ORIGINAL ARTICLE

Morbidity of implantation of a port-a-cath: Monocentric study conducted at the Salah Azaiez institute Tunis

Morbidité de la pose d'une chambre à cathéter implantable: Étude monocentrique réalisée à l'institut Salah Azaiez Tunis

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Abstract

Introduction: Port-A-cath (PAC), sinceits introduction in 1982, has seenrapid expansion in its use. However, its placement and use are not withoutrisk, as evidenced by the associated complication rate, which ranges from 10 to 38% in variousseries. Moreover, few Tunisianstudies have investigated ports and their complications. The aim of ourstudywas to evaluate the complications associatedwiththisdevice, identifyriskfactors for complications, and gather patient satisfaction.

Methods: Weconducted an observational, descriptive, and analyticalstudy, involving 112 patients whounderwent PAC implantation at the Salah Azaiez Institut (SAI) betweenFebruary and April 2021. These patients werethenfollowed up at day 0, 3 months, 9 months, and 15 months post-implantation.

Results: All our port placement procedureswereperformedusing the percutaneousmethodguided by anatomicallandmarks. The internaljugularveinwasusedin 98.2% of ourprocedures. Over the 16-month follow-up, 17 complications wereidentified, resulting in an incidence rate of 15%. Most complications (59%) occurredintraoperatively, corresponding to the formation of an intraoperativehematoma, graded Clavien-Dindo I. The main risk factor for complication wasseveralvenouspuncturesgreaterthantwo. Introducingultrasound guidance during placement reduces the complication rate. Regarding patient satisfaction withtheir care at SAI, only 8% reportedbeing "unsatisfied". The reasonsgiven for this dissatisfaction weremainlyrelated to organizationalfactorsinherent to SAI.

Conclusion: PAC placement is a safeprocedurewith a low rate of complications. However, implementing specific measures could reduce its morbidity.

Key words: Cancer, Central venous catheter, Postoperative complications, Intraoperative complications, Vascular access devices

Résumé

Introduction: La chambre à cathéter implantable (CCI) depuis son introduction en 1982, a connu un essor rapide. Néanmoins, sa pose et son utilisation ne sont pas sans danger, comme en témoigne les taux d'incidence de complications associés, variant de 10 à 38% selon les séries. Le but de notre étude était d'évaluer les complications associées à la pose de CCI en peropératoire et à distance de la pose puis d'identifier les facteurs de risque de complications et de recueillir la satisfaction des patients.

Méthodes: Nous avons mené une étude observationnelle, descriptive et analytique, avec recueil transversal répété dans le temps des données, colligeant 112 consultants ayant bénéficiés de la pose d'une CCI à l'Institut Salah Azaiez (ISA) entre février et avril 2021 que nous avons ensuite suivis respectivement à J0, trois mois, neuf mois et 15 mois après la pose.

Résultats: Au total, 17 complications ont été recensées, établissant une incidence de 15%. La majorité des complications (59%) étaient survenues en peropératoire. Le principal facteur de risque de complication était un nombre de ponctions veineuses supérieur à deux. Instaurer un échoguidage lors de la pose diminue l'incidence des complications. Concernant la satisfaction des patients par rapport à leur prise en charge à l'ISA, 8% seulement se disaient « non satisfaits ».

Conclusion: La pose de CCI est une procédure sûre avec un faible taux de complications. Cependant la mise en place de mesures spécifiques pourrait réduire sa morbidité.

Mots clés: Cancer, Cathéter veineux central, Complications postopératoires, Complications peropératoires, Dispositif d'accès vasculaire

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Introduction

Totally Implantable Central Venous Access Port or Port-A-Cath (PAC) enables the repeated delivery of aggressive treatments such as chemotherapy or parenteral nutrition, resulting in a clear enhancement of the quality of life for cancer patients (1).
However, PAC implantation carries risks, including catheter migration, hematoma, infection, thrombosis, and pneumothorax (2).
The percentage of complications associated with this procedure varies according to studies, techniques used, and patient characteristics, ranging from 10% to 38% in the literature (3–5).
Various risk factors for complications have been identified, including advanced age, high body mass index (BMI), history of previous catheterization, parenteral nutrition, and hematologic cancers(4). Moreover, a history of radiotherapy in the access area, prior surgical interventions in the axillary and neck regions, operator inexperience, as well as more than two attempts at venous punctures, are associated with increased morbidity (6).
Few studies in Tunisia have assessed PAC-related complications. Due to the variability in complication rates reported in the literature, we conducted this study within the oncological surgery department of the Salah Azaiez Institute (SAI) to evaluate our quality of care and support its continuous improvement.
In our study, we aimed to assess complications related to PAC placement at different time points : intraoperatively (day 0), as well as at three, nine, and 15 months post-implantation, using the Clavien-Dindo classification (7). Furthermore, we aimed to identify the factors influencing the occurrence of these complications and to assess patient satisfaction with PAC implantation at SAI.

