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Effectiveness of mechanical recanalization for intraluminal occlusion of totally implantable venous access ports

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Abstract

Purpose: To evaluate if the mechanical injection of saline is effective in restoring patency of a totally implantable venous access port (TIVAP) with an intraluminal occlusion.

Materials and methods: From January 2017 to June 2019, 64 cases of dysfunction of a TIVAP were referred to interventional radiology. Among these, 16 cases showed normal function of the TIVAP, 19 cases the showed the appearance of a fibroblastic sheath, and 29 cases showed intraluminal occlusion. Mechanical recanalization was performed for intraluminal occlusion of the TIVAP with an indeflator and a 20G non-coring needle. Linograms were performed in all recanalized cases. The success or failure of recanalization and the pressure of the indeflator were recorded. Linograms were evaluated for breakage or migration of catheters. Medical records were retrospectively reviewed.

Results: Among the 29 intraluminal occlusion cases, 24 cases (82.7%) were recanalized by mechanical recanalization via an indeflator. The pressure of the indeflator ranged from 29 to 220 psi (median: 118 psi). Linograms revealed breakage of the catheter of the TIVAP in two failed cases. The median interval from implantation to dysfunction was 405 days (range: 43–1723 days). The median interval from last use to dysfunction was 8 days (mean: 15.4 days; range: 1–119 days). The median re-occlusion free period after successful mechanical recanalization was 100.5 days (range: 6–859 days).

Conclusion: In the absence of an available thrombolytic agent, mechanical injection of saline was a tolerable alternative method for restoring occluded catheters and sustaining the function of catheters. Because breakage of the catheter can occur during mechanical recanalization of a TIVAP, a linogram should follow the procedure.

Keywords

Venous access port, mechanical recanalization, intraluminal occlusion, clot occlusion, saline injection

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Introduction

The totally implantable venous access port (TIVAP) is considered appropriate for the care of patients with cancer, and it is widely used for long term venous access for drug administration, blood sampling, and nutrition support.[1,2] TIVAPs reduce patient discomfort and anxiety during repetitive episodes of venous access, and they increase patients' overall quality of life.[1] However, indwelling TIVAPs may be associated with various complications such as catheter occlusion, extravasation of infusions, catheter migration, deep vein thrombosis, and infection.[3] These complications can disturb and delay the treatment of patients' underlying disease, thereby affecting their outcomes. Clot occlusion is the most common underlying mechanism of port malfunctions.[3] Mechanical occlusion of a TIVAP requires treatment that is tailored for its specific cause, and clot occlusion is usually treated with a thrombolytic agent, such as urokinase, alteplase, reteplase, tenecteplase, and alfimeprase.[3,4] Previously, thrombolysis with urokinase was usually performed for clot occlusion in

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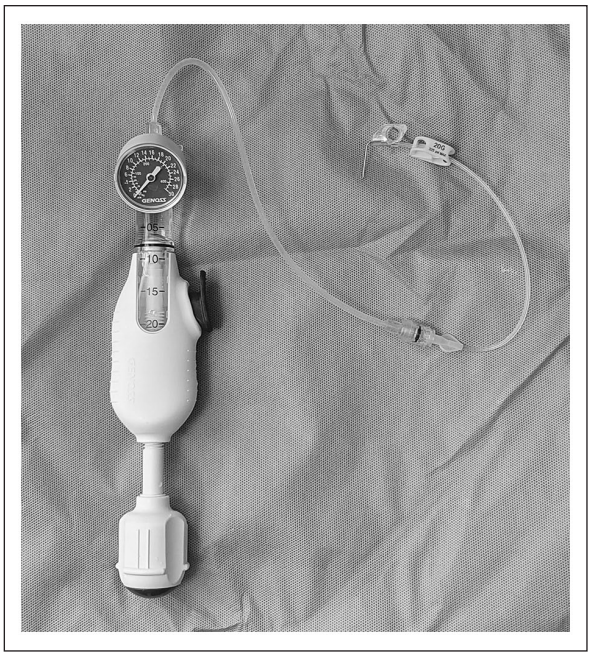

Figure 1. Schematic figure of the device used to recanalize occlusions of the TIVAP. The device consisted of an indeflator and a power-injectable non-coring needle.

our country. However, urokinase has been unavailable due to permanent interruption from its supply. Furthermore, thrombolytic agents were not covered for dysfunction of TIVAPs by the national health insurance.

