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ScienceDirect

EJSO 43 (2017) 689–695

EJSO the Journal of Cancer Surgery

www.ejso.com

Complication-related removal of totally implantable venous access port systems: Does the interval between placement and first use and the neutropenia-inducing potential of chemotherapy regimens influence their incidence? A four-year prospective study of 4045 patients

A. Kakkos [a,*,1], L. Bresson [a], D. Hudry [a], S. Cousin [b], C. Lervat [c], E. Bogart [d], J.P. Meurant [d], S. El Bedoui [a], G. Decanter [a], K. Hannebicque [a], C. Regis [a], A. Hamdani [e], N. Penel [f], E. Tresch-Bruneel [d], F. Narducci [a]

[a] *Department of Oncologic Surgery, Centre Régional de Lutte Contre le Cancer Oscar Lambret, 3 Rue Fréderic Combemale, BP 307, 59020 Lille Cedex, France*

[b] *Department of Medical Oncology, Centre Régional de Lutte Contre le Cancer Institut Bergonié, 229 Cours de l' Argonne, 33076 Bordeaux Cedex, France*

[c] *Department of Pediatric Oncology, Centre Régional de Lutte Contre le Cancer Oscar Lambret, 3 Rue Fréderic Combemale, BP 307, 59020 Lille Cedex, France*

[d] *Department of Methodology and Biostatistics, Centre Régional de Lutte Contre le Cancer Oscar Lambret, 3 Rue Fréderic Combemale, BP 307, 59020 Lille Cedex, France*

[e] *Department of Anesthesiology and Reanimation, Centre Régional de Lutte Contre le Cancer Oscar Lambret, 3 Rue Fréderic Combemale, BP 307, 59020 Lille Cedex, France*

[f] *Department of Medical Oncology, Centre Régional de Lutte Contre le Cancer Oscar Lambret, 3 Rue Fréderic Combemale, BP 307, 59020 Lille Cedex, France*

Accepted 21 October 2016
Available online 5 November 2016

Abstract

Background: Totally implantable venous access port systems are widely used in oncology, with frequent complications that sometimes necessitate device removal. The aim of this study is to investigate the impact of the time interval between port placement and initiation of chemotherapy and the neutropenia-inducing potential of the chemotherapy administered upon complication-related port removal.

Patients and methods: Between January 2010 and December 2013, 4045 consecutive patients were included in this observational, single-center prospective study. The chemotherapy regimens were classified as having a low (<10%), intermediate (10–20%), or high (>20%) risk for inducing neutropenia.

Results: The overall removal rate due to complications was 7.2%. Among them, port-related infection (2.5%) and port expulsion (1%) were the most frequent. The interval between port insertion and its first use was shown to be a predictive factor for complication-related removal rates. A cut-off of 6 days was statistically significant ($p = 0.008$), as the removal rate for complications was 9.4% when this interval was 0–5 days and 5.7% when it was ≥6 days. Another factor associated with port complication rate was the neutropenia-inducing potential of the chemotherapy regimens used, with removal for complications involved in 5.5% of low-risk regimens versus 9.4% for the intermediate- and high-risk regimens ($p = 0.003$).

* Corresponding author. Fax: +33 3 20 29 59 28.
E-mail address: athanasios.kakkos@gmail.com (A. Kakkos).
[1] Permanent address: Department of Obstetrics and Gynecology, CHU de Liège, site N. -D. des Bruyères Rue Gaillarmont 600, 4032 Chênée, Belgium. Fax: +32 4 367 95 14.

http://dx.doi.org/10.1016/j.ejso.2016.10.020

Conclusion: An interval of 6 days between placement and first use of the port reduces the removal rate from complications. The intermediate- and high-risk for neutropenia chemotherapy regimens are related to higher port removal rates from complications than low-risk regimens.