Methods

We conducted an observational, descriptive, and analytical study, involving 112 patients who underwent PAC implantation at the Salah AzaiezInstitut (SAI) between February and April 2021. These patients were then followed-up at day 0, 3 months, 9 months, and 15 months post-implantation.
We included consenting patients who underwent PAC placement for anticancer chemotherapy in the oncologic surgery department at SAI from February 24 to April 21, 2021, regardless of cancer type or stage.
Patients lost to follow-up within three months were excluded from our study.
We collected epidemiological, clinical, and operative data for each included patient.
A form containing two questions related to patient satisfaction was distributed and collected during follow up.
The questionnaire included two items. The first assessed patient satisfaction with their management at SAI. With options 'not satisfied', 'moderately satisfied', and 'very satisfied'. The second item invited patients to explain any dissatisfaction. Responses were later translated from Arabic to English, then summarized and categorized.
All PACs were inserted using the modified Seldinger technique via percutaneous access through the internal jugular vein (anterior or posterior approach) or the subclavian vein. Operators were considered experienced if they had performed at least 50 port implantations prior to the study.
We used the standardized Clavien-Dindo classification (7) for describing surgical complications.
Statistical analysis was performed using SPSS version 26 (Statistical Package for the Social Sciences) software. We first conducted descriptive statistics on all potential risk factors. We then performed a bivariate analysis using either Pearson's chi-square test or Fisher's exact test. We then performed multivariate analysis using a binary logistic regression model, including variables with a p-value less than 0.3 in the bivariate analysis. For all statistical analyses, the significance level was set at 0.05.

Results

Our study was conducted at a single center over an 18-month period divided into two phases: The first phase lasted two months (from February 21, 2021, to April 24, 2021), corresponding to patient recruitment at SAI for PAC placement. The second phase involved follow-up of patients who underwent PAC placement, respectively, at day 0 of implantation, at three, nine, and 15-months post-implantation. Initially, 113 patients were included after meeting the inclusion criteria. However, one patient was later excluded from our study due to loss to follow-up one month after enrollment.
The study population had a median age of 56 years, with ages ranging from 17 to 94. Breast cancer was the most prevalent malignancy (44.6%), followed by gastrointestinal cancers (35.7%).
The main comorbidities were arterial hypertension (11.6%) and diabetes mellitus (8.9%). All patients had a normal preoperative hemostasis profile. No patient had a history of major surgery or radiotherapy in the axillary or neck region, nor prior central venous catheterization before PAC placement.
All PACs were placed percutaneously using anatomical landmarks, without ultrasound guidance. The internal jugular vein was used in 98.2% of cases, and the subclavian vein in 1.8%. Experienced operators performed 95.5% of the procedures. A single venous puncture was sufficient in 88% of cases.
Among the 112 patients enrolled, sixty (53.6%) were followed up for up to 15 months after port placement. The mean follow-up duration for our 112 patients was 308 ± 189 days, ranging from 90 to 450 days.
Over the 15-month follow-up period, 17 complications were recorded, yielding an incidence rate of 15%. The most common morbidity was intraoperative hematoma (8.9%), all classified as Grade I on the Clavien-Dindo scale and resolved spontaneously. No PAC-related mortality was observed. Table I summarizes the complications by time of onset and Clavien-Dindo grade.

Table 1. Complications of PAC according to onset time and Clavien-Dindo Classification

	Hematoma		Wound dehiscence		Port-Associated Infection		Port-related DVT	
	Number of Cases	CD Grade	Number of Cases	CD Grade	Number of Cases	CD Grade	Number of Cases	CD Grade
Day 0	10	I	0	-	0	-	0	-
3 months	0	-	1	IIIa	1	IIIa	2	II IIIa
9 months	0	-	0	-	1	IIIa	-	-
15 months	0	-	0	-	0	-	2	II IIIa

Day 0 indicates intraoperatively; CD Grade indicates Clavien-Dindo Classification 's Grade ; Port-related DVT indicates Port-related Deep Vein Thrombosis

Hematoma

The main risk factor for Hematoma occurrence was several venous punctures greater than two with $p < 0.001$.

Wound dehiscence

No demographic or clinical factor showed significant differences in the occurrence of wound dehiscence.
Port-related Deep Vein Thrombosis (DVT):
Gastrointestinal cancers and several venous punctures greater than two were associated with a higher risk of Port-related DVT with p<.001 and p=0.0011 respectively.

Port-related Infection

Male sex was correlated with an increased risk of occurrence of Port-related Infections with p=0.015.

