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
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PICC management led by technicians: establishment of a cooperation program with radiologists and evaluation of complications.

Short title:

PICC management led by technicians

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Abstract

Purpose: The purpose of this study was to evaluate a cooperation program in order to compare incidence of complications after peripherally inserted central catheter (PICC) placement between radiologists and technicians.

Materials and methods: PICC placement technique was standardized with ultrasound-guided puncture and fluoroscopic guidance. Numbers of PICC delegated to technicians, and PICC placement difficulties, were prospectively recorded for the whole study population whereas complications such as PICC infection, deep venous thrombosis and catheter occlusion were prospectively recorded until PICC removal for a subgroup of patients included during one month.

Results: A total of 722 patients had PICC placement. There were 382 men and 340 women with a mean age of 66.8 ± 15.8 (SD) years (range: 18-94 years); of these, 442/722 patients (61.22%) were included in the cooperation program with 433/722 patients (59.97%) who effectively had PICC placement by technicians and 289/722 (40.03%) by radiologists. Technicians needed radiologists' help for 23/442 patients (5.20%) including 6 failed PICC placement subsequently performed by radiologists. Twenty complications (20/77; 26%) were recorded in the subgroup of 77 patients studied for complications. No differences in complications rate were found between the 33 patients who underwent PICC placement by radiologists (6/33; 18%) and the 44 patients who underwent PICC placement by technicians (14/44; 32%) ($P=0.296$). Complications included 8 PICC-related infections (8/77; 10.4%), 3 deep venous thromboses (3/77; 3.9%) and 9 catheter occlusions (9/77; 11.7%).

Conclusion: PICC placement led by technicians is feasible and safe without statistical difference in terms of complications compared to PICC placement made by radiologists.

Keywords: Peripherally inserted central catheter (PICC); Venous access; Cooperation program; Safety; Complication.

Introduction

Peripherally inserted central catheters (PICC) are central venous catheters (CVC) inserted via peripheral veins in the ante-cubital fossa or above, and terminate at the junction of the superior vena cava with the right atrium [1, 2]. Over the past decade, the use of PICC has steadily grown. They allow durable and non-permanent venous access with several benefits

over classic CVC including a less invasive alternative with fewer perioperative complications and greater cost-effectiveness [3–5].

However, PICCs are also associated with severe complications including catheter related bloodstream infection and deep venous thrombosis (DVT), and minor complications such as catheter occlusions, insertion site redness, discomfort or difficult removal. These complications can lead to extended hospital stay and increased costs [4,6]. It has been proven that educating healthcare personnel “regarding the indications for intravascular catheter use and proper procedures for the insertion and maintenance of intravascular catheters could prevent the risk of complications” [7].

In many countries, PICCs are inserted both by interventional radiologists or a dedicated nursing-based venous access team. This relatively new specialty allows nurses to place and manage venous access in hospitalized patients [8–10]. A growing number of hospitals have introduced vascular nursing teams who are responsible for insertion of devices [11].

In France, PICC placement was previously considered as a medical procedure that could not be delegated. However since 2015, radiology technicians are allowed to insert PICCs under radiologist supervision [12,13]. In a context of a growing number of PICCs insertions in our hospital, a cooperation program started in April 2016.

The purpose of this study was to evaluate the cooperation program in order to compare incidence of complications after PICC placement between radiologists and technicians

Patients and Methods

Study population and cooperation program

The local institutional review board approved our protocol and all patients signed written informed consent. The cooperation program began in April 2016 and all patients who underwent PICC placement were recorded in a database (RedCap® software, 7.6.0 version). When patients had more than one PICC placement during the study period, only the first placement was considered for analysis. Data including operator (radiologist or technician), patient demographic data, catheter type and size, site of insertion, date of PICC insertion and removal, were collected for all patients. Analysis ended in February 2017.

Patients who underwent PICC placement from January 1st to January 31st 2017, were followed-up until PICC removal. Complications and reasons for PICC removal were prospectively recorded.

The cohort was composed of adult patients only. Patients from intensive care unit (ICU) were not addressed to our department. The follow-up period ended upon PICC removal for each patient.

