ORIGINAL ARTICLE



Late complications associated with totally implantable venous access port implantation via the internal jugular vein

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Abstract

Purpose Several studies have analyzed late complications associated with totally implantable venous access ports (TIVAP) implantation via the internal jugular vein (IJV); however, the reported results are inconclusive. The aim of the study is to elucidate the characteristics and risk factors of late complications associated with TIVAP implantation via the IJV.

Methods The study included 482 patients who underwent TIVAP implantation for long-term chemotherapy and/or nutritional support between April 2012 and December 2017. Most patients (95.2%) had malignant diseases. Events requiring TIVAP removal were defined as TIVAP-related complications.

Results The median TIVAP and global follow-ups were 319 days (IQR 152–661) and 218,971 catheter days, respectively. The 3year cumulative TIVAP availability rate was 70%. There were 44 complications (incidence of 9.1%; 0.201 complications/1000 catheter days). Infectious, catheter-related, and port-related complications occurred in 21, 14, and 9 patients, respectively with infectious complications occurring earlier and more frequently than catheter- and port-related complications. Multivariate analysis revealed that age < 65 years and presence of non-gastrointestinal diseases were significant unfavorable factors for TIVAPrelated complications. Patients with 1 and 2 of these factors had an elevated risk (2.2 and 5.4 times, respectively) compared with those without.

Conclusions Among the late complications associated with TIVAP implantation via the IJV, infectious complications occur earlier and more frequently than catheter- and port-related complications. Patients with an age < 65 years and having non-gastrointestinal diseases have a significantly high risk of TIVAP-related complications.

Keywords Totally implantable venous access port · Internal jugular vein · Complication · Infection

Introduction

Totally implantable venous access ports (TIVAP) have been widely used as a simple and safe means to access the vascular

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system for intravenous administration of chemotherapeutic drugs and nutritional supportive care of patients with malignancies or insufficient gastrointestinal function [1–3]. A secure venous access is required for long-term chemotherapy and nutritional support. A TIVAP can be implanted via the basilic vein, subclavian vein, or external or internal jugular vein (IJV). Puncturing of the subclavian vein is associated with serious complications including pneumothorax, hemothorax, and catheter pinch-off in the costoclavicular space [2–4]. A TIVAP via the basilic vein is associated with a higher risk of major complications in patients with breast cancer [5]. On the other hand, implantation of a TIVAP via the IJV can be performed safely [6, 7]; therefore, the IJV has been routinely selected as the insertion vein for TIVAP since 2012 in our institute.

Late complications associated with the TIVAP include infection, thrombosis, occlusion, rupture, dislocation, catheter kinking, rotation and flip of the port, and skin ulceration around the catheter or port [8]. There have been several studies on the late complications of a TIVAP via the IJV; however, they were inconclusive due to several factors including small number of cases, inconsistent definition of TIVAP-related complications, and insufficient analysis [9–12]. Therefore, the aim of this study was to analyze the characteristics and risk factors of late complications of TIVAP via IJV.

Patients and methods

We retrospectively reviewed a database of patients who had undergone subcutaneous implantation of TIVAP via the IJV at the Japanese Red Cross Nagoya First Hospital between April 2012 and December 2017. Four hundred eighty-two patients were identified and included in the study. They included 38 patients (7.9%) requiring re-implantation. Patient demographics are shown in Table 1. The mean age was 65 ± 11

Table 1 Patient demographics

Age	65 ± 11 (range 20–91)
Sex (male/female)	
Male	251 (52.0%)
Female	231 (48.0%)
BMI	21.7 ± 4.0 (range 11.0–36.8)
< 18.5	96 (20.6%)
18.5–25.0	278 (59.5%)
≥ 25.0	93 (19.9%)
Background disease	
Non-malignant	23 (4.8%)
Malignant	459 (95.2%)
Colorectal cancer	271
Gastric cancer	40
Breast cancer	39
Hematological malignancy	29
Hepatobiliary-pancreatic cancer	21
Urinary cancer	14
Esophageal cancer	11
Gynecological malignancy	11
Head and neck cancer	5
Others	11
Implantation side	
Right	425 (88.2%)
Left	57 (11.8%)
Purpose of TIVAP	
Chemotherapy	394 (81.7%)
Nutritional supplementation	72 (14.9%)
Both	16 (3.3%)
Years of implantation	
2012–2014	244 (50.6%)
2015–2017	238 (49.4%)

years (range, 20–91 years), with men comprising 52.0%. The mean body mass index (BMI) was 21.7 ± 4.0 (range, 11.0-36.8). TIVAP had been done for long-term chemotherapy (more than 6 months) and/or nutritional supplementation. Most patients (95.2%) had suffered from malignancies including colorectal cancer (56.2%), gastric cancer (8.3%), breast cancer (8.1%), hematologic malignancy (5.8%), hepatobiliary-pancreatic cancer (4.4%), urinary cancer (2.7%), esophageal cancer (2.3%), gynecological cancer (2.3%), head and neck cancer (1.0%), and other malignancies (2.3%). Twenty-three patients (4.8%) had non-malignant diseases including short bowel syndrome, malnutrition due to severe liver disease, and cerebrovascular disease causing dysphagia.