Satisfaction

A minority of patients (8%) reported dissatisfaction with their care at SAI. Notably, none attributed their dissatisfaction to the PAC. The main reasons cited were organizational issues, including long waiting times in outpatient clinics (82%), poor medical record management (4%), changes in attending physicians during follow-up (2%), and recurrent imaging equipment failures (2%).

Discussion

PACs represent a safe option with a low complication rate. The 15% complication rate observed in our study aligns with data reported in the literature (3,4,6,8). No deaths related to port placement or use were recorded. The most common complication was intraoperative hematoma (8.9%), all classified as Grade I on the Clavien-Dindo scale and resolved spontaneously. This complication was significantly associated with more than two venous puncture attempts. Although over 95% of procedures were performed by experienced operators, a single puncture was achieved in only 88% of cases using anatomical landmarks alone. Indeed, the internal jugular vein has an atypical position in 15 to 30% of case (9). Employing ultrasound guidance for vein localization could therefore reduce the incidence of this complication as recommended in the literature (9–12). Indeed, fewer venipunctures are noted with ultrasound guidance compared to the blind technique (12,13).

Cancer type

No cases of hematological malignancy were included, as these patients are managed at a separate oncology center. It is important to note that individuals with hematological cancers are at a higher risk of infectious complications compared to those with solid tumors (4,14,15). This may explain the low incidence of infectious complications observed in our study (2%). Tabatabaie et al. reported that infection affected 5.6 to 8% of devices (4).

Table 2. Comparison of demographic characteristics

	Median age (years)	Sex-ratio (W/M)	Mean BMI (kg/m²)	Indication for PAC placement
Present study	56	2	26.1	100 % Solid cancers
Kartsouni et al.(14)	61.6	2	27.2	-99.3% Solid cancers -0.7% Haematological cancers
Huttne ret al.(16)	61.7	1.1	26.1	-92.1% Solid cancers -7.9% Haematological cancers
Granziera et al.(2)	61	1.2	24.2	-96.36% Solid cancers -3.64% Haematological cancers

Side of insertion

We preferred the right side for PAC placement due to the direct path of the right internal jugular vein to the superior vena cava (SVC). In contrast, the left internal jugular vein forms a right angle with the SVC, which may complicate catheter insertion (7). Furthermore, the

pulmonary apex rises higher on the left side than on the right (7). This increases the risk of pneumothorax when using the left SVC for PAC placement. In our study, the right side was used in 67% of cases. The left side was chosen in 33% of cases, primarily for patients with right-sided cervical lymphadenopathy or right breast cancer. Our findings are consistent with those reported in the literature (8). A review from Hüttner et al.(16) found that 63% of PAC were placed on the right side, compared to 37% on the left.

Insertion Technique and site of insertion

All procedures were performed using the modified Seldinger technique with percutaneous access guided by anatomical landmarks. No formal guidelines exist regarding the superiority of the subclavian vein (SCV) over the internal jugular vein (IJV) in terms of complication rates (1,17,18). However, specific risk factors may influence the choice of one vein over the other. Severe obesity, which makes identification of anatomical landmarks difficult, should deter the use of the IJV (17). Conversely, the SCV should be avoided in patients with hypoxemia, as the risk of pneumothorax is higher with this technique and may be less tolerated in such patients (17). In our study, there was no significant difference in complication rates between the two veins (IJV and SCV). This finding is consistent with the literature review by Zhou et al.(19). However, this result should be interpreted cautiously as only two patients in our study underwent PAC placement via SCV puncture.

Complications

Our complication rate aligns with the findings reported in the literature (Table III). Moreover, none of these complications led to life-threatening outcomes for the patients in our study.

Table 3. Comparison of complication incidence

Clinical trials and Reviews	Complication incidence
Present study	15%
Huttner et al.(16)	8.6%
Tabatabaie et al.(4)	11.7 to 19.1%
Oliveira et al.(20)	10%
Granic et al.(6)	38%
ANAES 2000 (3)	10 to 13%

Hematoma

Our results are consistent with the literature, which reports a prevalence of hematoma occurrence ranging from 1.8% to 8.0% (1).
The percutaneous method of port placement involves venipuncture through the skin. A high number of venipunctures appears to be a significant factor in the occurrence of intraoperative hematoma. This finding is consistent with the literature which identifies poor operative technique and coagulation disorders as the primary risk factors (21).In our study, all patients had normal preoperative hemostasis profiles. Furthermore, 95.5% of our operators were experienced in PAC placement using anatomical landmarks. It should be noted that anatomical variation in the positioning of veins is common. In fact, the internal jugular vein has an atypical position in 15 to 30% of patients. Fragou et al.(12) and Milling et al.(13) support that the use of ultrasound guidance allows for a higher success rate with fewer venipuncture attempts compared to the blind technique. This highlights the need for routine ultrasound guidance during port placement, as recommended in the literature (9–12).