Patients were eligible for the cooperation-delegation program when they were able to understand the program, speak the country language, be without mental disease or immunodeficiency, have an insertion scheduled within normal working hours, and have a delegated radiology technician available. If these criteria were validated, they were proposed the cooperation program and included in the technician group. The others insertions were radiologist-led and patients were included in the radiologist group. The cooperation program was available from 8 AM to 6 PM from Monday to Friday. Patients were not randomized.

PICC placement technique

PICC line protocol was standardized between groups and consisted of chlorhexidine skin preparation, hand washing prior PICC placement, use of sterile gloves, sterile gown, cap, mask for providers inserting and assisting with insertion, full-body sterile drape for patient. All PICCs were placed under ultrasound guidance (selection of the appropriate vein so that the vein diameter in mm should be at least the catheter diameter in Fr) and fluoroscopic guidance (tip placement) in a dedicated fluoroscopy ward for vascular access placement either by a trained interventional radiologist (5 radiologists with more than 5 years of experiment in central line placements) or by a trained technician. Five technicians with extensive experience in PICC placement assistance and volunteered to participate, were trained following a specific procedure including: 20 hours of theoretical training, 20 PICC insertions as main assistant of radiologist, 10 PICC insertions as operator with a senior radiologist as assistant and a practical examination under a senior radiologist supervision at the end. Before the procedure, the agreement of the patient was always obtained for the insertion led by technicians. When PICC placement was performed by a technician, a senior radiologist was always available should he be needed. The PICC devices used were valved PowerPicc solo2® single-lumen (4F) or double-lumen (5F) (Bard Access Systems). PICCs were maintained in place with StatLock® adhesive dressings (StatLock, Bard).

Definitions of cooperation indicators and complications

The analysis included number of patients eligible to the program and adhesion rate; number of help requests from the radiology technician to the radiologist and justified alarm rate; insertion rate by radiologist after a failed insertion by the technician; delegated insertion rate with at least one declared adverse effect during the insertion; patient rate with less than two days between the demand and PICC placement; satisfaction level from patients, radiologist and technicians.

After each PICC placement led by a technician, the patient satisfaction was orally evaluated on a scale from 1 to 5: (1 very unsatisfied; 2: unsatisfied; 3: neutral; 4: satisfied; 5: very satisfied). For scores below 4, a written questionnaire was used to determine the patient feeling. The technician and the radiologist satisfaction were evaluated with the same scale in separate interviews with the head of department.

Central line-associated bloodstream infection (BSI) was defined as a bacteremia in a patient who had at least one positive blood culture result obtained from a peripheral vein, clinical manifestations of infection and no other apparent source for bloodstream infection except the catheter placement in the 48-hour period before the BSI (7). Catheter-related bloodstream infections were defined by the same organism recovered from peripheral blood culture and from quantitative culture of the catheter. DVT was defined as thrombosis involving the deep veins of the arm detected by Doppler ultrasound. Suspected DVT was defined as clinical signs without ultrasound confirmation. Catheter occlusion was defined as a total occlusion of the device (*i.e.*, if unable to perform injection or sampling and/or no blood reflux). Catheter dwell time was calculated as the difference between the insertion and removal dates.

Statistical analysis

Data were analyzed on a per PICC placement basis. The incidence rates of PICC infections were estimated as incidence rate per 1000 catheter days. Quantitative variables were expressed as mean, SD and ranges; Qualitative variables were expressed as raw numbers, proportions and percentages. Comparisons of qualitative variables between patients who had PICC placement by radiologists and those who had PICC placement by technicians were performed using Chi² test or Fisher's exact test. Student test was used to compare quantitative variables. *P* values ≤ 0.05 were considered statistically significant. Data analysis was performed using SPSS® software (23.0 version).

Results

Population

From April 2016 to end of February 2017, a total of 722 patients had PICC placement. There were 382 men and 340 women with a mean age of 66.8 ± 15.8 (SD) years (range: 18-94 years); of these, 433/722 patients (59.97%) had PICC placement by technicians and 289/722 (40.03%) by radiologists (Fig. 1).

A total of 442/722 patients (61.22%) were included in the cooperation program (Table 1). Technicians needed radiologists' help in 23/442 patients (5.20%) because of puncture failure after 2 attempts (16/23, 70%) or failure of progression of the wire in the vein (7/23, 30%); 6 of these 23 insertions (6/23; 26%) were subsequently achieved by radiologists. One declared adverse event (1/442, 0.23%) occurred during insertion with abundant bleeding at the insertion puncture.

