Original research article

JVA The Journal of Vascular Access

A multicenter retrospective study on 4480 implanted PICC-ports: A GAVeCeLT project

The Journal of Vascular Access
1–7

DOI: 10.1177/11297298211067683
journals.sagepub.com/home/jva
SAGE

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Abstract

Background: PICC-ports may be defined as totally implantable central venous devices inserted in the upper limb using the current state-of-the-art techniques of PICC insertion (ultrasound-guided venipuncture of deep veins of the arm, micro-puncture kits, proper location of the tip preferably by intracavitary ECG), with placement of the reservoir at the middle third of the arm. A previous report on breast cancer patients demonstrated the safety and efficacy of these devices, with a very low failure rate.

Methods: This retrospective multicenter cohort study—developed by GAVeCeLT (the Italian Group of Long-Term Venous Access Devices)—investigated the outcomes of PICC-ports in a large cohort of unselected patients. The study included 4480 adult patients who underwent PICC-port insertion in five Italian centers, during a period of 60 months. The primary outcome was device failure, defined as any serious adverse event (SAE) requiring removal. The secondary outcome was the incidence of temporary adverse events (TAE) not requiring removal.

Results: The median follow-up was 15.5 months. Device failure occurred in 52 cases (1.2%), the main causes being local infection ($n = 7$; 0.16%) and CRBSI ($n = 19$; 0.42%). Symptomatic catheter-related thrombosis occurred in 93 cases (2.1%), but removal was required only in one case (0.02%). Early/immediate and late TAE occurred in 904 cases (20.2%) and in 176 cases (3.9%), respectively.

Conclusions: PICC-ports are safe venous access devices that should be considered as an alternative option to traditional arm-ports and chest-ports when planning chemotherapy or other long-term intermittent intravenous treatments.

Keywords

Central venous catheter, totally implantable access devices, peripherally inserted central catheters, complications, adverse events, PICC-ports

Date received: 29 October 2021; accepted: 1 December 2021

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Introduction

Totally implantable venous access devices with subcutaneous reservoir (ports) are commonly used in several settings. Ports are mostly popular for chemotherapy administration in cancer patients; though, their implantation and removal are considered invasive, and patients are sometimes reluctant to have them. Traditionally, ports are inserted by direct cannulation of deep veins of supra/infraclavicular area, with the placement of the reservoir in a subcutaneous pocket in the chest wall; the alternative insertion in the upper arm or forearm has also been advocated over the last two decades, based on low invasiveness, easy insertion, good patient compliance, and—most importantly—the absence of risks of severe complications during insertion.[1–3] Though, arm-ports have been recently reported to have a high risk of catheter-related thrombosis (CRT) if compared to chest-ports, as well as a relevant risk of failure ranging from 2% to 17%.[4–6]

The PICC-port represents an evolution of the traditional arm-port, and—compared to the latter—it may be associated with better clinical outcome in terms of complications and device failure.[7] The main difference between PICC-ports and traditional arm-ports is the consistent adoption of the current state-of-the-art techniques of PICC insertion (ultrasound-guided venipuncture of the deep veins at the proximal third of the upper limb, using micro-puncture kits), plus the proper location of the catheter tip according to the current guidelines (i.e. preferably by intracavitary ECG), with the placement of the reservoir in a pocket located in the mid-third of the upper arm. The technique of PICC-port insertion has been described in previous studies on breast cancer patients receiving chemotherapy[7] and on cancer patients with extensive burns of the chest and neck.[8] The clinical study on breast cancer patients has reported a very low incidence of PICC-port failure (2.6%), similar to the figures reported for chest-ports.[7]

In the current literature, there are no recommendations or selection criteria regarding the choice of the type of ports (i.e. chest-ports vs arm-ports vs femoral-ports); though, during the last 5 years, PICC-ports have gained popularity, since they appear to be safe, effective, easy to insert, and well tolerated by the patients. For these reasons, in some Italian clinical centers, PICC-ports are increasingly considered as a first option when a totally implantable central vascular access device is required.

The GAVeCeLT (the Italian Group of Long-Term Venous Access Devices) has developed the project of a large retrospective cohort clinical study, extended to five Italian hospitals, with the purpose of evaluating the clinical effectiveness and the actual safety of PICC-ports.