In the past decade, the use of the TIVAPs in radiology was associated with complications caused by the high-pressure administration of contrast media, such as breakage of the catheter and occlusion of the TIVAP.[1] Recently, a power-certified TIVAP, developed to endure the high pressure of contrast media administration, solved these problems. Based on this development of TIVAP, Song et al. reported that mechanical saline injection is safe and effective in restoring patency to the TIVAP with an intraluminal occlusion in an experimental port occlusion model.[5] The purpose of this study is to evaluate if mechanical injection of saline is effective in restoring patency to a TIVAP with an intraluminal occlusion in a clinical setting.

Materials and methods

The Institutional Review Board of our hospital approved this retrospective study, and the consenting process to participate in the present study was waived.

Patients

A retrospective search of the hospital information system database for records from January 2017 to June 2019 showed that 64 consecutive cases of dysfunction of a TIVAP were referred to interventional radiology. Among these, 16 cases showed normal function of TIVAPs, 19 cases showed only withdrawal occlusion (appearance of a fibroblastic sheath), and 29 cases showed intraluminal occlusion. Therefore, this study finally included 29 cases: 11 men and 12 women with a mean age of 61.8 years (range: 30–84 years) for mechanical recanalization. Six cases were from four patients who required repetitive mechanical recanalization. All TIVAPs were power-injectable Celsite Discreet STL and STR ports with a silicone catheter (6.5F, 325 psi (pounds per square inch), B. Braun Medical, Boulogne, France). The types of Celsite Discreet ports were the STL and STR for access to the right or left axillary vein, respectively.

Dysfunction of the TIVAP

In our hospital, dysfunction of a TIVAP was managed as follows. Mechanical dysfunction, such as kinking of the catheter, pinch-off syndrome, or migration of the catheter, was evaluated with a chest plain radiogram. In cases without mechanical dysfunction, patients were referred to interventional radiology. Function of the TIVAP was evaluated with a 10 ml saline syringe with a non-coring needle. Normal function was defined as good passage of saline through the catheter when it was infused and gently withdrawn. Intraluminal occlusion was defined as complete inability to both infuse fluid into the TIVAP and withdraw blood from the TIVAP. Withdrawal occlusion was defined as ability to infuse fluid into the TIVAP but inability to withdrawal blood from the TIVAP.

Mechanical recanalization of the intraluminal occlusion

Written informed consent was obtained from all patients before the procedure. In case of intraluminal occlusion, mechanical recanalization with a saline injection was performed using an indeflator (Inflator B30, GENOSS, Suwon, Korea) and a 20G Winged Surecan (power-injectable non-coring needle, B. Braun Medical, Boulogne, France) (Figure 1). Mechanical recanalization was performed by increasing the pressure with an indeflator to 300 psi. The success or failure of mechanical recanalization was recorded. If an intraluminal occlusion was successfully recanalized, the pressure from indeflator was also recorded. In all recanalized cases, a linogram was performed by injection of contrast media (VISIPAQUE 320, GE Healthcare, Shanghai, China) though the TIVAP (Figure 2). Linograms were evaluated for breakage or migration of the catheters. If mechanical recanalization of the TIVAP failed or the linogram showed breakage of the catheter after attempts at mechanical recanalization, the TIVAP was removed.

