Difficult removal of totally implantable venous access devices in adult patients : Incidence, risk factors, and management.

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Abstract

Background Totally implantable venous access devices (TIVADs) have played an important role of medical oncology practice. However, operators sometimes encounter considerable difficulty when removing TIVADs. This study aimed to investigate the incidence of difficult TIVAD removal, determine associated risk factors, and investigate interventional radiology (IR) approaches to difficult removal.

Methods A total of 514 TIVAD removal procedures performed in a single-center between January 2014 and May 2021 were retrospectively analyzed to determine incidence of difficult removal and associated risk factors. IR approaches applied in difficult removal cases were also reviewed.

Results The incidence of difficult removal was 7.4 % (38/514). In univariable analysis, indwelling duration, silicone catheter, and subcutaneous leakage of fluid were identified as significant risk factors for difficult removal. Multivariable analysis showed that indwelling duration per year (odds ratio [OR], 1.46; 95% confidence interval [CI], 1.28–1.67; $P < 0.01$) and subcutaneous leakage of fluid (OR, 6.04; 95% CI, 2.45–14.91; $P < 0.01$) were significantly associated with difficult removal. In the 38 difficult

removal cases, 32 TIVADs could be removed using more dissection and traction than the standard removal method. In the other 6, TIVADs were successfully removed by using several IR techniques, including insertion of a guide wire (n = 1), dissection using an introducer sheath (n = 2), pushing with a dilator (n = 1), and pulling with a snare (n = 2).

Conclusion Difficult TIVAD removal is uncommon. However, operators should expect it when removing long indwelling TIVADs and those with subcutaneous leakage. IR approaches to difficult removal are minimally invasive and can be useful.

Introduction

Totally implantable venous access devices (TIVADs) have played a crucial role in treatment of cancer patients since they were first described in 1982 [1]. They can improve patient quality of life by providing a safe and effective means of sampling venous blood and administering medications, blood, and nutrients [2]. In conjunction with improvements in cancer patient survival, long-term TIVAD use in this population has been reported in several previous studies [3-7].

In general, TIVADs are removed when complications such as infection, malfunction, and skin erosion occur. Removal is also considered when they are no longer clinically required [8, 9]. However, TIVAD removal can be difficult on occasion [10, 11]. Device adhesion to surrounding tissues is responsible in some cases, which may result in retained catheter fragments within the vein [12-14]. Several studies have reported the utility of interventional radiology (IR) approaches to difficult removals, which are less invasive than surgical approaches [10, 13-16]. Although a few studies have evaluated risk factors for difficult TIVAD removal in children, similar studies in adults are lacking [10-12, 14]. Therefore, this study aimed to examine the incidence of

difficult TIVAD removal in an adult population, determine associated risk factors, and review IR removal approaches.

Methods

Data collection

This retrospective single-center study was approved by the institutional review board of our hospital (Protocol No: 2021-1-098) and conducted in accordance with the Declaration of Helsinki and its later amendments. Written informed consent for TIVAD removal was obtained from all patients. The requirement for informed consent for study inclusion was waived because of the retrospective nature of the study.

Five hundred twenty-two consecutive TIVAD removals that were performed in the IR department of our hospital from January 2014 to May 2021 were eligible for study inclusion. Removals performed because of retained intravascular catheter fragments (n = 6) or accidental catheter migration into the central vein during the procedure (n = 2) were excluded. Therefore, 514 removals in 480 patients were included for analysis.

Five hundred eleven (99.4%) TIVAD removals were in cancer patients. The types of TIVAD removed were (1) DewX series (Terumo Corp., Tokyo, Japan), (2) PowerPort isp M.R.I. Implantable Port (BD, Franklin Lakes, NJ, USA), (3) X-Port ISP Implantable Port (BD), (4) Cell site series (Toray Medical Co., Ltd, Chiba, Japan), (5) Safe Guide MicroNeedle Port (Cardinal Health, Inc., Dublin, OH, USA), and (6) Orphic CV kit (Sumitomo Bakelite Co., Ltd, Tokyo, Japan). Catheter material was polyurethane in 376 catheters (73.2%) and silicone in 138 (26.8%). Most TIVADs were placed in the right subclavian vein; however, the placement site was individualized for each patient based on pathology and venous anatomy. TIVADs were placed in another hospital in 43 patients (8.4%). Indications for TIVAD removal were as follows: infection including local infection and/or bacteremia in 202 patients (39.3%), TIVAD no longer clinically required in 190 (37.0%), malfunction such as blocked and/or broken device in 83 (16.1%), skin erosion in 24 (4.7%), and other in 15 (2.9%). Median age at the time of removal was 64 years (range, 16–95). Median indwelling time was 398 days (range, 1–5543). Patient characteristics are presented in Table 1.

Removal procedure

TIVAD removals were performed under local anesthesia by several interventional radiologists with varied experience. The standard procedure involved a single incision in the skin adjacent to the port followed by dissection of the fibrous tissue around the port and catheter. Then, gentle traction was applied to remove the device through the incision.