The satisfaction levels ≥ 4 (*i. e.*, 4/5) from patients, radiologists and radiology technicians were respectively at 98.41% ($n = 435/442$), 100% ($n = 5/5$), 100% ($n = 5/5$). For the 7/442 patients (1.6%) with a satisfaction level < 4 (*i. e.*, 1/2/3), 4 indicated pain ($n = 3$) and delay between the demand and PICC insertion ($n = 1$).

Subgroup results

From the 1st to 31st January 2017, 77 patients underwent PICC insertion (Fig. 2); of these three patients (3/77; 3.9%) were lost to follow-up. Trained technicians inserted 44/77 PICCs (57.1%) whereas radiologists inserted 33/77 PICCs (42.9%). For a total of 2713 catheter days, the median PICC dwell time was 18.9 days (mean 36.7 ± 42.8 [SD] days; range 1-182 days). The mean age of this subgroup was 67.1 ± 16.5 (SD) years, with older patients in the radiologist group ($P = 0.053$), most of them were male (40/77, 52.0%) (Table 2).

The complication rate was 26.0% (7.4 per 1000 PICC-days, $n = 20/77$) without statistical difference between technicians and radiologists ($P = 0.296$) (Table 3). Complications included 8 PICC-related infections (8/77, 10.4%) for an incidence rate of 2.95 per 1000 catheter days; 3 DVT (3/77, 3.9%), and 9 catheter occlusions (9/77, 11.7%), without statistically significant difference between the groups.

Discussion

The study evaluated the feasibility of a new cooperation program for PICC insertions in our center. Patients, technicians, and radiologists showed great satisfaction with the program. No significant differences in terms of complications between radiologists and radiology technician operators were found. To the best of our knowledge no data exists concerning the PICC insertion delegation to the radiology technicians and the related complications.

Our 11-month results showed that 60.8% of PICC insertions were delegated. This proportion was also found during our one-month prospective period (57.1% of PICC insertions delegated). Baker et al. in their delegation program of PICC insertions to nurses achieved a 74 % delegation rate [14]. Our lower results could be explained by the technicians' availability and restrictive inclusion criteria for cooperation. Indeed, this study represented the first delegation program in our center and several months were needed to train technicians with a standardized program, thus the pool of trained technicians was small. We also had to maintain patient safety and be very strict with delegation criteria. Another reason was the non-availability of the ward, some PICC insertions on eligible patients had to be done by radiologists at the end of the scheduled program, so outside "delegation hours". 76 % of PICC insertions were in less than 48 hours. With a dedicated ward (only for PICC insertions and no other interventional procedures) and less exclusive delegation criteria, the delegation ratio would have been higher and waiting time between the demand and the PICC insertions would have been reduced.

In our study, the low rate of insertions done by radiologists after a failed insertion by the technician (1.4%) and delegated insertion rate with at least one declared adverse effect (0.2%) showed that radiology technicians were able to independently manage most PICC insertions. These results favorably compare with those from other delegation programs with nurses [14,15]. This could be explained by the theoretical and practical training, the PICC insertion protocol with adequate vein selection by ultrasound and fluoroscopic guidance and the selection of experimented technicians familiar with endovascular procedures. When they were not able to, the radiologists were always available to evaluate and help make decisions, and in each case the request for radiologist help was justified (100% rate). Similarly, the high satisfaction levels of patients, radiologists and radiology technicians showed that the cooperation program could be a satisfactory solution.

The comparison tests for the demographic profile and the device characteristics showed no significant differences between the 2 groups of patients. There was a trend for age ($P = 0.053$) with older patients in RG, which could be due to a higher rate of protocol exclusion and more disabled patients.

In this study, the confirmed PICC related infection rate (CRBSI) was 0.74 per 1000 catheter-days, which was lower than reported in the literature. This could be explained by the absence of ICU patients, the small size of our cohort compared to those found in the literature [16-18] and by insertions in an interventional radiology ward in sterile conditions with a high level of microbiological control (ISO class 7 room). There were less CRBSI in RG group but without statistical significance ($P = 0.202$). If we consider the suspected infections (CLABSI), this rate is higher, closer to what is found in the literature and similar in the two groups. Despite positive blood cultures, these infections were considered “suspected” only because a negative culture of the PICC tip was observed after the device removal. However, all of these patients were under prophylactic antibiotic therapy potentially explaining the negative culture of the device.