Keywords: Totally implantable venous access port systems; Removal for complications; Interval insertion-first use; Neutropenia-inducing potential of chemotherapy

Introduction

The use of totally implantable venous access port systems (TIVAPS) has revolutionized the care and quality of life for cancer patients and patients requiring long-term intravenous therapy. They allow for chemotherapy infusion, antibiotic administration, and blood sampling without the need for repeated venipunctures.[1]

Although TIVAPS are generally associated with a lower long-term risk of infection compared with Hickman-type central venous catheters,[2] complications during their placement and long-term use are still a matter of concern. These complications, including infection, catheter fracture, thrombosis, and extravasation,[3–5] may necessitate device replacement, resulting in additional patient stress and treatment delays.

Several studies in oncology patients have addressed potential risk factors for TIVAPS-related complications, including the vein catheterized, patient age, gender, and BMI, with somewhat conflicting results. Özdemir et al.[6] found that it is safe to start chemotherapy administration the day of TIVAPS insertion. Similarly, Karanlik et al.[7] indicated that the use of the TIVAPS during the first day after its insertion has no effect on the incidence of complications. However, Narducci et al.[8] reported that the interval between the insertion of the TIVAPS and its first use impacted the complication rate, particularly the removal rates, because of confirmed infections and skin disorders, suggesting that an interval of 8 days should be respected.

The aim of this study is to evaluate the impact of the interval between the insertion of TIVAPS and its first use as well as to examine the possible implication of the neutropenia-inducing potential of the chemotherapy regimens used on documented infections and consequent removal rates.

Patients and methods

Study design

This was a prospective, observational, non-randomized descriptive study of the insertion and use of TIVAPS in a specialized cancer treatment center. The primary objective was to determine the removal rates due to TIVAPS-related complications during the 6 months following the last chemotherapy administration and analyze potential risk factors, such as the TIVAPS insertion-first use interval and the neutropenia-inducing potential of the administered chemotherapy regimens.

Inclusion and exclusion criteria

Adult and pediatric patients with documented cancer treated in the Oscar Lambret Regional Anticancer Centre (Lille, France) and requiring long-term venous access were eligible for the study, provided they met none of the specified exclusion criteria. The exclusion criteria were medical contraindications to surgical intervention under local or general anesthesia; history of allergy to lidocaine; clinical evidence of superior vena cava syndrome; clinical, biological, or medication-related contraindication to TIVAPS placement; geographical, social, or psychological obstacles to the medical follow-up; and inability to provide informed consent.

The study was approved by the Ministry of Education, Research and Technology (Ministère de l'Education Nationale, de la Recherche et de la Technologie) and the National Commission for Computerization and Freedom (Commission Nationale de l'Informatique et des Libertés – CNIL); ethics committee approval was not required in France for this type of observational study. Patients received detailed information about the study, and written informed consent was obtained from all participants.

Evaluation criteria

Incidence of complication-related removals and potential risk factors (primary endpoint)

Likely complications of TIVAPS application comprised documented infection, port expulsion, catheter obstruction, catheter rupture, catheter migration, thrombosis, extravasation of the product injected and local hematoma. Regarding documented infections, we considered any infections related to the TIVAPS, including local (at the insertion site) or systemic infections (bloodstream) that had positive cultures.[9] Any complications related to TIVAPS placement, as well as those necessitating an emergency consultation, were recorded by the surgeon responsible for device insertion. Complications during TIVAPS use were recorded by the medical oncologist during the consultations preceding

each chemotherapy session as well as by the medico-surgical team during monitoring consultations.

Parameters potentially constituting risk factors for complications, including patient characteristics, hygiene, TIVAPS insertion procedure, conditions of use of the TIVAPS, and interval between insertion and first use, were also recorded. The chemotherapy regimens used were classified as having a low risk (lower than 10%), intermediate risk (10–20%) or high risk (more than 20%) of inducing neutropenia.

Surgical technique

All the port devices were placed by a senior surgeon.

Cephalic vein approach

A small inferolateral incision to the clavicle into the deltopectoral region was performed; subcutaneous tissue was dissected down to the fascia overlying the deltopectoral groove, where the cephalic vein was identified.

External jugular vein approach

A small supraclavicular transverse incision was performed between the sternal and clavicular heads of the sternocleidomastoid muscle, and the incision was deepened cautiously until vein identification.