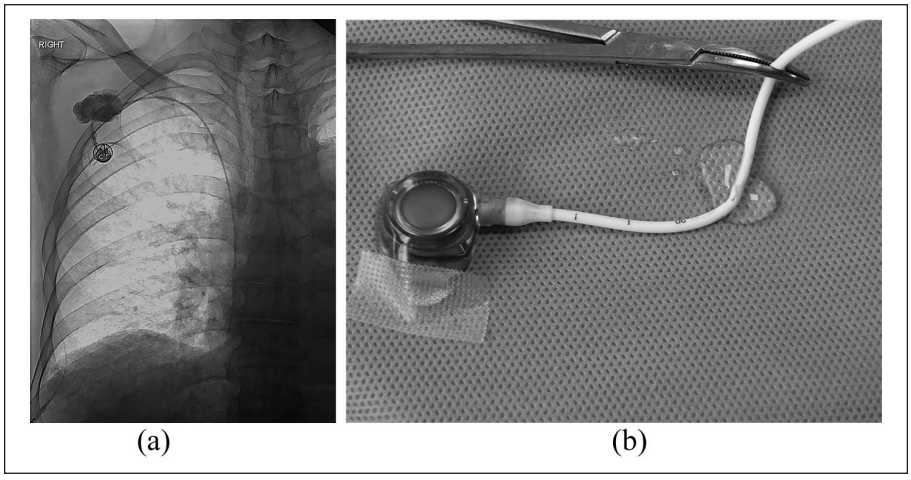

Figure 2. A 65-year-old female with diffuse large B cell lymphoma. The patient was referred to interventional radiology for a third mechanical recanalization of an occluded TIVAP. During attempts at mechanical recanalization with an indeflator and a power-injectable non-coring needle, the pressure on the indeflator rapidly decreased from 88 psi. A linogram was performed to confirm the catheter's condition. The linogram (a) shows leakage of contrast media in the proximal part of the catheter. After removal of the TIVAP, saline was infused through the chamber of the TIVAP. We confirmed breakage of the catheter without discontinuity (b).

Table 1. Characteristics of mechanical recanalization for intraluminal occlusion.

	Successful recanalization	Failed recanalization
Mechanical recanalization, *n*	24 (82.7%)	5(17.3%)
Pressure of indeflator	118 psi[§] (29–220)*	n/a[¶]
Repeated cases ($n = 6$)	3 (50%)	3 (50%)
Last purpose for use of TIVAP[#]		
Blood sampling	11 (91.6%)	1 (8.4%)
Blood transfusion	2 (100%)	0
Chemotherapy	7 (70%)	3 (30%)
Pharmacologic treatment	4 (80%)	1 (20%)
Interval from implantation to dysfunction	426 days (43–1702)*	364 days (101–1723)*
Interval from last using to dysfunction	8 days (1–119)*	4 days (1–37)*
Re-occlusion free period after successful recanalization	100.5 days (6–859)*	n/a[¶]
Re-occlusion free period after first successful recanalization	113 days (6–859)*	n/a[¶]
Causes of last follow-up		n/a[¶]
Death	9	
Lost to follow up	2	
Port removal after cessation of chemotherapy	6	
Re-occlusion	6	
Last follow up day	1	

*Median (range).
[#]Totally implantable venous access port.
[§]Pound per square inch.
[¶]Not available.

Data

We retrospectively reviewed patients' electronic medical records to evaluate the following: the last purpose for the use of the TIVAP, insertion date of the TIVAP, and the date of the intraluminal occlusion to calculate the interval from implantation to dysfunction; date of last use of the TIVAP to calculate the interval from last use to dysfunction; date of last follow-up to calculate re-occlusion free period after mechanical recanalization; and causes of last follow-up such as death, lost to follow up, port removal after cessation of chemotherapy, and re-occlusion. Patients' symptoms during mechanical recanalization of the TIVAP were also reviewed.