In accordance with a previous study, difficult removal was defined as a removal in which the procedure report specified severe adhesion between the device and surrounding tissue or commented that maneuvers, techniques, or equipment in addition to those of the standard method were required [10]. Easy removal was defined as a removal in which the TIVAD was removed without difficulty using the standard method.

Statistical analyses

Statistical analyses were performed using Stata MP software version 16 (StataCorp LLC, College Station, TX, USA). The incidence of difficult removal was calculated. To

clarify the correlation between indwelling duration and difficult removal, all cases were classified according to indwelling duration (<1 year, 1–2 years, 3–5 years, and ≥6 years) and the incidence of difficult removal for each duration was examined. Uni- and multivariable logistic regression was performed to identify risk factors for difficult removal. Variables that showed probable association in univariable analysis were included in the multivariable analysis. $P < 0.05$ was considered significant.

Results

Incidence and risk factors

The study flowchart is presented in Figure 1. Difficult removal was identified in 38 of 514 procedures (incidence 7.4%; 95% confidence interval [CI], 5.4–10.0). Incidence of difficult removal in devices in place for <1 year, 1–2 years, 3–5 years, and ≥6 years was 2.4% (6/245), 6.6% (10/151), 11.8% (11/93) and 44.0% (11/25), respectively (Figure 2).

In univariable analysis, three variables were identified as significant risk factors for difficult removal. Median indwelling duration was significantly longer (1259 days [range, 84–3876] vs. 363 days [range, 1–5543]; $P < 0.01$), the proportion of

silicone catheters was significantly higher (44.7% vs. 25.4%; $P = 0.01$), and the proportion of TIVADs presenting with subcutaneous leakage of fluid was significantly higher (23.7% vs. 4.8%; $P < 0.01$) in the difficult removal cases than the easy removal cases. Multivariable analysis showed that indwelling duration per year (odds ratio [OR], 1.46; 95% CI, 1.28–1.67; $P < 0.01$) and subcutaneous leakage of fluid (OR, 6.04; 95% CI, 2.45–14.91; $P < 0.01$) were independently associated with difficult removal (Table 2).

IR approaches to difficult removal

In the 38 difficult removal cases, 32 devices could be removed using more dissection and traction than the standard removal method. In the other 6, the following techniques were applied sequentially: insertion of a guide wire (n = 1), dissection of the adherent tissue around the catheter using an introducer sheath (n = 2), pushing the catheter into the vein using a dilator (n = 1), and pulling out the catheter using a snare inserted via additional femoral vein access (n = 2) (Figures 3, 4). Eventually, all TIVADs were completely removed. No remnants were left behind and no serious procedure-related

complications occurred. Median procedural time was significantly longer for difficult removals than easy removals (25 min [range, 11–112] vs. 10 min [range, 3–35]; $P < 0.001$).

Discussion

The present study showed that difficult removal was experienced in 7.4% of all TIVAD removals in our adult study population, which is comparable with previously reported incidence rates in children (2–16%) [10-12, 14]. Moreover, we identified indwelling duration and subcutaneous leakage of fluid as risk factors for difficult removal.

Indwelling duration as a risk factor has been previously reported. In previous studies, median indwelling duration in difficult removal cases ranged from 1087 to 1200 days, which is similar to our finding (1259 days) [10, 11]. We also found that every year the TIVAD was in place caused a 1.46 odds increase in difficult removal and that difficult removal was observed in 44.0% of cases with indwelling duration ≥6 years. This suggests that TIVADs should be removed as soon as they are no longer being used. Furthermore, clinicians should expect difficult removal in TIVADs with longer

indwelling duration and explain this to the patient before the procedure.

In most difficult removal cases, TIVADs could be removed with more traction and/or dissection along the subcutaneous tunnel without the need for extra equipment. However, dissection around the port and catheter was inadequate in six of our cases and IR techniques were required. Firm adhesion of the catheter to the vein wall was considered the cause. Histologic changes in the vein wall adjacent to an indwelling catheter have been discussed by several studies [17-20]. With long-term indwelling duration, vein wall thickening is observed along the length of the catheter; fixation of the catheter to the vein wall occurs via bridging tissue that includes fibrin, collagen, and endothelial cells. We also identified subcutaneous leakage as a risk factor for difficult removal. Inflammation induced by infusions of anti-cancer agents or hyperalimentation solution that leak subcutaneously can result in severe adhesion [21, 22]. In addition, catheter compression between the clavicle and first rib at subclavian access sites, known as pinch-off syndrome, may promote the vein wall changes described above [23].