Internal jugular vein ultrasound-guided approach

Real-time ultrasound permits the direct visualization needle entry and advancement into the vessel, reducing complication rates.[10,11] After accessing the vein, the use of the Seldinger technique with guidewire, dilator, and peel away sheath was used to catheterize it.

After catheter insertion, its position was checked either radiologically or with an intracavitary electrocardiogram method (Nautilus, Romedex International Srl, Bucharest, Romania). For external and internal jugular approaches, a second incision in the deltopectoral region was used to place the chamber. A subcutaneous tunnel was made to pass the catheter from the cervical incision. Ports were placed in a tight subcutaneous area over the pectoralis fascia, with or without holding sutures. The implanted port was positioned and tested for permeability. Ultimately, the wound was closed in two planes with absorbable monofilament 3/0 sutures.

Statistical analysis

Characteristics were summarized using descriptive methods: means, standard deviations, medians and ranges were used for continuous parameters, and frequencies and percentages were used for categorical parameters.

The association between the occurrence of TIVAPS complication-related removals and various parameters (age, vascular access, number of venous approaches, interval insertion-first use, neutropenia-inducing chemotherapy) were analyzed using the Chi-square test for categorical variables or Fisher's exact test in the case of small counts. Tests were performed considering overall complications and the most frequent types of complications. The significance level was set to $p < 0.05$.

Research of the optimal cut-off for the delay between the insertion of TIVAPS and its first use was performed. Clinically relevant cutoff points[8] (4 days, 5, 6, 7 and 8 days) were tested. The significance level was set to $p < 0.01$ using Bonferroni's correction for multiple testing; the best cutoff points were those for which the minimum significant p-value was obtained.

A multivariate logistic regression was performed. Parameters associated with the occurrence of TIVAPS complication-related removals with $p < 0.10$ in univariate analysis were included in the multivariate model.

Statistical analysis was performed using Stata v13.1 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX, USA: StataCorp LP).

Results

Patient characteristics

A total of 4045 consecutive patients were enrolled between January 2010 and December 2013. The mean age (±SD) at inclusion was 54 ± 16.5 years, and the median age was 57 years (range: 1–89). All patients were treated for solid tumors.

Materials

The TIVAPS used was a Polysite® 3007 Echo (Laboratoires Perouse, France). This device consists of a titanium/polyoxymethylene mini chamber with a silicon catheter.

Choice of venous access

The veins selected initially were primarily the internal (69.2%; 78 missing data) and external jugular vein (23.7%). They were similar when catheterized (internal jugular vein 68.2% and external jugular vein 23.3%; 170 missing data). Catheterization was successful using the first vein selected in 94.8% of the patients (187 missing data) and a second vein in an additional 4.3%.

Use of the TIVAPS

The median and mean (±SD) interval between the insertion of the TIVAPS and its first use was 8 days (range: 0–180) and 13.8 ± 17.2 days, respectively. In the majority of patients (97.2%), TIVAPS was inserted to facilitate chemotherapy administration.

Complication-related removals

TIVAPS removal due to complications and their characteristics are shown in Table 1. Most of the complication-related TIVAPS removals (73.4%; 25 missing data) were recorded during the first month from the administration of chemotherapy. The most common complications necessitating the removal of the device less than 1 month from the last chemotherapy administration were documented infections (2.5%), exteriorization of the chamber (1%), drug extravasation (0.4%), and mechanical complications (0.3%). Less common causes for removal were thrombotic accidents (6 cases), migration of the catheter (2 cases), rupture of the catheter (1 case), and local hematoma (1 case). No deaths occurred during the study.

Table 1
Complication-related TIVAPS removals and their characteristics.

