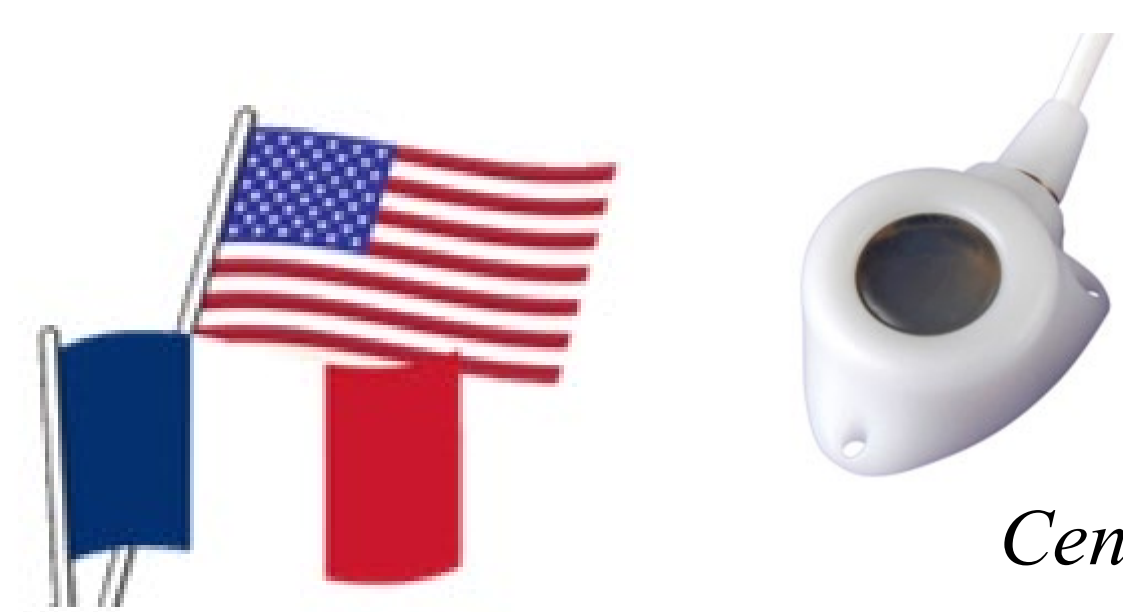




Performance and safety evaluation: a monocentric study on central venous access implantable ports over 5 years

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INTRODUCTION

Daily clinical practice requires repeated and prolonged venous access for delivering chemotherapy, antibiotics, antivirals, parenteral nutrition, or blood transfusions, with the optimal approach under constant discussion. Totally implantable vascular access devices (TIVADs) are routinely used for the long-term delivery of these fluids. The aim of this study was to investigate the performance and the safety of TIVADs over a 5-year follow-up period through a standardized well-trained surgical technique and patient management under local anesthesia.

SURGICAL TECHNIQUE

The TIVAD placement involved a surgical technique with patients positioned on radiolucent wheeled stretchers. A solution of 150 mg 7.5% Naropein®, diluted with normal saline, was injected into the delto-pectoral groove site. Subsequently, the TIVAD was rinsed with normal saline solution for preparation. An incision parallel to the deltopectoral groove was made for aesthetic reasons, enabling access to the cephalic vein for ligation. The catheter was inserted into the vein and guided radiologically to a placement approximately one to two centimeters below the carina. After connection to the port on the pectoral muscle, functionality was verified using a 'Huber' needle for blood reflux flow and injection of normal saline solution. Closure was achieved using resorbable sutures, followed by a final radiological assessment for confirmation of proper TIVAD placement. Notably, no antibiotic prophylaxis was administered in this study.

RESULTS

	Total		Male		Female	
Mean age (SD)	62.2 (12.25)		65.0 (12.55)		60.9 (12.02)	
Population Age Groups	n	%	n	%	n	%
< 50 years	14	20.0%	3	13.6%	11	22.9%
50-70 years	41	58.6%	13	59.1%	28	58.3%
> 70 years	15	21.4%	6	27.3%	9	18.8%
TOTAL	70		22	31.4	48	68.6

Figure 1: Overview of Patient Characteristics.