All procedures were performed by surgeons with sufficient experience and were guided by ultrasonography (US) under local anesthesia equipped with mobile X-ray fluoroscopy (Supplementary Figure 1). We used the MicroNeedle Port (Covidien, Tokyo) consisting of a $22 \times 28 \times 12$ mm port and an 8 Fr catheter. Nurses in our inpatient and ambulant chemotherapy departments followed the same procedures. The right IJV was favored to the left IJV, which was frequently selected after the removal of TIVAP via the right IJV. A larger number of TIVAPs were introduced from the right IJV (88.2%) than the left IJV (11.8%). The indications for the TIVAP placement were systemic chemotherapy (81.7%), nutritional supplementation (14.9%), and both (3.3%). There was no patient with TIVAP for neoadjuvant chemotherapy.

In this study, situations requiring TIVAP removal were defined as TIVAP-related complications. All the reasons for TIVAP removal were obtained from the patients' medical records. Patient follow-up information was compiled through March 2018. The TIVAPs were left for death (n = 227, n)47.1%), on used (n = 163, 33.8%) and removed for the end of chemotherapy and/or nutritional supplementation (n = 48,9.9%) or TIVAP-related complication (n = 44, 9.1%). The TIVAP-related complications were classified as infection (catheter infection and/or septicemia), catheter-related, and port-related complications. The removed catheters were cultured in case of suspected blood stream infection. Catheter infection was confirmed by positive blood cultures, and signs and symptoms of infection such as fever, elevated C-reactive protein, and leukocytosis in the absence of obvious foci other than the TIVAP; or by a positive culture of the removed catheter. The causative microorganisms were identified by blood or catheter culture. Venous thrombosis was confirmed by enhanced computed tomography (CT), magnetic resonance imaging (MRI), or US, although we did not have screening program for deep vein thrombosis. Catheter obstruction was defined as failure to flush the contents via a TIVAP. Catheter disruption and dislocation were identified by plain X-ray radiograph or CT. Fluid leakage from a port or catheter was visually identified in a removed TIVAP.

The risk of TIVAP-related complications was evaluated in terms of patient age, gender, BMI, background diseases, side of insertion, purpose of TIVAP (chemotherapy/nutritional support), and years of TIVAP implantation (2012–2014/2015–2017).

We analyzed types, incidence, and risk factors of late complications associated with TIVAP insertion via the IJV. This study was conducted in accordance with the Helsinki Declaration. The study protocol was approved by the ethics committee of our hospital, which waived the need for informed consent due to the retrospective nature of the study (2018-113).

Statistical analysis

Continuous variables were expressed as mean \pm SD or median (IQR) and were compared using the Student t test. The incidence of complications associated with TIVAP was defined in percent and per 1000 catheter days. The Kaplan-Meier analysis was used to estimate the cumulative TIVAP availability rates or complication rates, and the log-rank test was used to analyze differences between groups. Patient death and scheduled port removal without any TIVAP-related complications were categorized as censored cases. Factors with p values of < 0.05 in the univariate analysis were included in a multivariate analysis using a Cox proportional hazards model. Hazard ratios (HR) and 95% confidence intervals (CI) were calculated with the multivariate analysis. Statistical analyses were performed using the JMP version 10.0 for Windows (SAS Institute Inc., Cary, NC, USA) at a significance level of p <0.05.

Results

The median follow-up duration for the TIVAPs was 319 days (range 1–2016, IQR 152–661), and global follow-up was 218,971 catheter days. The cumulative TIVAP availability rates were 91%, 87%, and 70% at 1, 2, and 3 years, respectively. There were 44 recorded complications (Table 2): an incidence of 9.1% and 0.201 complications/1000 catheter days. Infection, catheter-related, and port-related complications occurred in 21, 14, and 9 patients, respectively. The incidences were 4.4%, 0.096 infections/1000 catheter days; 2.9%, 0.064 catheter-related complications/1000 catheter days; and 1.9%, 0.041 port-related complications/1000 catheter days; respectively.