Materials and methods

A retrospective observational cohort study was carried out in five Italian clinical centers located in Aviano, Florence, Foggia, Genova, and Rome, evaluating the clinical outcome of 4408 PICC-ports inserted in adult patients from September 1, 2015, to September 1, 2020. The study followed the STROBE statement and checklist recommendation for observational studies[9]; it followed the principles of the Helsinki declaration and was approved by the institutional review boards.

Study design and patients' characteristics

This study analyzes the clinical outcome of all PICC-ports inserted in adults requiring intermittent long-term venous access for different purposes. Insertion technique was in accordance with institutional protocols and is described below. Chronic severe renal failure stage 3b—4–5 was an exclusion criterion for PICC-port insertion. Patients were followed monthly or at every use of the port. Post-procedural ultrasound venous scan was not performed routinely but only when clinically indicated (i.e. in case of suspected CRT).

A database was extracted from hospital records and many relevant data were evaluated: demographics, reason for the implant, type and size of the device, modality of anesthesia, method of catheter tip location, presence/absence of tunneling between puncture site and reservoir, duration of the procedure, length of stay of the device, intraoperative adverse events, immediate and late post-operative adverse events, rate of device failure (removal due to complication). Follow-up period was at least 12 months for each device and data collection terminated on September 30, 2021.

Insertion and maintenance of the device

PICC-ports insertion was consistently performed by properly trained clinicians (physicians or nurses), in a dedicated procedural room, adopting maximal barrier and antiseptic precautions, as required by local institutional protocols. The procedure was usually performed under local anesthesia only; intravenous sedation was added only in non-compliant or uncooperative patients.

Both the right and the left upper limb were utilized for insertion, the choice being guided by pre-procedural scan of the veins, also considering possible local contraindications (previous venous thrombosis, previous axillary dissection, abnormalities of the limb, etc.)[7,10] and the patient's preference. Catheter insertion was performed by ultrasound-guided puncture and cannulation of deep veins (basilic, brachial, or axillary vein) at the proximal third of the upper arm (the "yellow zone," according to Dawson's ZIM—Zone Insertion Method) (Figure 2).[11] The accessed vein was measured and a catheter/vein ratio $\leqslant 0.33$ was considered appropriate.[12] Location of the catheter tip in the proximity of the cavo-atrial junction was consistently verified by intra-procedural methods (preferably by intracavitary ECG, or—as an alternative—by ultrasound-based tip location or fluoroscopy).

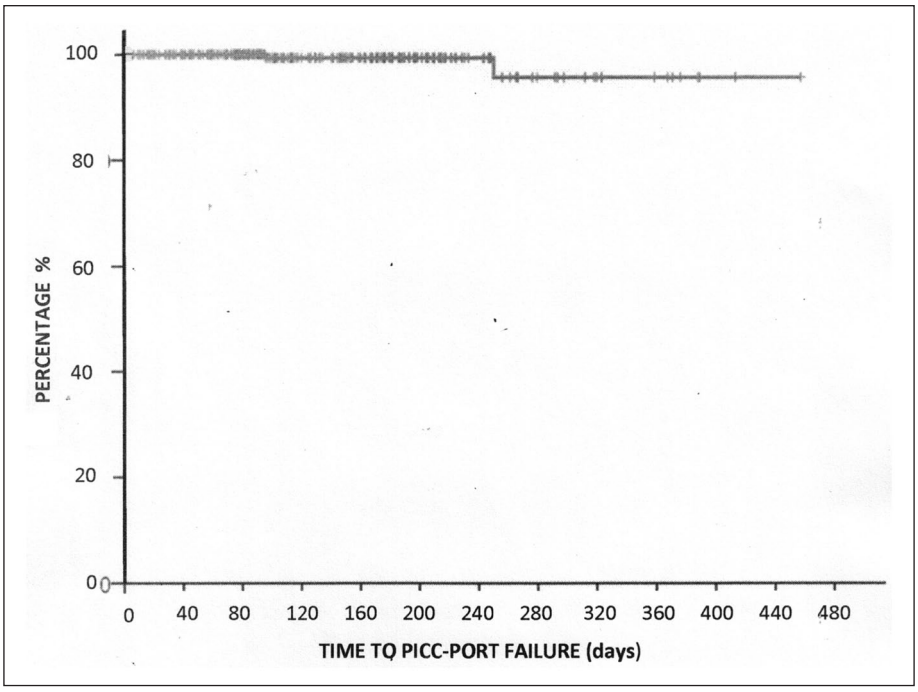

Figure 1. Kaplan-Meier curve for overall device survival (free from failure).

