

THE COMPLICATIONS OF TOTALLY IMPLANTABLE CENTRAL VENOUS ACCESS PORTS: RESULTS FROM A PROSPECTIVE STUDY IN MOROCCO

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Published in June 2024

Abstract

Background: The purpose of this work is to present a prospective study on the implantation of a totally implantable central venous port system (TICVPS) for chemotherapy patients as well as to assess and compare the complications that have occurred in our department to those reported in the literature. **Methods and Materials:** The oncology center hosted the study, which involved 100 cancer patients between July 7, 2020, and July 25, 2021, with an average age of 58.4 years. A right subclavian vein percutaneous puncture was the preferred method in the series. **Results:** The following incidents occurred during device implantation: 1% of accidental arterial puncture hematomas, 2% of failed placements, and 1% of pneumothorax cases (necessity of drainage). The long-term evolution was characterized by obstruction, which accounts for 1% of all placements, infection, 3%, thrombosis, and extravasation, which together account for 1% of all placements. **Conclusion:** The use of implantable catheters enhances both the patient's and the healthcare team's comfort, but the procedure has complications that can occasionally be dangerous despite its generally benign reputation.

Keywords: Cancer; Complications; Case series; TICVPS; Prospective study; Morocco.

Introduction

The totally implantable central venous port system (TICVPS) first appeared in oncology in the early 1980s [1] to protect the venous capital in patients needing long-term treatments (chemotherapy, parenteral nutrition, antibiotic therapy, and transfusion of blood derivatives) and when a peripheral venous approach is not feasible. It consists of a central catheter connected to an injection chamber placed under the skin.

We present results of a prospective 12-month study. In order to determine whether the complication rate was comparable to that which has been reported in the literature, this study set out to identify the immediate and late complications of inserting a TICVPS.

Methods

This prospective study, known as the cases series, is a single observational and descriptive investigation of the insertion and use of a TICVPS. It tracked a cohort of 100 patients at the cancer center over the course of 12 months, from July 7, 2020, and July 25, 2021.

The goal was to assess the TICVPS-related complications, taking into account the following information: age, sex, tumor type, WHO, approach, amount of time between catheter placement and use, difficulty of catheter placement, and early and late complications.

The procedure has been programmed, and we have established a file of details for each patient, explaining to them the procedure, the materials to be used, and the indication. The inclusion criteria are patients who have been diagnosed with a tumor and need anti-cancer treatment.

Excluded from our study were patients who underwent Totally Implantable Venous Access Port System

(TIVAPS) placement outside the study period or for reasons other than chemotherapy.

Except for patients with a right breast tumor, a right lung tumor, or who have had radiation treatment on this side, local anesthesia with 2% Xylocaine was administered before systematically puncturing the right subclavian vein. Chest radiography was done after the procedure to rule out pneumothorax and confirm site position. The vein was approached using the blind Seldinger technique through a percutaneous approach. Following placement, implantable sites were used 24 hours later. For our patients, a paracetamol-based analgesic was prescribed, as well as local care, with thread removal after 21 days. We didn't administer systemic antibiotic prophylaxis. The equipment used for this study was the *Vygon* and *Bard Port*.

The surgical procedures were carried out by a single practitioner, a university professor and anesthesiologist, who has 12 years of experience in intensive care at a university hospital. After the patients left, follow-up was carried out by phone consultations in addition to clinical and paraclinical examinations in the event that symptoms persisted. Anticancer chemotherapy, whose etiologies are listed in (Table 1), has been the primary reason for the placement of a TICVPS.