In our study, the DVT rate was 1.3%, which was lower than the results found in the literature [4,19,20]. In their systematic review and meta-analysis Chopra et al. found a PICC-related DVT rate of 2-7% [4] whereas Fallouh et al. reported rates varying between 2-75% according to study population, testing modality and threshold for diagnosis [20]. The PICC diameter and the vein evaluation before placement may explain this low rate: 62.3% of PICCs inserted were 4F devices. In a retrospective cohort study of 966 single PICC placements, patients who received 5- and 6-French PICCs were more likely to develop PICC-DVT compared to 4-French PICCs (OR 3.56, [95 % CI: 1.31-9.66] vs. OR 2.21, 95% CI: 1.04-4.70, respectively) [21].

In our study, the 11.7% PICC occlusion rate was greater than those reported in the literature and led to catheter removal. The incidence of lumen occlusion is between 2.4% and 8.7% among in- and outpatients [22-25]. Our higher rate can be explained by the lack of institutional nursing care for PICC use (systematic pulse flushing with saline before and after every use on every lumen) and the lack of institutional procedure to deal with occlusion at the time of the study. Although there is no evidence of the superiority of valved PICC to prevent PICC occlusion [26, 27], we chose to use proximal valved PICC line.

The low complication rate in this study compared with published rates can potentially be explained by the level of training required by the operators and the skills and competence

achieved. In Australia, credentialing involved didactic learning with tutorials administered by senior ICU physicians with a written examination involving pre-insertion assessment, intra-procedural complication management and post-insertion assessment and management [28]. In our center, practical training included the technician observing an important number of catheter insertions prior to undertaking the skill. Procedural volume also played a role where technicians undertook 10 supervised PICC insertions. The interventional radiologists supervised the credentialing of the radiology technicians.

Robinson et al. found that introduction of a dedicated PICC team resulted in a 33% reduction in CVC placement as inappropriate patients were identified and CVCs not inserted [29]. In our study, we found that 76% of the PICC insertions led by radiology technicians were done in less than two days. Robinson et al. found similar results with an 80% decrease in average patient waiting time for PICC insertion, facilitating a more timely discharge from hospital. The study concluded that a dedicated PICC service should become the standard of care for all hospitals with high-volume PICC use [29]. In addition, PICC insertion led by technicians could be cost effective: Walker et al. found that the radiologist group had a statistically significant increased cost (42%) over the nurse group [30]. For the same reason vascular access nurses seemed to increasingly represent a key partner in the care of hospitalized patients [31], the radiology technicians had an important and a legitimate role in the PICC circuit at our hospital. Moreover, delegation programs with technicians facilitate logistic issues involved in coordinating the availability of operators in radiology departments which have no nursing team.

This study has some limitations. The major limitation was that the study was conducted in a unique center with a relatively small subgroup of patients who were prospectively studied. No randomization was applied and the cooperation program was analyzed retrospectively. At the time of the study, PICC were placed in an interventional ward with fluoroscopic guidance in our center. More modern guidance systems are developing such as electrocardiogram guidance [32]. With these new technologies, most of the PICC insertions don't require interventional radiology suite. Cooperation program with radiology technicians seemed not to be the more suitable. We could consider less cost effective solutions for radiology department such as bedside insertion delegated to nurses.

In conclusion, this study is the first delegation program in our country showing no significant difference in terms of complications between PICC insertions led by technicians or radiologists. Other studies on larger randomized cohorts are needed to confirm these results in

other centers. It would be interesting to apply a medico-economic approach of these results to confirm whether PICC placements done by technicians will be cost effective.

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Conflicts of interest

The authors have no conflicts of interest to disclose in relation with this study.