Figure 1 shows the reservoir's site of placement in a subcutaneous pocket created most frequently in the middle third of the upper arm (the "green zone" according to Dawson's ZIM) or, alternatively, in the proximity of the site of venipuncture (the "yellow zone"). The pocket was closed by intradermic stitches (with absorbable monofilament suture) and cyanoacrylate glue. Following current guidelines, no antibiotic prophylaxis was used and anticoagulant prophylaxis for CRT was adopted only in very selected cases.[13,14]

Four different brands of PICC-ports were used: Health-Port MiniMax, Plan-1-Health; Dignity Mini, MedComp; Polysite PICC-port, Perouse-Vygon; Port Celsite Brachial, B. Braun. All devices consisted of a very-low-profile reservoir (full titanium or hybrid plastic-titanium) connected to a 5Fr polyurethane catheter.

Maintenance of the device was assigned to specifically trained nurses, following local institutional protocols. The reservoir was accessed by non-coring needles (size 20–22 G; length 15–20 mm). Flushing and locking procedures were performed by the pulsatile method, with normal saline, before and after each infusion or at a 2-month interval of time if the device was not in use.[15]

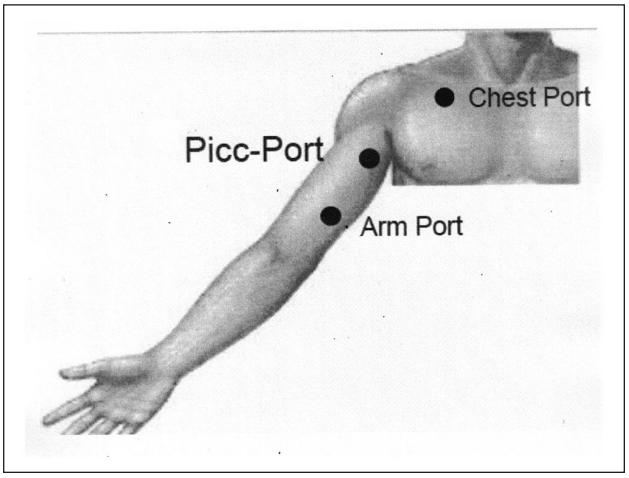

Figure 2. Graphic representation of the different locations of the PICC-port, arm-port, and chest-port subcutaneous reservoir positioning. Picc-port reservoir is positioned at the proximal one-third of the upper arm. PICC-port placement technique requirements are an adequate reservoir location site, US-guided venous access, and a non-invasive micro-Seldinger technique for venous catheter insertion.

Endpoint and definitions

The primary study endpoint was the incidence of device failure, that is, removal secondary to complication. The secondary endpoint was the incidence of any other adverse event associated with the device.

An adverse event requiring removal was defined as a serious adverse event (SAE). Adverse events not requiring removal of the device were defined as transient adverse events (TAE).

Several possible adverse events were considered: pocket and wound infection, catheter-related bloodstream infection (CRBSI), symptomatic catheter-related thrombosis (CRT), malfunction/occlusion of the device, partial withdrawal occlusion (PWO), catheter dislodgment with tip malposition, hematoma, transient skin ecchymosis,

subcutaneous inflammation, relevant local pain (score >4 at a visual analog scale), skin dehiscence, skin decubitus with reservoir exposition, subcutaneous drug extravasation, cardiac arrhythmia, and others.

Pocket/wound infection was defined by the presence of purulent discharge with erythema and/or tenderness at the pocket and/or in the subcutaneous tunnel from the puncture site and the reservoir.

CRBSI was defined according to Infectious Disease Society of America guidelines[16]:

(1) isolation of the same micro-organism in the cultures from peripheral blood and from the central venous access device
(2) or threefold difference in paired quantitative cultures of blood samples drawn from the device and from the peripheral vein
(3) or differential time to positivity (DTP) in paired peripheral/device blood cultures, with the device culture becoming positive at least 2 h before the peripheral culture.

Diagnosis of symptomatic CRT was established by ultrasound venous scan (compression ultrasonography or color-doppler), performed only in case of clinically suspected CRT.