Catheter Placement		
Selected vein	Number of cases	%
Left cephalic	14	20
Right cephalic	36	51.4
Left subclavian	2	2.9
Right subclavian	12	17.1
Right jugular	6	8.6
TOTAL	70	
Port Placement		
Selected Muscle	Number of cases	%
Left pectoral muscle	16	22.9
Right Pectoral muscle	54	77.1
TOTAL	70	

Figure 4: Overview of the selected vein and muscle for the catheter and port placement. The procedural success rate was 100%.

Device Range	Implantable Port Features	Catheter Features				Studied Devices (Total = 70)	
		Diameter (mm)		French Size	Catheter Length (cm)	Number	%
		Outer	Inner				
3007 ISP	0.35	2.16	1.02	6.5	60	4	5.7
4008 ECHO	0.6	2.4	1.2	7.2	60	3	4.3
4008 ISP	0.6	2.4	1.2	7.2	60	63	90

Figure 2: Characteristics of POLYSITE® Medical Devices. Implantable ports and catheters were constructed using Titanium-Polyoxy-methylene (POM) and silicone, respectively.

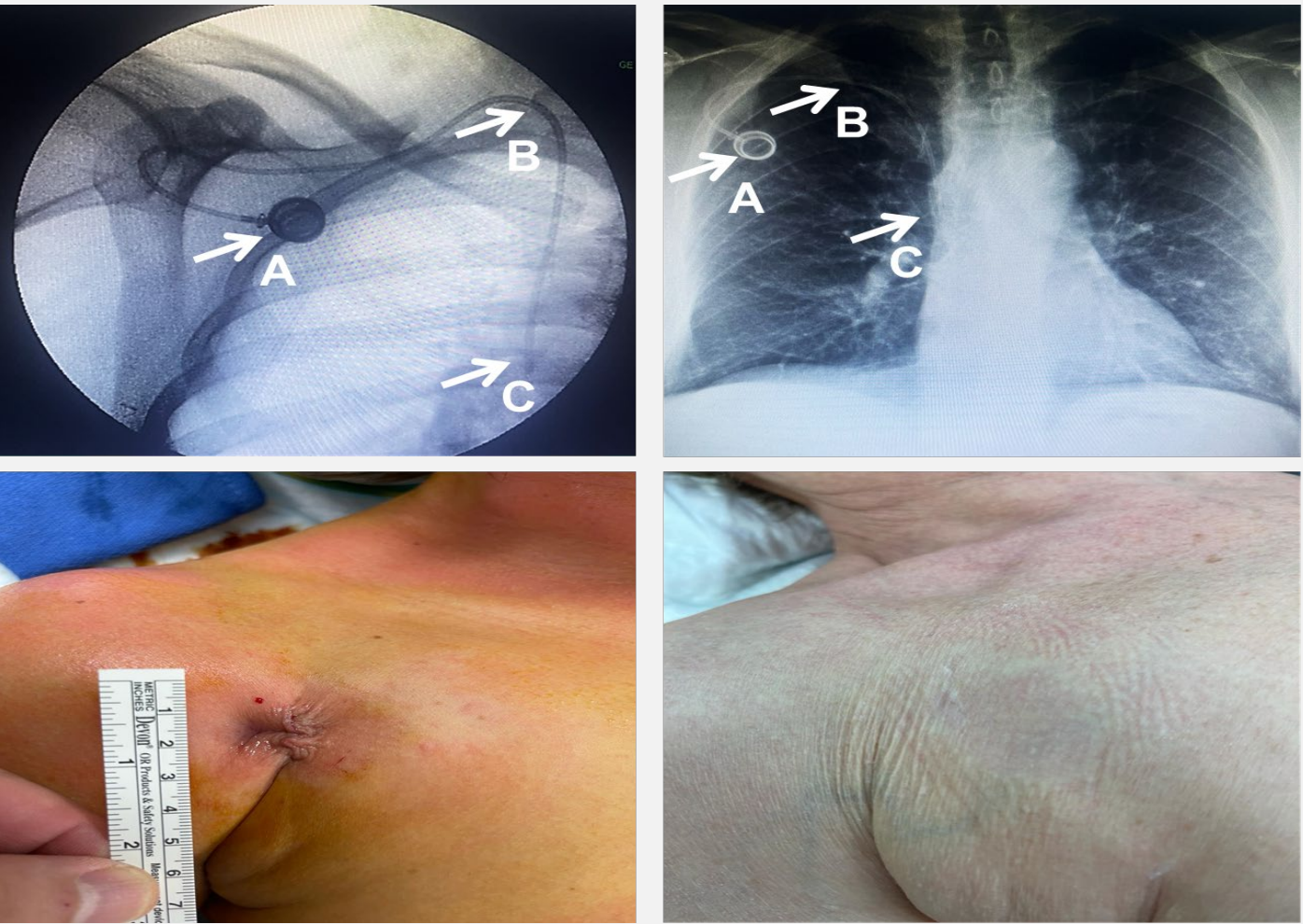


Figure 5: Radiological confirmation of correct TIVAD placement and wound healing. Upper Row: A. Port, B. Catheter, C. Catheter tip. Lower Row: Surgical wound immediately after catheter placement (left), and 2 months post-surgery (right).

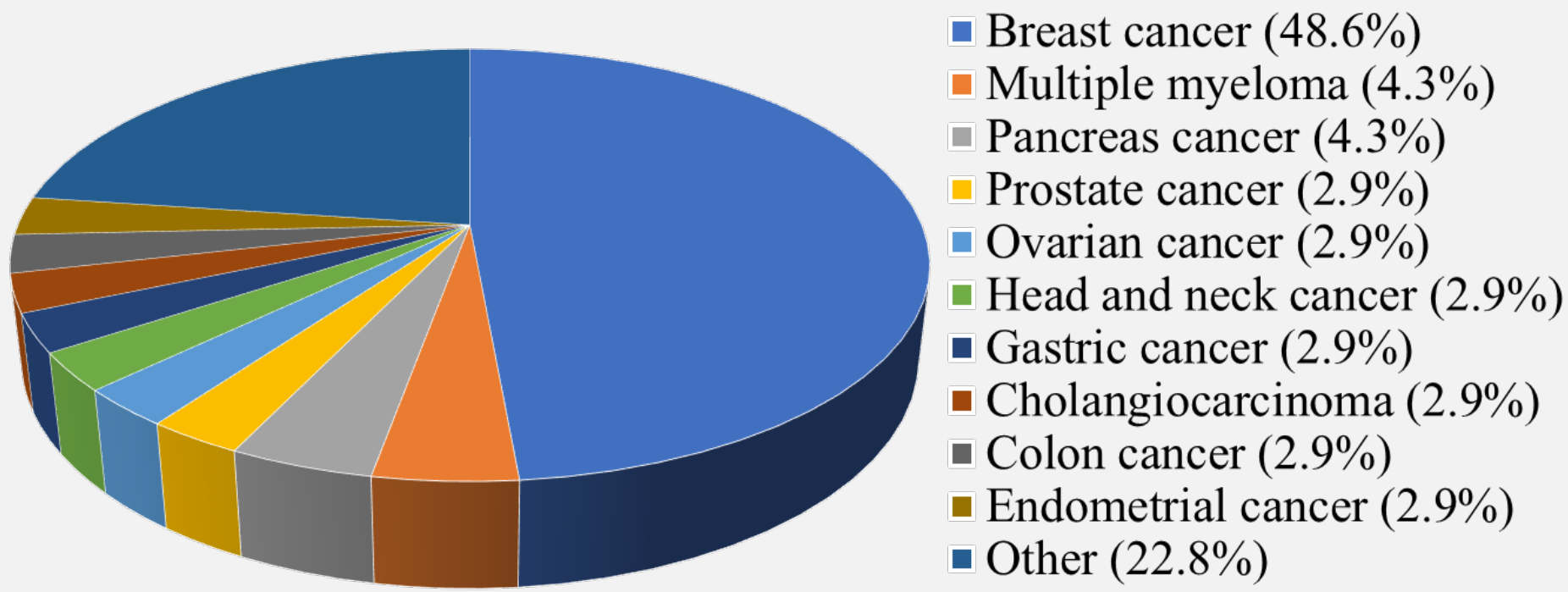


Figure 3: Overview of study participants with different malignancies. TIVADs were primarily utilized to deliver chemotherapy to primarily breast cancer patients.