Twenty-one patients had infectious complications and the causative microorganisms were methicillin-susceptible *Staphylococcus aureus* (n = 6), methicillin-resistant *Staphylococcus aureus* (n = 4), methicillin-resistant *Staphylococcus epidermidis* (n = 4), *E. coli* (n = 2), and others

(n = 5). They included some patients with evident infectious foci such as subcutaneous phlegmon, urinary tract infection, and pneumonia. Fourteen patients had catheter-related complications due to venous thrombosis around the catheter (n = 4) without symptom, catheter obstruction (n = 3), disruption (n = 3), skin ulcer around the catheter (n = 2), and catheter dislocation (n = 2). No case of symptomatic pulmonary embolism attributable to catheter-related thrombosis was recorded. Nine port-related complications were documented: skin ulcer around the port (n = 7), port flip (n = 1), and fluid leakage (n = 1). The cumulative TIVAP-related complication rates according to three complication types are shown in Fig. 1. Infectious complications occurred earlier and more frequently as compared to catheter-related and port-related complications.

The univariate analysis showed that patient age, background diseases, and purpose of the TIVAP were significantly correlated with TIVAP-related complication rates (Table 3, Fig. 2, and Supplementary Figure 2). Subsequent multivariate analysis showed that age < 65 and non-gastrointestinal diseases were significant independent unfavorable risk factors for TIVAP-related complications. Patients with 1 and 2 of these factors had an elevated risk (2.2 and 5.4 times, respectively) of complications.

To analyze the reasons for a relationship between age < 65, non-gastrointestinal diseases, and higher TIVAP-related complication rates, additional analyses were performed (Supplementary Table 1). The mean age of patients with non-gastrointestinal diseases was significantly lower than those with gastrointestinal disease; especially, those of patients with gynecological, hematological, and breast malignancy (54, 56, and 62 years) were less than those with gastrointestinal diseases. The 1-year cumulative TIVAP availability rates were lower in patients with gynecological and hematological malignancy (70% and 86%, respectively) than in those with other diseases. The follow-up durations of patients with age < 65 and \geq 65 were 447 and 460 days, respectively (*p* = 0.7401), while the follow-up durations of patients with gastrointestinal diseases and non-gastrointestinal diseases were 496 and 340 days, respectively (p = 0.0003).

Discussion

In this study, the incidence of late complications of TIVAP via the IJV was 9.1% and 0.201 cases per 1000 catheter days. Infectious complications occurred earlier and more frequently as compared to catheter-related and port-related complications. Univariate and multivariate analysis of the risk of developing TIVAP-related complications showed that age < 65 and non-gastrointestinal diseases were significant independent unfavorable factors.

Table 2 Types and incidences of TIVAP-related complications

	Number	Incidence (%)	Incidence (per 1000 catheter days)
Infection	21	4.4	0.096
Methicillin-susceptible Staphylococcus aureus	6	1.2	0.027
Methicillin-resistant Staphylococcus aureus	4	0.8	0.018
Methicillin-resistant Staphylococcus epidermidis	4	0.8	0.018
E. coli	2	0.4	0.009
Streptococcus constellatus/milleri	1	0.2	0.005
Eggerthella lenta	1	0.2	0.005
Stenotrophomonas maltophilia	1	0.2	0.005
Elizabethkingia meningoseptica	1	0.2	0.005
Candida	1	0.2	0.005
Catheter-related complications	14	2.9	0.064
Venous thrombosis around the catheter	4	0.8	0.018
Catheter obstruction	3	0.6	0.014
Catheter disruption	3	0.6	0.014
Skin ulcer around the catheter	2	0.4	0.009
Catheter dislocation	2	0.4	0.009
Port-related complications	9	1.9	0.041
Skin ulcer around the port	7	1.5	0.032
Port flip	1	0.2	0.005
Fluid leakage	1	0.2	0.005

The incidence of TIVAP-related complication of published reports was between 5.4–19.2% and 0.11–0.41 cases per 1000 catheter days depending on definition of complications, age, background diseases, venous access routes, purpose of TIVAP, frequency of TIVAP handling, and study duration [13–20]. The incidence in our study was comparable to the results of previous studies, and relatively lower. The reason for the low incidence in our study can be attributable to safe surgical techniques and standardized management with patient

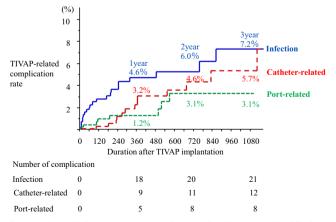


Fig. 1 Cumulative TIVAP-related complication rate classified as infection, catheter-related, and port-related complications

education for chemotherapy and parenteral nutrition in our inpatient and ambulant chemotherapy departments. Results of published data on the late complications of TIVAP via the IJV are summarized in Table 4 [9–12]. The current study is the second largest with the highest incidence of total complications among five studies probably due to the longer follow-up.