Occlusion/malfunction of the device was defined as the inability to infuse normal saline solution despite the manual pressure performed by a 10 ml syringe.

PWO was defined as the persistent impossibility to withdraw blood, with the device well-functioning during infusion.

Catheter dislodgment with tip malposition was defined as a tip migration from its initial position.

Hematoma was defined as an abnormal collection of blood in the subcutaneous tissues.

Ecchymosis (bruising) was defined as a discoloration area of the skin, resulting from local bleeding inside the tissues, but without collection of blood.

Drug extravasation was defined as the presence of the infused solution in the subcutaneous tissue, secondary to needle dislodgment from the reservoir, or to defects of the silicon membrane with fluid leakage, or to the inefficient connection between the reservoir and the catheter.

Statistical analysis

In the primary study analysis, "time to device failure" was evaluated with standard survival analyses: Kaplan–Meier curves were used to estimate the cumulative probability that a device would be still in place at any time since the day of insertion (device survival, free from failure); when a device was removed due to end of use, the device survival time was censored on that date. Overall device survival was computed from the day of the insertion to the day of removal either for end of use or for SAE, whichever first. STATA/SE 11.0 (Statacorp LP 2009) and SPSS 20 (IBM SPSS Statistics, ed. 20, 2014) statistical software were used for all analyses.

Results

We evaluated the clinical outcome of 4,480 PICC-ports implanted in five different centers during a period of 60 months. The distribution of PICC-ports per single center was as follows: Aviano 421 (9.4%), Florence 294 (6.6%), Foggia 1342 (29.9%), Genova 642 (14.3%) and Rome 1781 (39.7%).

Table 1 lists the patients' characteristics and the main details of the insertion procedure. Most patients were female (80%). Most insertions were performed in cancer patients (97%), and particularly in breast cancer patients (61%). Almost all procedures were performed under local anesthesia, as sedation was required only in 14 patients (0.3%). Tip location of the catheter was verified by intracavitary ECG in most cases (93%). In most cases (63%), the subcutaneous pocket was created 3–5 cm away from the puncture site by a subcutaneous tunnel. The median duration of the procedure was 28 min (range 15–50).

The minimum follow-up period, excluding removal for SAE, was 12 months. Median follow-up was 15.5 months (range 12–19). Most PICC-ports ($n = 3608$; 82.1%) were removed because of end of use, and not because of complications. Removal of the device because of complications occurred in 52 patients (1.2%); 10 devices (0.2%) were removed within 30 days (early SAE), while 42 (0.9%) were removed after 1 month (late SAE). The Kaplan–Meier survival curve of the device (if free from failure) is shown in Figure 1. The proportion of patients without device failure was 98.8% (95% CI, 95%–99%).

Table 2 shows the incidence of immediate/early adverse events. TAEs were reported in 904 devices (20%) while SAE occurred only in 10 cases (0.2%). Transient subcutaneous ecchymosis (with complete regression within 5–7 days) was the most frequent adverse event (806 cases, 18%). Local infection was observed in 24 cases (0.5%); in 7 cases (0.2%) removal of the device was required. CRBSI was diagnosed in two patients (0.04%) and in one case (0.02%) required removal. Symptomatic CRT was diagnosed in 33 cases (0.7%); none of them required removal. Hematoma occurred in nine patients (0.2%), leading to device removal only in one case (0.02%). Wound healing complications occurred in 10 patients (0,2%); only 1 of them (0.02%) required removal. Post-procedural pain (visual analog score >4) was reported in 10 patients (0.2%). As expected from previous experiences with arm-ports, no major complications occurred during the insertion procedure.

Table 3 shows the incidence of late adverse events. Late TAE was reported in 176 cases (3.9%) and late SAE in 42 cases (0.9%). Symptomatic CRT was diagnosed in 60 cases (1.3%): all patients with CRT were treated by anticoagulant therapy, and only one device (0.02%) eventually

Table 1. Patients' characteristics and insertion procedure.