Table 1 : Distribution of tumours

Tumours	Prospective study	
	Number	%
Breast tumour	27	27 %
Gastric tumour	24	24 %
Colon tumour	20	20 %
Lung tumour	5	5 %
Tumour of the rectum	4	4 %
Prostate tumour	3	3 %
Pancreatic Tumor	3	3 %
Endometrial tumour	2	2 %
Brain tumour	2	2 %
Lymphoma	2	2 %
Bladder tumour	1	1 %
Laryngeal tumour	1	1 %
Abdominal wall tumour	1	1 %
Bone tumour	1	1 %
Cervical tumour	1	1 %
Tumour of head and neck	1	1 %
Liver tumour	1	1 %
Dual location (gastric tumour + lung tumour)	1	1 %

Results

In our prospective study, the population is composed of 45% men and 45% women, including a 9-year-old child. The extremes ranged from 9 to 86 years, with a mean age of 58.4 years. The most frequent type of tumor in patients is breast cancer (27%), which is followed by gastric cancer (24%), colon cancer (20%), lung tumors (5%), and rectum tumors (4%), prostate tumors (3%), pancreatic tumors (3%), lymphoma cancer (2%), endometrial cancer (2%), brain cancer (2%), as well as tumors of the head and neck, cervical, larynx, abdominal wall, liver, bone, bladder, and double location (gastric and lung) (1%).

The performance status had the following values: 0 for 4%, 1 for 67%, 2 for 23%, 3 for 5%, and 4 for 1%.

In all of our series, percutaneous subclavian vein puncture was the preferred method; 80% of patients had the procedure done on the right, 19% on the left, and 1% where the route was changed from right to left. The interval between placement and the first use of the site varied from 24 hours to 2 months. In our study, there was a correlation between operational challenges and complications: 74% of patients had straightforward postoperative care without operational challenges, 17% had operational challenges but simple postoperative care, and 7% had operational challenges and complications (Pneumothorax, hematoma). The majority of postoperative complications (immediate complications) were minor, with the exception of 1% of cases of hematoma from accidental arterial puncture, 2% of cases of placement failure with a change in route, and 1% of cases of pneumothorax (requiring drainage). No cases of gas embolism were reported. Late complications include obstruction, which occurs in 1% of all placements, 3% of infection cases, 1% of thrombosis cases, 1% of extravasation cases, and no cases of catheter migration or rupture.

In our series, removal of the chamber was necessary in 5% of patients; in 2% of cases of infection, 2% of cases at the end of therapy, and 1% of cases of catheter thrombosis.

The long-term mortality rate from the evolving element of cancer disease was 20%.

Discussion

In our study, the median age was 58.4 years, with the range of extremes being 9 to 86 years. We observe a predominance of the over-60 age group, which can be explained by the fact that tumor pathology is a disease of the elderly. The majority of tumors were in females, and the most common tumor was breast cancer, followed by digestive cancers. The subclavian vein was punctured most frequently; the right side was routinely punctured because the left side has a risk

factor for thrombosis [2]. In the following situations, the left side was punctured instead: when the right puncture failed, when a right breast tumor required surgical intervention, when a right lung tumor was present, and when there was a local contraindication to the right puncture, such as a skin infection, radiation exposure in the past, or skin metastases.

In the literature (Table 2), the frequency of pneumothorax is less than 5% for the subclavian route

and less frequent for the internal jugular route. This frequency increases in subjects with atypical morphology (cachectic, obese, emphysematous...) and decreases with the experience of the operator [3]. In our prospective series of 100 percutaneously placed central venous catheters, the incidence of pneumothorax is 1%, compared to 3.1% reported by LEFRANT in a prospective series of 707 surgically placed central venous catheters [4].

Table 2 : Comparison of the frequency of pneumothorax in our series versus the literature

Author	Study	Country	Year	Number	Frequency of PNO
Paoli [7]	Prospective	France	1994	164	3.04%
Boussen [8]	Prospective	Tunisia	2001	205	1.5%
El Kabiri [9]	Retrospective	Morocco (Rabat)	2012	970	0.2%
Our series	Prospective	Morocco (Oujda)	2021	100	1%

According to the literature (Table 3), postoperative hematomas occur anywhere between 0.86% and 2.9% of the time. One case (1% of the total) was noted in our prospective series. A pressure dressing was used

to treat the patient, who had a normal platelet count, no history of thromboembolism, and required only basic aftercare.

