter. In addition, the proportion of patients who developed symptomatic VT was similar between those who received single or double-lumen PowerPICC catheters. Regarding

the study's secondary safety endpoints, there were no observed cases of extravasation or phlebitis and only three cases of vein laceration or vein perforation across all patients who received one of the studied PowerPICC devices. The most common complication observed across all devices was the incidence of local infection, which occurred in 4.5% of all patients. Notably, local infections are also linked to improper catheter placement/maintenance practices (eg, aseptic care) that may be beyond the control of the device.[17] In this regard, our findings are similar to previously published evidence on local infections using PICC devices; Grau *et al* found an incidence of local infections in 4.7% of patients who received PICCs at a single-site hospital in France.[18] Collectively, our findings reveal that complications are rare when using PowerPICC devices, demonstrating that these devices are safely used in the general patient setting in health centres across Europe.

Our study expands on the limited existing knowledge regarding the safety of the PowerPICC catheters. Previous studies were limited to observations of specific patient cohorts, studies that did not distinguish data across specific PowerPICC catheters, or studies that were limited to a single site.[19–22] Our findings of a 1.6% incidence of symptomatic VT are similar to findings reported by González *et al*, which found an incidence rate of upper extremity deep VT in 2.01% of patients when using PowerPICC catheters. In contrast, the incidence of CRBSI observed in the current study is lower than previously reported values for PowerPICC catheters. Sato *et al* found a CRBSI incidence rate of 1.4 per 1000 catheter days in patients being treated for head and neck cancer when using either PowerGroshong PICC or single-lumen PowerPICC catheters.[21] Morano *et al* found a CRBSI incidence rate of 0.59 per 1000 catheter days in haematological patients treated at a single haematology centre in Italy when using PowerGroshong or PowerPICC catheters.[23] Our findings of a CRBSI incidence rate of 0.17 per 1000 catheter days indicate that CRBSI occurs less commonly than these previously reported studies focused on specific patient cohorts. Although it is plausible that the differences observed between prior studies and the current findings are reflective of the underlying health conditions of the studied patient populations, our study included patients admitted for a variety of health conditions and reflects the health outcomes that occur in a general hospital setting.

It is important to note that some complications that occur with the use of PICCs may be outside of the control of the device. While the current study's protocols require clinicians to follow care plans according to the IFU of the specific PowerPICC device and hospital standards, medical errors are an unfortunate reality that can negatively impact patient health.[24] For instance, bloodstream infections are linked to improper catheter placement/maintenance practices (eg, aseptic care).[17] Successful prevention of complications can also be dependent on the selection of the appropriate catheter (eg, the fewest number of lumens possible and adequate vein diameter to catheter size ratio based on the patient's needs) and proper catheter management (eg, care of the insertion site, catheter stabilisation, routine flushing).[16 25 26] Nonetheless, given that there was a low occurrence of complications and that clinicians overwhelmingly reported that PowerPICC devices were easy to use, the current study suggests that these devices are capable of being successfully implemented in the clinical setting and that proper maintenance is readily achievable.

In addition to the safety of these devices, our findings indicate that the PowerPICC catheters perform well in the clinical setting and that clinicians find these devices easy to use. Over 93% of clinicians agreed that both the guidewire and stylet were easy or very easy to use and remove. Indeed, 90.4% of all PowerPICC devices were successfully placed on their first insertion attempt with an overall success rate for placement of 99.6%. The overall success rate across all PowerPICC catheters is higher than compiled values reported by the Society of Interventional Radiology Standard of Practice Committee in their quality improvement guidelines for central venous access, which reports PICC placement success rates of 96% in adult populations.[27] Appropriate positioning of PICCs is an important consideration for patient care, as poorly positioned catheter tips may increase the risk of PICC-associated complications including phlebitis, deep vein thrombosis, and catheter malfunctioning.[28–30] Malpositioned PICCs can also delay the start of patient treatment, require additional hospital resources (eg, repeated PICC procedures and chest X-rays), and increase hospital costs.[31] Further, receiving multiple PICCs may increase the risk of vascular complications and bloodstream infections.[32 33] Given that 93.9% of all PowerPICC catheters remained patent through the completion of therapy in the current study, these findings suggest that few patients would require replacement PICCs when using one of the PowerPICC line of catheters. Taken together, these findings highlight the high-performance standard of PowerPICC catheters in the clinical setting, benefitting both clinicians and patients.

Notably, a key distinction between the devices in the PowerPICC catheters is their valve properties; PowerPICC catheters are open-ended, PowerPICC SOLO 2 catheters have a pressure-activated proximal hub valve, and PowerGroshong catheters are closed-ended with a three-position valve (or valves) which allows fluids to flow in or out but remains closed when not in use. Furthermore, the devices differ in their material composition (ie, thermoplastic urethane for PowerPICC and PowerPICC SOLO2; silicone for PowerGroshong). The selection of a PICC with a particular valve type may depend on multiple factors such as patient risk for complications, flow requirements, anticipated PICC maintenance (eg, frequency of flushes), need for intermittent infusion, and considerations of home

discharge. Overall, our findings reveal a similar safety and performance profile across the studied devices indicating that clinicians may select the specific PowerPICC device according to patient needs without concerns of varying efficacy across the PowerPICC devices.

Limitations

There are several limitations of this study. First, standard care practices vary across hospitals and European countries,[34] which may have an impact on the safety and performance of PowerPICC catheters. Nonetheless, the low rate of complications and effective performance observed across all PowerPICC devices used at the 14 health centres in the current study indicates that these devices are readily employed in hospital systems across Europe. The specific PowerPICC device used for patients was also not randomised, and PICC selection was performed at the discretion of the clinician in accordance with standard of care practices. Hence, it is plausible that clinician expertise and experience in selecting appropriate VADs may have impacted the outcomes observed in the current study. For instance, the secondary safety outcomes of vein laceration and vein perforation are also inserter-dependent, and only three cases were reported for these outcomes across all observed devices. Inherent differences among catheters may also contribute to findings, such as the availability of catheter sizes; the smallest size available for the PowerGroshong PICC is 5Fr, whereas PowerPICC and PowerPICC SOLO 2 are available in 4Fr sizes. Larger catheter sizes have previously been shown to have an association with an increased incidence of relevant complications (ie, VT).[16] Additionally, although this study included a diverse patient population with patients admitted to the hospital for various health diagnoses, our sample is represented by a large portion of oncology patients. Patients were also admitted for other reasons, including infection, surgical, cardiac, gastrointestinal, and neurological conditions. Nonetheless, the underlying health of the patients included in this study may have impacted the current findings. Due to the relatively low rate of complications, this study did not assess safety outcomes across patients admitted for various diagnoses or different indications for PICC placement. The study design also did not allow for comparisons between other power-injectable compatible devices that may be available, and this approach is a worthy consideration for future studies.

CONCLUSIONS

This study provides robust real-world evidence on the safety and performance of the PowerPICC catheters in diverse patient populations across nine European countries. The low incidence of complications, such as only 1.6% of patients developing symptomatic VT, highlights the safety of these devices. PowerPICC catheters performed effectively with the majority of catheters successfully placed on their initial attempt and remaining patent through the completion of therapy. These findings support the safe and effective use of PowerPICC catheters in general hospital settings across Europe, providing valuable insights for clinicians and contributing to improved patient care.

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