Patients' characteristics			
Number of patients	4,480		
Mean age (range)	53.9 (12-91) years		
			%
Gender	Male	887	19.8
	Female	3593	80.2
Disease	Breast cancer	2742	61.2
	Colon cancer	694	15.5
	Head and neck cancer	220	4.9
	Lung cancer	189	4.2
	Ovarian cancer	117	2.6
	Miscellaneous cancer	391	8.7
	Non-cancer disease	127	2.8
Insertion procedure			
Mean duration (range)	28 min (15–42)		
Technical details	Local anesthesia only	4466	99.7
	Local anesthesia + sedation	14	0.3
	Tip location by intracavitary ECG	4,128	92.1
	Tip location by ultrasound or fluoroscopy	352	7.9
	Subcutaneous tunnel	2810	62.7
	No tunnel	1670	37.3

Table 2. Immediate/early adverse events (first 30 days after insertion).

	TAE		SAE	
	n	%	*n*	%
Transient ecchymosis	806	18	—	—
Symptomatic CRT	33	0.7	—	—
Local infection	24	0.5	7	0.2
CRBSI	2	0.04	1	0.02
Hematoma	9	0.2	1	0.02
Unpaired wound healing	10	0.2	1	0.02
Catheter occlusion	2	0.04	—	—
Chamber flip	4	0.09	—	—
Cardiac arrhythmia	3	0.07	—	—
Subcutaneous abnormal reaction	2	0.04	—	—
TOTAL	**904**	**20.2**	**10**	**0.2**

TAE: transient adverse event (i.e. not requiring removal); SAE: serious adverse event (i.e. requiring removal); CRT = catheter related thrombosis; CRBSI = catheter related bloodstream infection.

Table 3. Late adverse events (more than 30 days after insertion).

	TAE		SAE	
	n°	%	*n*°	%
Symptomatic CRT	60	1.3	1	0.02
PWO	55	0.4	—	—
Local infection	20	0.4	7	0.2
CRBSI	18	0.4	18	0.4
Skin decubitus and reservoir exposition	4	0.1	4	0.1
Catheter dislodgment with tip malposition	6	0.1	6	0.1
Catheter occlusion	4	0.1	1	0.02
Drug extravasation	5	0.1	5	0.1
Cardiac arrhythmia	4	0.1	—	—
TOTAL	**176**	**3.9**	**42**	**0.9**

TAE: transient adverse event (i.e. not requiring removal); SAE: serious adverse event (i.e. requiring removal); CRT: catheter related thrombosis; PWO: persistent withdrawal occlusion; CRBSI: catheter-related bloodstream infection.

required removal. The median time of onset of late CRT was 95 days. Local infection occurred in 20 cases (0.4%), and in 7 cases (0.2%) the device was removed; median time for late local infection was 66 days. CRBSI was observed in 18 patients (0.4%), leading to removal in all cases; the median time to late CRBSI was 104 days. Drug extravasation requiring removal occurred in five cases (0.1%); the median time to late drug extravasation was 74 days. Skin decubitus with chamber exposition and eventually device removal occurred in four patients (0.1%); median time to late decubitus was 69 days. Catheter dislodgment with tip malposition leading to device removal occurred in six cases (0.1%); the median time to late dislodgment was 92 days. Catheter occlusion occurred in four cases (0.1%), leading to removal in only one case (0.02%). PWO was observed in 55 patients (1.2%), and in no case the device was removed; the median time to late PWO was 97 days. Episodic cardiac arrhythmia was experienced in four (0.1%) of patients with PICC-port.

Discussion

Over the last decades, ports have gained popularity in many fields of clinical practice.[17–19] Recently, arm-ports have been considered as an alternative to chest port, so to reduce the invasiveness of the maneuver, decrease the risk of intraprocedural complications, and improve patients' satisfaction.[4–7] Though, arm ports have not been fully adopted in clinical practice, probably because of the evidence of high incidence of late complications leading to device failure and removal (in 4%–17% of patients), most of them attributable to CRT or infection.[4,6]

PICC-ports can be regarded as an evolution of traditional arm-ports. In a recent study, we evaluated outcomes of PICC-ports in a series of 418 adult breast cancer patients undergoing chemotherapy[7]; failure rate was 2.6%, similar or even inferior to the figures reported for chest-ports in the recent literature.[17–19]

The present retrospective study confirmed the favorable clinical outcome of PICC-ports in a very large cohort of 4480 cancer and non-cancer patients; to our knowledge, this is the first study on PICC-ports in which the study population was not represented solely by cancer patients.

The clinical outcome was excellent: over 80% of PICC-ports were removed because of end of use, and early and late complications were few: transient adverse events (not requiring removal) occurred in 24.1% and severe adverse events (requiring removal) occurred only in 1.1% of cases.