Wound dehiscence

Several risk factors associated with an increased risk of wound dehiscence have been identified in the literature. These include technical errors, impaired healing processes, and therapy with Bevacizumab, an anti-VEGF (Vascular Endothelial Growth Factor) antibody (4,21). Unfortunately, the type of chemotherapy administered was not included in our statistical analysis.

Port-related DVT

In the literature, as well as in our series, multiple venous punctures during PAC insertion ar associated with an increased risk of thrombosis (p=0.011). This factor, which indirectly reflects trauma to the endovenous wall, is considered by some authors to be a key determinant in the development of thrombosis (22,23). However, it is important to note that all thrombosis observed in our series occurred at least 3 months after PAC insertion, well beyond the surgical procedure, suggesting that they are likely no longer directly related to the number of venous punctures.
On the other hand, the type of cancer was significantly associated with the occurrence of thrombosis, with an increased risk for patients with digestive cancers (p<0.001). To our knowledge, studies assessing PAC morbidity have not identified a specific type of solid cancer as a primary risk factor for catheter-related thrombosis.
Several other risk factors for catheter-related venous thrombosis have been identified in the literature. For instance, De Cicco et al, (24) reported increased risk associated with left-side placement of the port. In a multicenter randomized study, Parienti et al.(25) found that using the SCV was associated with a lower thrombotic risk compared to the IJV. Our study shows that IJV placement is not associated with a higher incidence of thrombotic complications. Additionally, there was no significant difference observed between right-sided and left-sided placements in the occurrence of thrombosis. It is worth noting however that only 2% of the ports were implanted via the subclavian vein, with the right side used in 67% of procedures in our series.

Port-Associated Infection

In the literature, the rate of catheter-associated infections ranges from 2.4% to 16% (26). This variability in reported incidence stems from several factors, including the definition used, the study population (with higher rates observed in pediatric or immunocompromised patients), and the indications for implanting the port. An increased incidence is observed in patients with hematologic cancers, and a higher prevalence of Candida infections is noted in patients receiving parenteral nutrition (27–29). Boussen et al.(30) in a Tunisian study published in 2001 involving 205 patients including 26 children, of whom 10.2% had hematologic malignancies, reported an infection rate of 3.9%. The relatively low rate of infection occurrence in our study can be explained by the absence of pediatric patients, the lack of hematologic cancers, and the use of the implantable port exclusively for chemotherapy (no parenteral nutrition through the port). Furthermore, our multivariate analysis found that male sex and digestive cancers were associated with an increased risk of catheter-related infection. This finding should be interpreted cautiously due to the low incidence of this complication in our series, observed in only two male patients. Additional studies with larger samples are needed to reach definitive conclusions on this topic.

Satisfaction

It is essential to assess patient satisfaction with a medical intervention to evaluate its quality. However, our study did not utilize a validated arabic questionnaire that could be easily understood and self-administred by our tunisian, arabic-speaking study population. To draw more precise and representative conclusions, an appropriate and validated assessment tool should be used. However, it is worth noting that most of our patients expressed satisfaction with their care at SAI and their PAC. This finding is consistent with studies evaluating the quality of life among patients with ports, which generally report positive perceptions and minimal negative impact on daily life (31,32).

Ports have become essential in managing cancer patients receiving chemotherapy. However, few Tunisian studies have explored the complications associated with them. Our study investigated short- and long-term morbidity post-PAC placement, aiming to identify complication predictors and enhance patient care. We had a follow-up period of 480 days and evaluated patient satisfaction, highlighting the strengths of our study.

Nonetheless, there are still some limitations to consider: First, the single-center design and the lack of a control group. Secondly, the relatively low incidence of complications with the recruited sample size limited our ability to identify more prognostic factors. The type of chemotherapy administered as a confounding factor was not considered in our statistical analysis. Indeed, certain types of chemotherapy are recognized by some authors as risk factors for thrombosis (4).

Therefore, to enhance result quality, conducting multicenter studies with control groups and a larger patient cohort would be beneficial for more conclusive findings. Additionally, including more risk factors, such as the type of chemotherapy used, could provide valuable insights for healthcare providers and patients.

Conclusions

PAC placement is a safe procedure with a low rate of complications. However, implementing specific measures could reduce its morbidity. In our study, the most frequent complication was the development of an intraoperative hematoma. This was primarily due to the necessity for more than two venous punctures during vein localization using anatomical landmarks. Implementing ultrasound-guided venipuncture, as advised by medical guidelines, could significantly lower the occurrence of this complication.

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