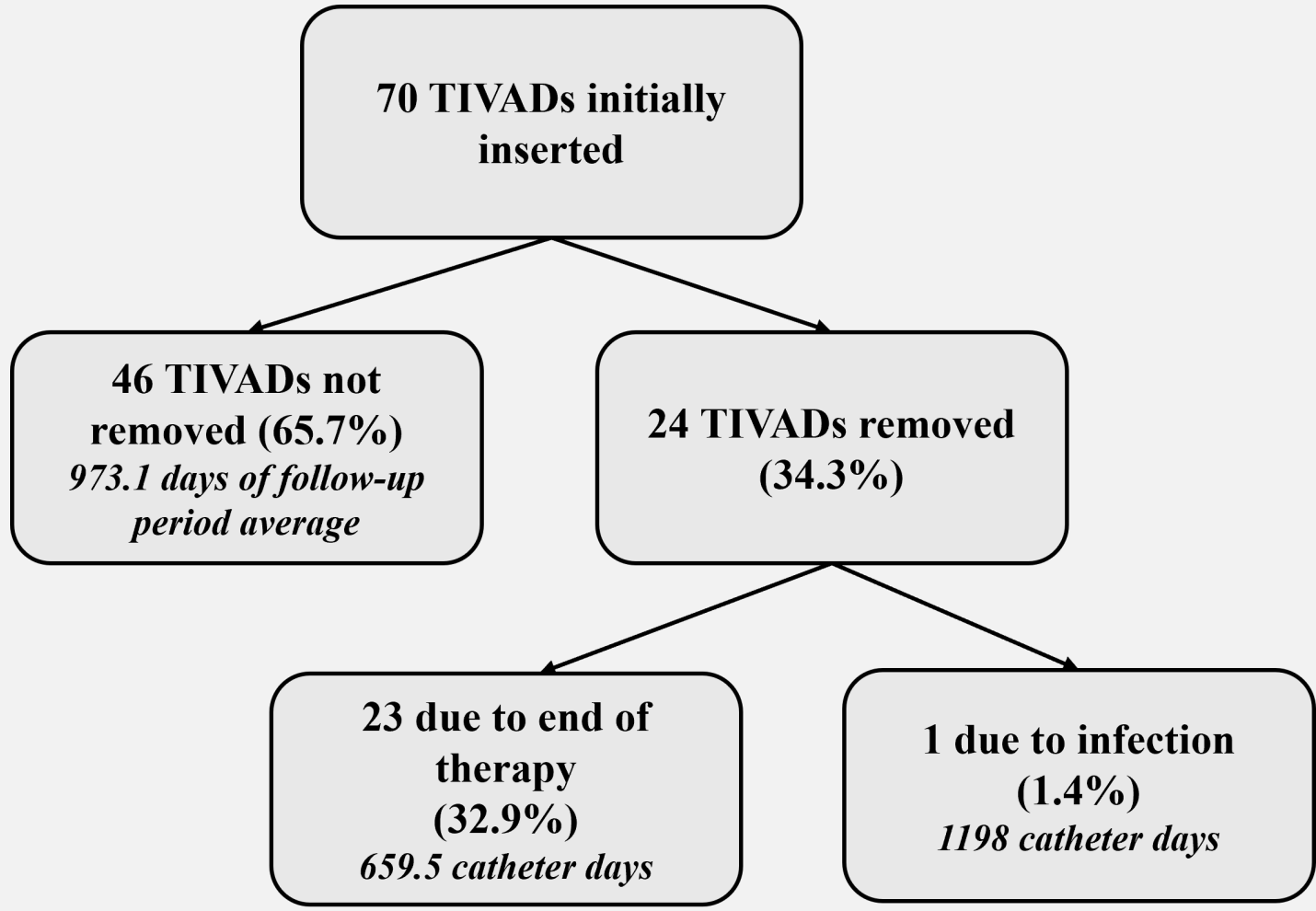


Figure 6: Overview of catheter status and catheter days. The infection was caused due to usage conditions and was successfully resolved within an appropriate timeframe.

CONCLUSION

A well-trained surgeon and surgical team, a dedicated operative time, a standardized surgical technique, and a well-managed protocol are crucial elements for ensuring a well-tolerated and comfortable surgical procedure under local anesthesia preventing the incidence of general anesthetic complications and particularly peri-operative infections. The TIVAD's use was demonstrated to be safe, reproducible, and well tolerated by the patients. Given the growing demand for long-term chemotherapy regimens and the increasing emphasis on improving patients' quality of life, there is likely to be a significant rise in the need for TIVADs in the future. Nevertheless, additional prospective studies or more inclusive cohort studies are necessary to validate and confirm these findings.

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