As arm-ports were particularly at risk for CRT and infection, it is interesting to observe the incidence of such complications in our study on PICC-ports.

In our series, the overall incidence of symptomatic CRT was 2%, and it required removal only in 0.02% of cases. The reduced risk of CRT may be explained by the technique of PICC-port insertion: the consistent use of the ultrasound-guided venipuncture; the adoption of micro-puncture kits with small size (21G) needles; the access site at the proximal third of the arm, where veins of optimal size are available, so to guarantee compliance with an optimal catheter-vein ratio $\leqslant 1/3$[7–12]; the adoption of intraprocedural methods for tip location, and in particularly intracavitary ECG, which is currently considered more accurate than radiology. Very few symptomatic CRT occurred in the first month after insertion (0.7%). Though some late CRT occurred (1.3%), the median dwell time before late CRT was 95 days, significantly greater compared to the figures reported in the literature for peripherally inserted central catheters (PICC), in which this complication mostly occurs within the first month after insertion.[6,20,21] In our opinion, this low rate of CRT is due to (a) the choice of a vein with appropriate catheter/vein ratio; (b) the systematic use of ultrasound-guided venipuncture; (c) the minimal trauma to the vein wall secondary to the adoption of micro-puncture kits; (d) the intra-procedural control of the catheter tip, mostly using intracavitary ECG.

As regards infective complications, in our study local infection occurred in 0.9%, with removal required only in 0.2%. CRBSI was observed in 0.4% of PICC-ports, leading to device removal in all but one case. The time of onset for local infections (66 days) and CRBSI (104 days) is similar to the data reported in the literature on PICCs.

Drug extravasation and decubitus of the reservoir were in the same range described in recent reports on arm-ports and chest-ports.[17]

The occurrence of catheter occlusion (0.1%) was particularly low in our study if compared to the literature; in our opinion, this was due to the compliance with the principles and practices of flushing and locking of the catheters expressed by the recent consensus GAVeCeLT for non-dialysis catheters (i.e. no heparin lock; flushing and locking with normal saline, adopting the pulsatile positive pressure technique during flushing).[22]

Postoperative subcutaneous ecchymosis of the arms was a frequent (18%) but transient and mild phenomenon; it was not associated with pain or discomfort and spontaneously disappeared within 5–7 days; it had no impact on the scheduled treatments. Nevertheless, to prevent fears and worries, patients should be aware of this harmless event.

Strengths and limitations of the study

Our retrospective cohort study has several strengths. This study accumulated data from a very large number of devices; also, patients were unselected, and PICC-ports were implanted in any type of patient regardless of their diagnosis. Moreover, the available follow-up was adequate (15.5 months).

On the other hand, there are some limitations. As with any retrospective study, there was poor control over the exposure factor, covariates, and potential confounders study. Moreover, the study includes existing data that have been recorded for reasons other than research. Even if each center accrual accounted for a minimum of 5% of the global number of insertions, distribution per center was somehow unbalanced. Also, there is an unbalance in the patient population, since most PICC-ports were implanted in cancer patients and—in particular—in breast cancer. Finally, we could not offer data about the patient's compliance to PICC-port as compared to chest-port or to traditional arm-ports.

Conclusions

PICC-port is a new totally implantable device, different from the traditional arm-port since it adopts the basic techniques and methods currently used for PICC insertion.

Our experience with PICC-ports has relevant clinical implications, since it suggests that this novel device can be considered as safe and reliable as other totally implantable devices, in terms of clinical outcome. The cannulation of deep veins of the arm implies the absence of any risk of

severe complications during insertion (pneumothorax, chest/neck hematoma, hemothorax), as in arm-ports; furthermore, PICC-ports are associated with an incidence of CRT and CRBSI lower than arm-ports and similar to chest ports.

Nevertheless, PICC-ports should be implemented in clinical practice keeping in mind that (a) before insertion, local contraindications should be properly ruled out, and (b) the insertion should be performed only by specifically trained clinicians.

Further prospective randomized clinical trials to compare PICC-ports with chest ports or with traditional arm-ports may be warranted.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Sergio Bertoglio M.D. is Chief Medical Officer of Plan 1 Health (Amaro UD, Italy). No conflict of interest was declared by the other authors.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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