Table 3 : Comparison of the frequency of hematoma in our series versus the literature

Author	Study	Country	Year	Number	Frequency of hematoma
Paoli	Prospective	France	1994	164	1.82 %
Boussen	Prospective	Tunisia	2001	205	2.9%
Talfer [10]	Retrospective	France	2003	116	0.86%
Rouzoukh [11]	Retrospective	Iran	2009	524	1.1%
EL Kabiri	Retrospective	Morocco	2012	970	2.47 %
Our series	Prospective	Morocco (Oujda)	2021	100	1%

Numerous studies have compared the rates of infection for implantable chambers and tunneled catheters. Onco-hematology patients were the subjects of the initial studies, which demonstrated the superiority of the implantable chamber in reducing the risk of infection. In a prospective, non-randomized study involving 1431 oncology patients, Groeger and al. found that using a tunneled catheter was associated with a 12 times higher risk of catheter-related infections than using an implantable chamber [5]. Our study found a rate of 3%, while the literature (Table 4) reports rates that vary depending on the series from 1.5% to 9.5%. Since TICVPS infection can range from a straightforward local infection to sepsis, which can be fatal, there is likely a large degree of variation between series. The standard treatment for these infections is still removal of the catheter along with systemic antibiotic therapy, but the use of the local antibiotic lock technique has been demonstrated to be

effective, with a high rate of healing and catheter salvage, and the combination of urokinase with a local antibiotic lock may enhance and encourage the maintenance of the implantable site in place. In our study, the health center served as the location for dressing changes and thread removal. The diameter of the catheter, the malposition, the left side, the location on the femur, the type of cancer, and chemotherapy are all thrombogenic risk factors that can lead to chamber dysfunction and a non-negligible risk of pulmonary embolism. Low molecular weight heparin in a curative dose continues to be the standard of care, followed by anti-vitamin K, with the possibility of saving the chamber if it is properly positioned, uninfected, and operational. When compared to our series, where the thrombosis rate was 1% and the chamber was removed because it was inoperable, the literature reports rates ranging from 1.3% to 8.5% depending on the series.

Table 4: Comparison of the frequency of infections in our series versus the literature

Author	Study	Country	Year	Number	frequency of infection
Paoli	Prospective	France	1994	164	1.8%
Boussen	Prospective	Tunisia	2001	205	3.9%
Talfer	Retrospective	France	2003	116	9.5%
Rouzoukh	Retrospective	Iran	2009	524	8.8%
EL kabiri	Retrospective	Morocco (Rabat)	2012	970	1.5%
Our series	Prospective	Morocco (Oujda)	2021	100	3%

The information at hand suggests that extravasation may be occurring less frequently. This could be brought about by better infusion practices, early medication leak identification, and continuous staff training on handling extravasation situations. In our study, only one extravasation case was found after six months of patient follow-up. This case was explained by the Huber needle accidentally being displaced, which led to soft tissue edema in the chamber without inflammatory symptoms or secondary infection. The treatment plan called for stopping and disconnecting the infusion, aspirating the maximum amount of an extravasated medication, injecting saline 0.9% to dilute the medication, and applying warm compresses

every 15 minutes while under clinical observation for 24 hours, the suites were simple.

According to the literature (**Table 5**), obstruction rates can range from 0.5% to 6.1%, depending on the series, and are usually caused by fibrin deposits that lead to blood clot formation. In our series, we only documented one obstruction case that was successfully treated with a diluted heparin flush and positive blood reflux. To reduce the risk of catheter obstruction, which can be brought on by thrombosis, precipitates associated with incompatible drugs, or lipid deposits, flushing of the TICVPS is advised after drug administration, checking for reflux, drawing blood, and when the needle is removed.