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Figure legends

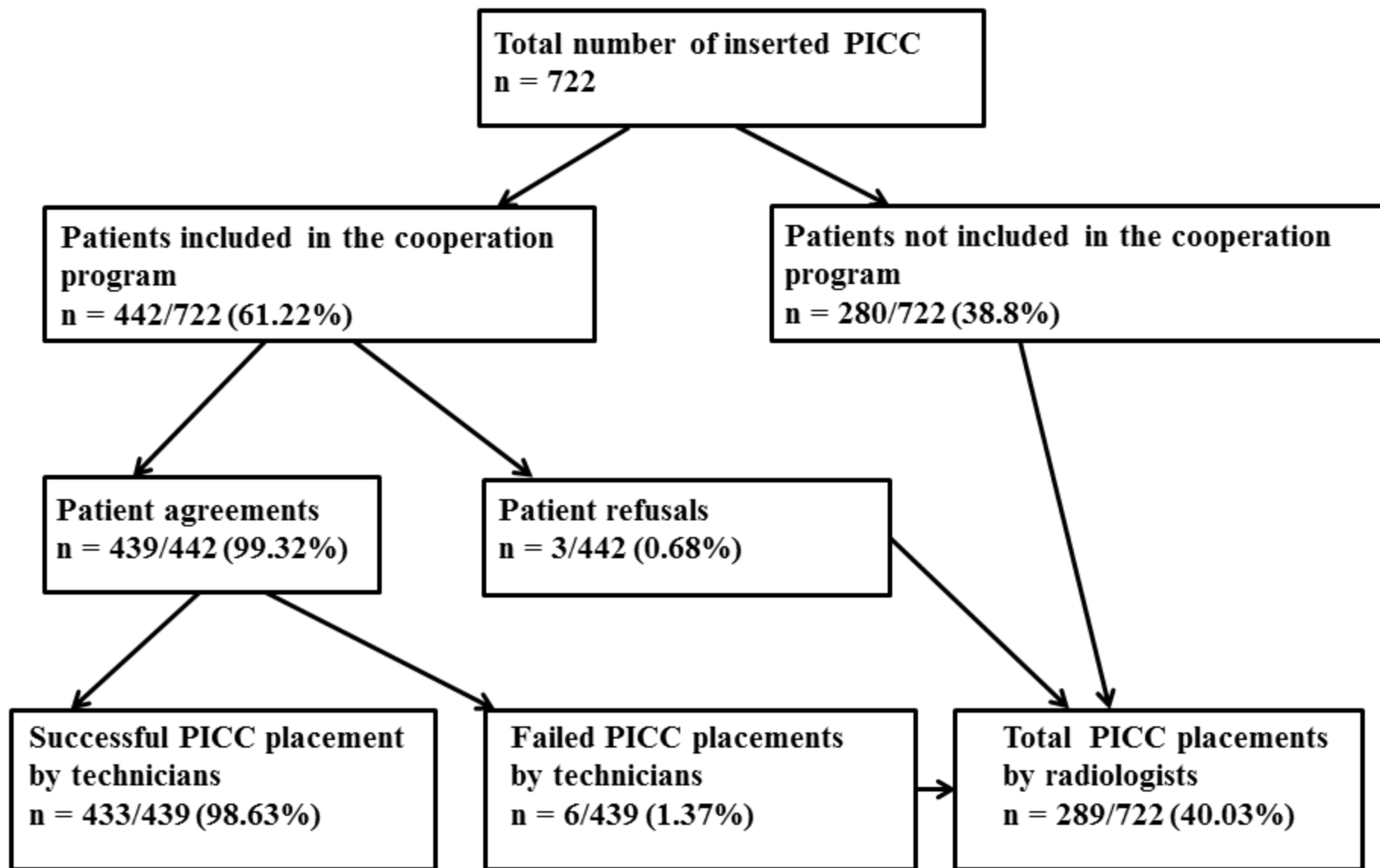
Figure 1. Flow chart of patients inclusion into the study.

Figure 2. Diagram shows reasons for PICC removal a subgroup of 77 patients who were prospectively studied.

Table 1. Cooperation indicators and 11-month follow-up results.

Table 2. Patients and PICC devices characteristics in the prospectively studied subgroup of patients.

Table 3. Complications in the prospectively studied subgroup of 77 patients.