Although surgical approaches such as venotomy and median sternotomy to retrieve a fixed catheter have been reported, they are invasive [11, 12, 24]. IR

approaches are less so and a variety of IR techniques have been reported [10, 13-16]. The simplest technique is insertion of a guide wire that can provide direct force to the catheter. Huang et al. described this technique and noted that applying a “squeezing” force by applying both “pull-out” and “push-in” forces over a guide wire can detach an adherent catheter from the vessel wall [15]. Dissection using an introducer sheath is also effective. In this technique, an introducer sheath is inserted over the catheter into the vein and rotated to dissect the fixed catheter from the vein wall [16]. Pushing by a dilator enables operators to apply strong force, although pull-through technique is required to prevent catheter migration. If these techniques fail, removal using a snare should be attempted. Although an additional venous femoral sheath is needed, greater traction can be applied using the snare in combination with above techniques [10, 13]. Other authors have described an endoluminal dilation technique using a balloon angioplasty catheter [25, 26]. In this technique, a balloon catheter is inserted within the central venous catheter to dilate and break surrounding adhesions. However, this technique was reported for removal of large-diameter hemodialysis catheters. When used for TIVAD removal, a balloon catheter that matches the size of the fixed catheter

must be used.

If IR approaches fail to remove the TIVAD, clinicians should discuss surgical removal with the patient. Leaving retained catheter fragments in the vein is another option, but potential related complications, such as persistent sepsis and thrombus, have been reported and should be disclosed [27-29].

The present study has several limitations. First, this was a single-center retrospective study. Differences in removal procedures between facilities may affect the incidence of difficult TIVAD removal. Second, difficult removal was defined based on comments stated in procedure reports, which are subjective. Numerous operators with varied experience performed the removal procedures and operator bias may have been a factor. Third, TIVADs were inserted at another hospital in 8.4% of cases. Although we gathered as much information as possible in these cases from the medical records of the other hospital, some factors such as catheter size, patient weight, and any insertion difficulties were not known. Therefore, we could not examine associations between these and difficult removal.

Conclusion

In conclusion, the incidence of difficult TIVAD removal in adult patients was 7.4%. Associated risk factors included indwelling duration and subcutaneous leakage of fluid. In cases with difficult removal, fixed TIVADs were successfully removed by using several IR minimally invasive techniques. These findings can assist clinicians with clinical decision making and preparation for difficult removal in cases at risk for difficult removal.

Declaration of conflicting interests

The authors declare that there is no conflict of interest.

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Table 1. Patient characteristics

Number of TIVAD removals	514
Number of patients (male/female)	480 (237/243)
Primary disease (%), on a per-patient basis	
- Gastrointestinal cancer	253 (52.7%)
- Bone and soft tissue sarcoma	54 (11.3%)
- Blood cancer	41 (8.5%)
- Breast cancer	39 (8.1%)
- Gynecological cancer	33 (6.9%)
- Hepato-biliary-pancreatic cancer	28 (5.8%)
- Head and neck cancer	15 (3.1%)
- Urinary tract cancer	5 (1.0%)
- Lung cancer	4 (0.8%)
- Other	8 (1.7%)
Median age at removal (range)	64 (16–95)
Median indwelling time in days (range)	398 (1–5543)
Median body mass index at removal (range)	21.0 (12.1–56.9)
Indwelling site	
- Right/left	441/73
- Subclavian/jugular/brachial/femoral	482/26/5/1
Catheter type	
- Polyurethane/silicone	376/138
Reason for removal (%)	
- Infection	202 (39.3%)
- TIVAD no longer indicated	190 (37.0%)
- Malfunction	83 (16.1%)
- Skin erosion	24 (4.7%)
- Other	15 (2.9%)

TIVAD, totally implantable venous access device

Table 2. Univariable and multivariable logistic regression analysis for difficult TIVAD removal

	Univariable analysis		Multivariable analysis	
Covariates	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Sex (male vs. female)	1.44 (0.74–2.80)	0.32	-	-
Age at removal (years)	0.99 (0.97–1.01)	0.20	-	-
Primary disease (GI cancer vs. no GI cancer)	1.60 (0.81–3.18)	0.18	-	-
Indwelling duration (years)	1.45 (1.28–1.65)	<0.01	1.46 (1.28–1.67)	<0.01
Body mass index at removal (≥25 vs. <25)	1.01 (0.50–2.27)	1.000	-	-
Device laterality (right vs. left)	0.50 (0.23–1.11)	0.09	1.49 (0.70–3.18)	0.39
Approach site (subclavian vs. other)	5.56 (0.34–99.99)	0.16	-	-
Catheter material (silicone vs. polyurethane)	2.38 (1.21–4.65)	0.01	1.40 (0.57–3.48)	0.30
Local infection (yes vs. no)	0.52 (0.12–2.23)	0.56	-	-
Subcutaneous leakage (yes vs. no)	6.11 (2.59–14.40)	<0.01	6.04 (2.45–14.91)	<0.01

OR, odds ratio; CI, confidence interval; GI, gastrointestinal

Covariates with $P < 0.1$ in univariable analysis (n = 4) were used in the multivariable logistic analysis model