Previous studies have recorded TIVAP-related infection incidences between 1.3 and 30% and between 0.10 and 2.2 cases per 1000 catheter days [3, 21, 22]. Most guidelines recommend 0.3 infections/1000 catheter days as an appropriate upper threshold for the insertion of a subcutaneous venous access device [23]. The incidence recorded in our study (4.4%, 0.096 cases per 1000 catheter days) was relatively low, as compared to previous studies. In the present study, microorganisms identified on blood and/or catheter cultures were Staphylococcus aureus, Staphylococcus epidermidis, and E. coli, which was similar to results from previous studies which identified Staphylococcus epidermidis, Staphylococcus aureus, Enterobacteriaceae, E. coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Candida albicans as the bacteria responsible for the TIVAP-related infections [18, 22, 24, 25]. These organisms can be from the patient's skin and environment, gastrointestinal tract, and the urinary system. Compared with catheter- and port-related complications, the

 Table 3
 Univariate and multivariate analyses of TIVAP-related complication rate

Related factors		n	Univariate analysis		Multivariate analysis	
			1 year TIVAP availability rate (%)	Р	Hazard ratio (95% confidence interval)	Р
Age	< 65	197	86.3	0.0022	2.65 (1.41–5.15)	0.0024
	≥ 65	285	95.0		1	
Sex	Male Female	251 231	89.3 93.3	0.3912		
BMI	< 18.5 18.5–25.0	96 278	97.9 92.0	0.2156		
	≧ 25.0	93	86.3			
Background disease	Malignant	461	91.4	0.0323	1	0.2525
	Non-malignant	21	84.0		2.34 (0.53-10.39)	
	Gastrointestinal	354	93.2	0.0041	1	
	Non-gastrointestinal	128	84.1		1.96 (1.01–3.28)	0.0454
Side	Right Left	425 57	92.3 82.3	0.0856		
Purpose of TIVAP	Chemotherapy	394	91.7	0.0082	1	
	Nutrition	72	78.2		1.61 (0.47-4.19)	0.4072
Year of TIVAP implantation	2012–2014 2015–2017	244 238	92.8 89.4	0.2319		

TIVAP-related infection rate rapidly increased after TIVAP implantation. Intensive sterile technique for surgery, proper

management protocol for keeping the TIVAP clean, synbiotics to reduce bacterial translocation [26], and patient education to

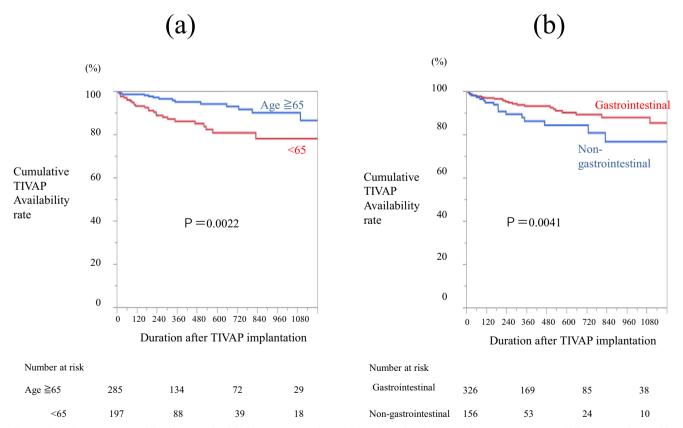


Fig. 2 Cumulative TIVAP availability rate classified by age. (a) Patients with < 65 and ≥ 65 years of age. (b) Background diseases (patients with gastrointestinal and non-gastrointestinal diseases)

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No.	No. Author	Institute	Year No. of patients	Institute Year No. of patients Median duration of follow-up Follow-up Total complication Infection	Follow-up	Total c	complication	Infection		Thrombosis	0	Occlusion	
				(days)	(cath. days)	(%)	(cath. days) (%) (1000 cath. days) (%) (1000 cath. days) (%) (1000 cath. days) (%) (1000 cath. days)	(%) (10)00 cath. days)	(%) (1000 cath.	days) (9	%) (1000	cath. da
	Yip [9]	USA	2002 117	342	40,450	6.8 0.20		4.2 0.2		1.7 0.15	1	1.7 0.05	
~	Charvat [10]	Czech	2006 101	407	I		0.14	3.0 0.0		1	I	Ι	
	Zhou [11] China	China	2014 492	359	176,694	4.3	I	0.8 –		2.4 –	1	1.2 –	
~	Nagasawa [12]	Japan		556	1	8.1 -	I	2.9 –		1.5 –	I	I	
Ś	Tsuruta	Japan	482	319	218,971	9.1 0	0.20	4.4 0.10		0.8 0.02	0	0.6 0.01	

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avert of infections are important. In addition, empiric antibiotic treatment for sensitive microorganisms is recommended when patients with TIVAP have a sign of infectious diseases.