Total of included PICCs
n = 77

PICCs lost to follow-up
n = 3/77 (3.9%)

Monitored PICCs
n = 74/77 (96.1%)

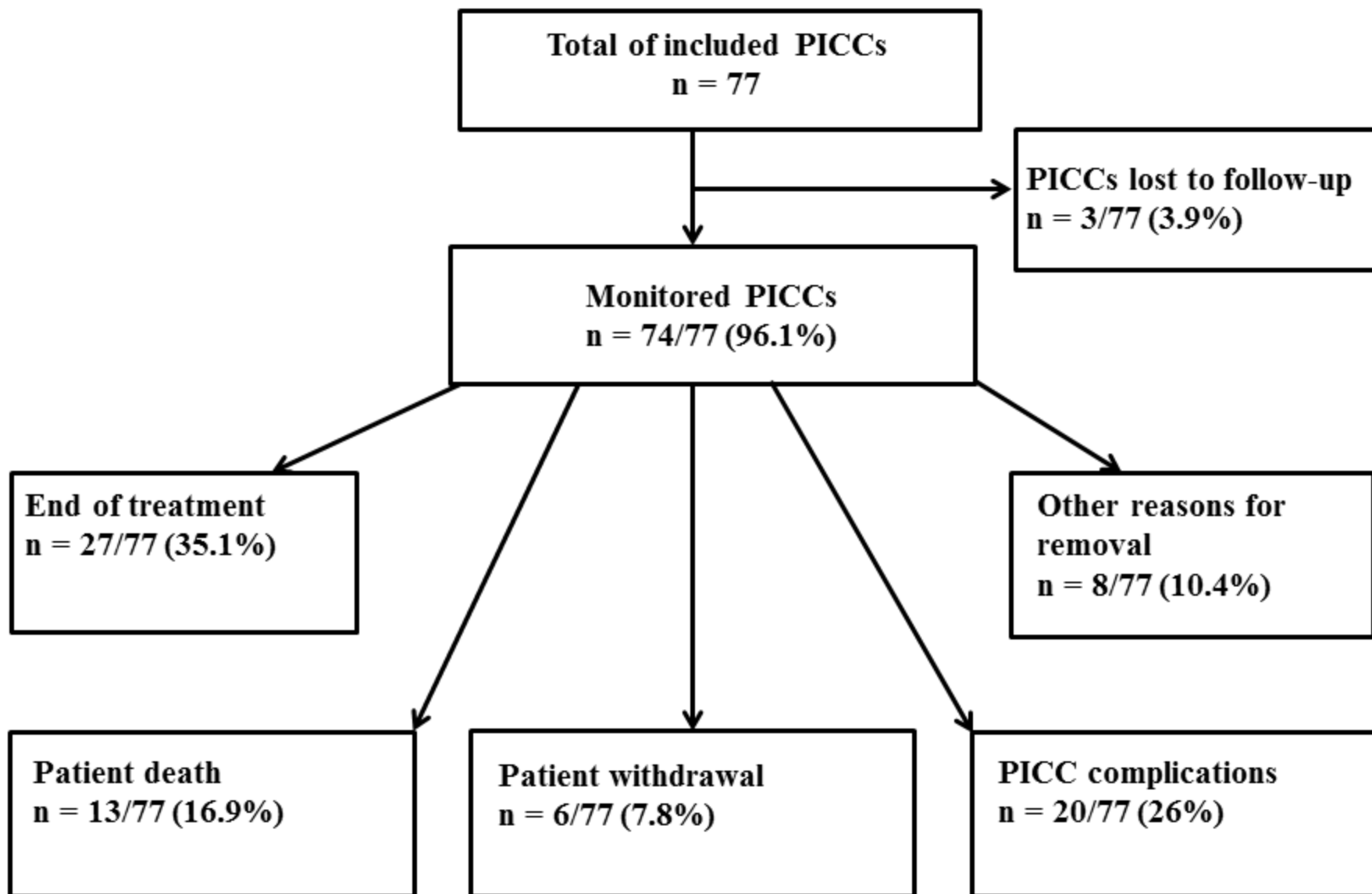
End of treatment
n = 27/77 (35.1%)

Other reasons for removal
n = 8/77 (10.4%)

Patient death
n = 13/77 (16.9%)

Patient withdrawal
n = 6/77 (7.8%)

PICC complications
n = 20/77 (26%)