Number of insertions	4045
Number of removals, n (%)	693 (17.1)
Reason for removal, n (%)	
Not precised	9 (0.002)
End of treatment	394 (9.8)
Complications	290 (7.2)
Interval from last CT, n (%)	
≤1 month	213 (5.3)
>1 month	52 (1.2)
Not precised	25 (0.6)
Type of complication, n (%)	
Documented infection	100 (2.3)
≤30 days after insertion	23 (0.7)
>30 days after insertion	77 (1.9)
Exteriorization of the chamber	41 (1.0)
Mechanical complication	14 (0.3)
Drug extravasation	17 (0.4)
Thrombosis	6 (0.1)
Rupture of the catheter	1 (0)
Local hematoma	1 (0)
Migration of the catheter	2 (0)
Suspected infection	1 (0)
Not precised	35 (0.9)

Risk factors for complication-related removals

Univariate analysis

The risk factors for complication-related removals are summarized in Table 2. A negative association was found between the age of the patients and TIVAPS removal rates for complications. Removals for complications less than a month from the last chemotherapy administration occurred in 6.3% of patients younger than 50 years old; the respective rate for patients older than 60 years old was 4.4% ($p = 0.021$). No association was shown between the removals for complications and the vein chosen for the insertion of the device. Similarly, the number of different venous approaches attempted for the insertion had no significant impact on the removal rates.

In contrast, we found an association between the interval insertion-first use of the device and the complication-related removal rates (Table 3). Although the cut-offs of 4 and 5 days showed no statistical significance, the intervals of 6 and 7 days were significant. The complication-related removal rates were 9.4% when the insertion-first use interval was less than 6 days and 5.7% when this interval was ≥6 days ($p = 0.008$). Respectively, the removal rates were 8.6% when this interval was ≥7 days, versus 5.6% for an interval <7 days ($p = 0.007$). More specifically, the only type of complication necessitating the removal of the device, which was influenced by the interval insertion-first use, was documented infection. These infections were more common for patients with an interval insertion-first use of their device of <6 and <7 days (5.4% and 4.8%) compared with those with an interval >6 days and >7 days (2.6% and 2.5%; $p = 0.005$ and 0.004). The other types of complications leading to the TIVAPS removal did not differ when considering the interval insertion-first use of the devices.

Regarding the impact of the neutropenia-inducing potential of the chemotherapy regimens used on the TIVAPS complication-related removal rates, we found that the intermediate- and high-risk regimens showed significantly higher removal rates than the low-risk group. In fact, the low-risk group showed a removal rate of 5.5% in the month following drug administration, whereas the respective rate for the intermediate- and high-risk groups was 9.4% ($p = 0.003$). The documented infections were significantly more common in the intermediate/high-risk group (5.1%) compared with the low-risk group (2.6%; $p = 0.009$). Similarly, the chamber exteriorizations were significantly higher for the intermediate/high, neutropenia-inducing group (2.3%) than for the low-risk group (1%; $p = 0.032$). An interval between insertion of the TIVAPS and first use ≥6 days had the same impact on removal rates for infectious complications for both groups. For the low-risk group, respecting the 6-day interval resulted in 2.4% removals for infections; in contrast, a first use sooner than 6 days showed a respective rate of 5.7% ($p = 0.012$). For the intermediate/high, neutropenia-inducing group, an interval of insertion-first use ≥6 days resulted in 4.1% removals due to infection; when this interval was shorter than 6 days, the removals for infection reached 13% ($p = 0.02$). Among the low risk for neutropenia chemotherapy group, 5.6% (159/2832) were initiated with an interval of less than 6 days after the TIVAPS insertion, whereas for the intermediate-high risk group, 10.5% (46/439) were initiated sooner than this interval ($p < 0.001$).

Multivariate analysis

A multivariate logistic regression was performed for overall complication-related removals and documented infection-related removals; however, the frequencies of other type of complications were not sufficient to allow multivariate analysis. Parameters associated with the

Table 2
Complication-related TIVAPS removals and risk factors.