In this study, the incidence of catheter-related complication was 2.9% and 0.064 cases per 1000 catheter days. Specifically, the incidence of venous thrombosis around the catheter was 0.8% and 0.018 cases per 1000 catheter days. The incidence was relatively low compared to the results of previous studies (0-3.2% and 0-0.11 thrombosis per 1000 catheter days) [1, 15, 27], even though specific management excluding a flush after drug administration was not performed in our hospital. Venous thrombosis in 4 cases was diagnosed by a poor fluid drip rate or an incidental computed tomography finding. The relatively low incidence may be due to the small number of patients with palliative nutritional support with TIVAP and patients with hypercoagulopathy due to disseminated malignancies [28]. Catheter disruption and dislocation were found in 3 and 2 patients, respectively. The reasons may be catheter movement along with the patient's neck or upper arm motion, chronic mechanical stress (e.g., backpack strap), and catheter fatigue. Compared to infection and portrelated complication rates, the catheter-related complication rate gradually increased after TIVAP implantation. Wang et al. defined the optimal catheter tip positions to be the distal one-third of the superior vena cava (SVC), the SVC-right atrial junction, and the upper half of the right atrium, and reported that a suboptimal tip position correlated with symptomatic TIVAP occlusion [29]. Scheduled checks for catheter shape and tip location by plain X-ray radiography or CT are important to avoid major events caused by catheter disruption and dislocation.

In this study, the incidence of port-related complications was 1.9%, 0.041 cases per 1000 catheter days. Skin ulcers around the port were common. Proper technique for a sufficient port space, careful handling of the TIVAP, and nutritional support will decrease the complication rate.

The univariate and multivariate analysis of the risk of TIVAPrelated complications showed that age < 65 and nongastrointestinal diseases were significant unfavorable risk factors, although the follow-up durations of patients with gastrointestinal diseases and non-gastrointestinal diseases were significantly different probably due to characteristics of the diseases including disease mortality. Obesity was reported to be a risk factor of TIVAP-related complications [5, 30, 31], and our univariate analysis supported this hypothesis (Table 3). Previous studies reported that risk factors for TIVAP-related infection were hematological malignancy [29, 32–35], upper gastrointestinal cancer [29], younger age [32, 33], chemotherapy in metastasis [35], hospitalized patients [36], use of parenteral nutrition [37], palliative use [12], and steroid administration [37]. Additionally, risk factors for catheter- and port-related complications were suboptimal position of the TIVAP [29, 38, 39], flushing a port with high pressure [40], inadequate pocket creation for a port, and early

administration of bevacizumab after TIVAP implantation [41]. The reasons for increased risk in patients aged < 65 and nongastrointestinal diseases were indefinite. As the 1 year cumulative TIVAP availability rates and mean age were lower in patients with gynecological, hematological, and breast carcinoma than those of other diseases, we hypothesized that the correlation might be due to disease and treatment specificity. The incidence of gynecological, hematological, and breast malignancy are frequent in younger patients compared with those with other malignancy in Japan [42]. In addition, intensive inpatient chemotherapy is often performed for these malignancies.

We acknowledge that the present study has several limitations. First, despite detailed analysis, it was a retrospective study in a single institute. Unknown background factors relating TIVAP complications may lead to a selection bias. A prospective multicenter study with planned systematic survey is necessary to determine the factors associated with of late complications of a TIVAP via the IJV. Second, the reasons for increased risk in patients with age < 65 and non-gastrointestinal diseases were not fully identified. Further studies investigating several factors including purpose of chemotherapy (adjuvant/metastatic setting), patient's performance status, nutritional status, length of hospital stay for chemotherapy, and steroid administration are needed. Third, the relationship between patient body motions and catheter movement was not analyzed. This will be necessary to fully understand the causes of catheter disruption and dislocation.

In conclusion, the incidence of late complications of TIVAP via the IJV was acceptable when compared to previous published reports. Infectious complications occurred earlier and more frequently as compared to catheter-related and port-related complications. Age < 65 and non-gastrointestinal diseases were significant independent unfavorable risk factors for TIVAP-related complications. Patients with 1 and 2 of these factors had a 2.2- and 5.4-times higher risk, respectively, of complication compared with those without.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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