Table 5: Comparison of the frequency of obstruction in our series versus the literature

Author	Study	Country	Year	Number	Frequency of obstruction
Paoli	Prospective	France	1994	164	1.3%
Talfer	Retrospective	France	2003	116	3.4%
Rouzoukh	Retrospective	Iran	2009	524	6.1%
EL kabiri	Retrospective	Morocco (Rabat)	2012	970	0.5%
Our series	Prospective	Morocco (Oujda)	2021	100	1%

No patient experienced catheter migration, which corresponds to a frequency of 0%, while data from the literature (**Table 6**) show rates that vary depending on

the series from 0.4% to 6.7%. Notably, the postoperative thoracic radiograph in our work is systematic.

Table 6: Comparison of the frequency of catheter migration in our series versus the literature

Author	Study	Country	Year	Number	Catheter migration frequency
Paoli	Prospective	France	1994	164	0.6%
Boussen	Prospective	Tunisia	2001	205	1%
Talfer	Retrospective	France	2003	116	3.4%
Rouzoukh	Retrospective	Iran	2009	524	6.7%
EL kabiri	Retrospective	Morocco (Rabat)	2012	970	0.4%
Our series	Prospective	Morocco (Oujda)	2021	100	0%

In our series, we found no instances of aberrant pathways. We developed a machine learning model aimed at predicting complications associated with TIVAPS, and we assessed the effectiveness of various machine learning techniques in this task. Utilizing the dataset collected during the study conducted at the Cancer Center, we applied methods such as Decision Tree, K Nearest Neighbors, Naive Bayes, Multilayer Perceptron, and Stochastic Gradient Descent, as well as ensemble learning techniques such as bagging,

voting, and stacking. Our analyses revealed that the voting technique, combining multiple methods, yielded the most accurate results, with an overall precision of 92.5% [6]. This research demonstrates the effectiveness of applying machine learning methods to predict and prevent complications associated with TIVAPS, thereby enhancing patient care. Currently, we are continuing our research to develop a model capable of predicting the specific type of complications encountered.

The study is reinforced by its comprehensive data collection, encompassing detailed information on patient demographics, tumor types, procedural techniques, and complication rates, thus enabling a thorough understanding of TICVPS implantation and its outcomes. Its prospective design minimizes recall bias and allows for systematic data collection, enhancing reliability. A consistent procedural protocol, from anesthesia administration to postoperative care, ensures uniform patient management, thereby reducing confounding variables. Additionally, the integration of machine learning techniques for complication prediction reflects the study's innovative approach to improving patient outcomes and advancing oncological research. The study's limitations include the relatively small sample size of 100 patients, limiting the generalizability of findings. Longer follow-up periods beyond the 12-month duration may be necessary to capture all potential long-term complications. Additionally, reliance on a single practitioner to perform the procedures introduces the potential for bias due to inter-operator variability. Variation in technique or experience among different operators could impact complication rates and outcomes. The inclusion criteria focusing solely on cancer patients might introduce selection bias, and the method of data collection primarily through phone consultations may lead to reporting bias. These limitations underscore the need for larger, multi-center studies with extended follow-up, diverse patient populations, and more rigorous data collection methods to better understand the outcomes and complications associated with totally implantable central venous port systems (TICVPS) implantation.

Conclusion

The use of implantable catheters has improved the management of cancer patients by providing them with a permanent and secure administration route. In our study, the rate of complications was decreased by proficient implantation technique, avoiding different risk factors, and providing adequate patient education and information.

Utilizing the findings of our investigation, we were able to create a machine learning algorithm that predicts implantable chamber-related complications.

Competing interests

The authors declare no competing interest.

Authors' contributions

All authors were involved in the placement of implantable catheter chambers and in the writing of this article.

Funding

This research received no external funding.

Ethical approval

The ethics committee's clearance was not necessary for this case series. On the other hand, every participant provided their oral informed consent after being completely explained about the nature of the study and before any involvement occurred. Everyone who did not want to participate in the study was free to decline.

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