Variables

Number of patients eligible to the cooperation program	442 (442/722; 61.22)
Number of refusals from patients eligible to the program	3 (3/442; 0.68)
Help requested from the technician to the radiologist	23 (23/442; 5.20)
Justified alarm rate from the radiology technician to the radiologist	23 (23/23; 100)
Insertion rate done by radiologist after a failed insertion by the technician	6 (6/442; 1.36)
Delegated insertion rate with at least one declared adverse effect	1 (1/442; 0.23)
Patient rate with less than two days between the demand and the PICC insertion	336 (336/442; 76.02)
Satisfaction level from patients $\geq 4^*$	435 (435/442; 98.41)
Satisfaction level from radiologists $\geq 4^*$	5 (5/5; 100)
Satisfaction level from radiology technicians $\geq 4^*$	5 (5/5; 100)

Note. Numbers are raw numbers. Numbers in parentheses are proportions followed by percentages

* On a Likert scale from 1 to 5

Characteristics	All operators (n=77)	Technicians (n=44)	Radiologist (n=33)	<i>P</i> value
Age (year)	67.1±16.5 [18-94]	63.9 ±16.8 [18-93]	71.3±15.4 [36-94]	0.053
Gender				
Men	40 (52)	25(56.8)	15(45.5)	0.576
Women	37 (48)	19(43.2)	18(54.5)	0.560
Indication for PICC insertion				
Long-term IV antibiotics	43 (55.8)	26 (59.1)	17 (51.5)	0.723
Chemotherapy	19 (24.7)	10 (22.8)	9 (27.3)	0.723
Blood transfusion	8 (13.4)	3 (6.8)	5 (15.2)	0.457
Parental nutrition	13 (16.9)	5 (11.4)	8 (24.4)	0.211
Hydration	51 (66.2)	31 (70.5)	20 (60.6)	0.682
Other (e.g. analgesics)	54 (70.1)	36 (81.9)	18 (54.5)	0.271
Side of PICC insertion				
Left	61 (79.2)	35 (79.5)	26 (78.8)	0.978
Right	16 (20.8)	9 (20.5)	7 (21.2)	0.948
Vein of PICC insertion				
Basilic	53 (68.8)	31(70.5)	22(66.7)	0.878
Brachial	24 (31.2)	13(29.5)	11(33.3)	0.797
Cephalic	0 (0)	0 (0)	0 (0)	1
PICC diameter				
4F	48 (62.3)	28 (63.6)	20 (60.6)	0.896
5F	29 (37.7)	16 (36.4)	13 (39.4)	0.855
Mean PICC dwell time (day)	36.7 ± 42.8 [1-182]	38.8 ± 45.8 [1-182]	33.6 ± 38.7 [1-143]	0.606

Note. Numbers are raw numbers. Numbers in parentheses are percentages.

Quantitative variables are expressed as mean ± SD. Numbers in brackets are ranges

Complications	All patients (n=77)		Technicians (n=44)		Radiologists (n=33)		<i>P</i> value
	Value	Rate*	Value	Rate*	Value	Rate*	
PICC related infection	8/77 (10.4)	2.95	4/44 (9)	2.34	4/33 (12)	3.97	0.724
<i>CRBSI</i>	2/77 (2.6)	0.74	2/44 (5)	1.17	0	0	0.507
<i>CLABSI</i>	6/77 (7.8)	2.21	2/44 (5)	1.17	4/33 (12)	3.97	0.4
DVT	3/77 (3.9)	1.11	3/44 (7)	1.76	0	0	0.264
<i>Confirmed</i>	1/77 (1.3)	0.37	1/44 (2)	0.59	0	0	1
<i>Suspected</i>	2/77 (2.6)	0.74	2/44 (5)	1.17	0	0	0.507
PICC occlusion	9/77 (11.7)	3.31	7/44 (16)	4.10	2/33 (6)	1.98	0.3
<i>Single lumen</i>	4/77 (5.2)	1.47	3/44 (7)	1.76	1/33 (3)	0.99	0.635
<i>Double lumen</i>	5/77 (6.5)	1.84	4/44 (9)	2.34	1/33 (3)	0.99	0.397
Total	20/77 (26)	7.37	14/44 (32)	8.2	6/33 (18.2)	5.95	0.296

Note. Numbers are proportions. Numbers in parentheses are percentages

* Rates are expressed as per 1000 catheter days