Univariate analysis	Number of insertions	Number of removals	Removal for complication ≤1 month from last CT			Documented infection			Exteriorization of the chambe		
	n	n	n	%	*p*-Value	n	%	*p*-Value	n	%	*p*-Value
Age											
<50 y	1242	256	78	6.3%	0.055[a]	40	3.30%	0.041[a]	15	1.2%	0.41[a]
50–60 y	1233	230	67	5.4%	0.035[b]	32	2.60%	0.025[b]	12	1.0%	0.54[b]
>60 y	1564	203	68	4.4%	0.021[c]	28	1.80%	0.018[c]	14	0.9%	0.41[c]
Venous access					0.10			0.71			0.43
CV[d]	304	48	11	3.6%		6	2.0%		1	0.3%	
EJV[e]	904	195	39	4.3%		21	2.3%		8	0.9%	
IJV[f]	2643	422	152	5.8%		70	2.7%		31	1.2%	
Number of venous approaches					0.63			0.64			0.27
1	3658	635	193	5.3%		90	2.5%		40	1.1%	
≥2	200	34	9	4.5%		6	3.0%		0	0.0%	
Neutropenia-inducing chemotherapy					0.003			0.009			0.032
Low (<10%)	2832	496	156	5.5%		74	2.6%		29	1.0%	
Intermediate–high (>10%)	439	102	41	9.4%		22	5.1%		10	2.3%	

[a] Test for age <50 years old versus ≥50 years old.
[b] Test for age <60 years old versus ≥60 years old.
[c] Test for age <50 years old versus ≥60 years old.
[d] Cephalic vein.
[e] External jugular vein.
[f] Internal jugular vein.

Table 3
Optimal cut point for interval insertion-first TIVAPS use.

Univariate analysis	Number of insertions	Number of removals	Removal for complication ≤1 month from last CT			Documented infection			Exteriorization of the chamber		
	n	n	n	%	*p*-Value[a]	n	%	*p*-Value[a]	n	%	*p*-Value[a]
Interval insertion-first CT											
<4 days	189	39	18	9.5%	0.041	8	4.3%	0.25	3	1.6%	0.49
≥4 days	3311	603	194	5.9%		92	2.8%		38	1.2%	
<5 days	235	47	22	9.4%	0.027	12	5.2%	0.032	3	1.3%	0.75
≥5 days	3265	595	190	5.8%		88	2.7%		38	1.2%	
<6 days	319	67	30	9.4%	0.008	17	5.4%	0.005	4	1.3%	0.79
≥6 days	3181	575	182	5.7%		83	2.6%		37	1.2%	
<7 days	548	108	47	8.6%	0.007	26	4.8%	0.004	9	1.7%	0.26
≥7 days	2952	534	165	5.6%		74	2.5%		32	1.1%	
<8 days	1388	275	96	6.9%	0.09	51	3.7%	0.019	19	1.4%	0.42
≥8 days	2112	367	116	5.5%		49	2.3%		22	1.1%	

[a] Significance level is set to $p < 0.01$ (Bonferroni correction for multiple testing).

occurrence of removals with $p < 0.10$ in univariate analysis were included in the multivariate model: age, neutropenia-inducing chemotherapy potential, interval between insertion and first use of TIVAPS. There were no significant interactions between these parameters. Two models were performed including interval insertion-first use categorized as <6 days/≥6 days (model 1) or as <7 days/≥7 days (model 2).

Overall complication-related removals were significantly associated with the neutropenia-inducing potential of chemotherapy (model 1: OR = 1.65 (CI 95%: 1.14–2.38), $p = 0.007$; model 2: OR = 1.61 (CI 95%: 1.11–2.33), $p = 0.012$) and to the interval between insertion and first chemotherapy administration (model 1: OR = 0.57 (CI 95%: 0.35–0.92), $p = 0.024$; model 2: OR = 0.67 (CI 95%: 0.46–0.98), $p = 0.039$), whereas age was not significant.

Documented infection-related removals were significantly associated with the delay between insertion and first CT administration (model 1: OR = 0.38 (CI 95%: 0.21–0.68), $p = 0.001$; model 2: OR = 0.50 (CI 95%: 0.31–0.82), $p = 0.006$) and with the neutropenia-inducing potential of chemotherapy in model 1 (OR = 1.70 (CI 95%: 1.03–2.80), $p = 0.039$) but not in model 2 (OR = 1.62 (CI 95%: 0.98–2.69), $p = 0.06$). Age was not significant in both models.

Discussion

Incidence of TIVAPS complication-related removals

The rate of device removal for complications in our study (7.2%) was comparable with the results of Ignatov et al.[12] (8%). Higher rates have been reported by Ji et al.[13] (15.25%), Seok et al.[14] (17%), and Biacchi et al.[15] (30,2%). Lower rates of catheter removals were found by Biffi et al.[16] (1.8%).

Risk factors for complication-related removals

The age of the patients represents a risk factor in our study for the risk of TIVAPS removal due to complications in the univariate analysis; however, in the multivariate model, it does not represent a significant factor, constituting a confounding factor. Literature findings concerning the impact of age on TIVAPS removals for complications is controversial, with some studies[12,14] showing no correlation between them, whereas others[2,13] reported that the younger age represents a risk factor for infections. In our study, the veins catheterized the most were the internal and external jugular veins, with the choice of vascular access not impacting the complication rates and the subsequent port removals. We had very few cases of subclavian vein access (15 patients; 0.4%) traditionally used for TIVAPS placement, but it was associated with higher early and late morbidity.[12,17]

The factor most associated with the TIVAPS removal rates for complications in our study was the interval between the insertion of the device and its first use. The complication rate (especially infectious morbidity) was higher when this interval was shorter than 6 days, leading to significantly higher removal rates. However, literature data are scarce, and evidence is controversial. In 2009, Ozdemir et al.[6] reported in a study of 180 patients who the early use of port devices (1–4 h after insertion) was as safe as late use, in terms of early and late morbidity. In contrast, in a prospective study of 815 patients, Narducci et al.[8] suggested that an insertion-first use interval of at least 8 days may reduce the incidence of complications and the need for premature removal. In 2015, Karanlik et al. reported in a 1315-patient observational study that the delayed first use of the port devices has no effect on the complication rate. The study compared the incidence of complications between two groups; the first group consisting of patients whose TIVAPS were used in less than 24 h from the insertion, and the second group included patients with the first use of TIVAPS after the first 24 h from the insertion. However, we note that the median time to first port use of the second group was the fourth day after insertion, whereas in our study, the respective interval was 8 days. Our later first TIVAPS use could explain the statistically significant difference of removals due to complications found for the delayed first use of the device, as our threshold of 6 days was longer than Karanlik's delayed group first use interval of 4 days.

The other factor associated with higher port removal rates for complications was the neutropenia-inducing potential of the chemotherapy regimens administered. We found that the intermediate/high-risk regimens for inducing neutropenia had significantly higher TIVAPS removal rates than the low-risk regimens ($p = 0.003$). The most common complication motivating port removals is infection, with the intermediate/high risk for the neutropenia chemotherapy group showing higher infection rates than the low-risk group ($p = 0.009$). To the best of our knowledge, this relationship has not been reported directly by other studies and warrants further investigation. However, some studies[2,13] have shown that hematogenous malignancies, which necessitate more aggressive chemotherapy and consequently more frequent treatment-induced neutropenia, are correlated with higher TIVAPS infection rates and therefore port removals.

The strength of this study was the evaluation of a large population (N = 4045), which enabled a multivariate logistic regression analysis with interaction testing to minimize confounding issues. However, the main weakness was that data collection is not dedicated in clinical research, so there was a limited control of the quality and coherence of data. Furthermore, another weakness was the existence of some missing data.

Conclusions

The results of our study suggest that adherence to a 6-day interval between the insertion and first use of TIVAPS for the administration of chemotherapy may reduce port removal rates due to complications and especially infectious morbidity. Furthermore, the neutropenia-inducing potential of the chemotherapy regimens administered affects the TIVAPS removal rates because intermediate- and high-risk regimens for post-treatment neutropenia have significantly higher port removal rates than low-risk regimens.

Role of the funding source

The study was partially funded by Perouse Medical, a company that manufactures implantable venous access port systems. This funding was used to remunerate the clinical research personnel involved in the project.

Conflict of interest

The authors declare that they have no financial or personal relationships with other people or organizations that could have inappropriately influenced or biased their work.

Acknowledgments

The authors thank all the medical, nursing, and auxiliary staff of the Oscar Lambret Regional Anticancer Centre for their dedicated teamwork during this study, Muriel Chapoutier for monitoring the study, Brice Dubois and Samia Swyndauw for their valuable assistance with data management, and the Clinical Research Unit (in particular, Stephanie Clisant).

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