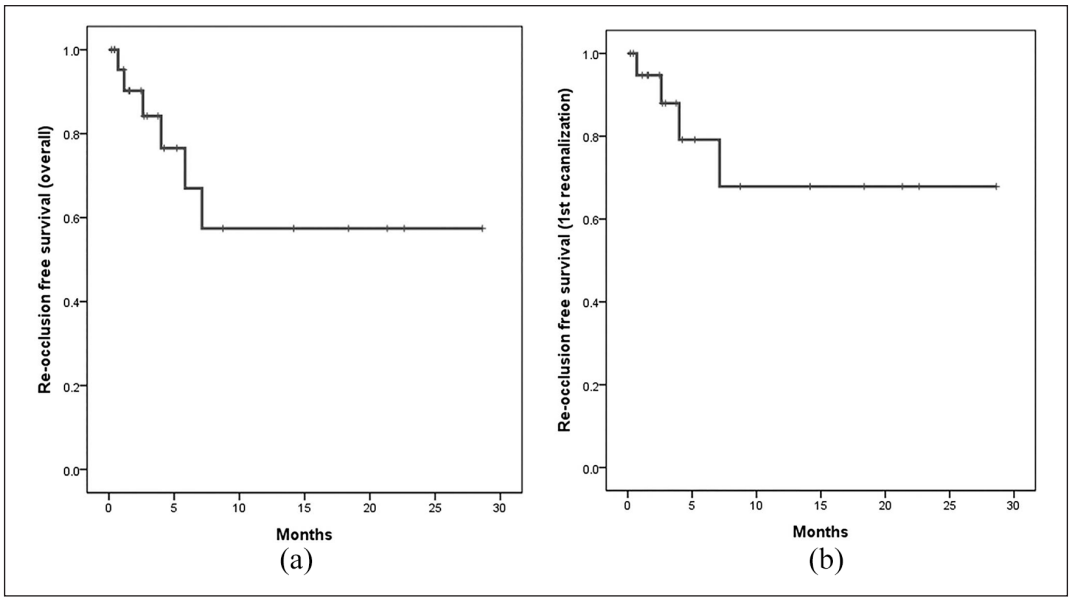

Figure 3. Kaplan-Meier analysis of re-occlusion free survival among patients who underwent successful mechanical recanalization (a). Kaplan-Meier analysis of re-occlusion free survival among patients who underwent first successful mechanical recanalization (b).

Statistical analysis

Statistical analysis was performed using SPSS® (version 20.0; SPSS Inc., Chicago, IL, USA). Medical records were analyzed using descriptive methods. Data were presented as the number and median with range. Cumulative incidence of re-occlusion was calculated in months based on the length of time between the date of mechanical recanalization of the TIVAP and date of last follow-up using the Kaplan-Meier method.

Results

Characteristics of mechanical recanalization for the intraluminal occlusions are shown in the Table 1. Among the 29 cases with intraluminal occlusion, 24 cases (82.7%) were recanalized by mechanical saline injection via the indeflator. The indeflator pressure ranged from 29 to 220 psi (median: 118 psi). The linograms demonstrated two cases of contrast media leakage from the catheter due to breakage of the TIVAP catheter after mechanical recanalization (Figure 2(a)). Removal of the TIVAP in the cases with contrast media leakage revealed that the catheter had ruptured, although the continuity of the catheter was preserved (Figure 2(b)). The linograms demonstrated no evidence of migration or embolization of a distal fragment. In addition, no patient complained of symptoms, such as sudden chest pain or dyspnea, after mechanical recanalization. Among six cases that had to be repeated, three cases showed successful mechanical recanalization and three cases showed failure of mechanical recanalization.

The recorded last purposes for use of the TIVAPs were blood sampling ($n = 12$), blood transfusion ($n = 2$), chemotherapy ($n = 10$), and pharmacologic treatment ($n = 5$). The median interval from implantation to dysfunction was 405 days (range: 43–1723 days). The median interval from last use to dysfunction was 8 days (mean: 15.4 days; range: 1–119 days). When considering the interval from last use, mechanical recanalization was tried within and beyond 30 days in 24 cases and 5 cases, respectively. Success rates were 83% (20/24) and 80% (4/5) in cases within and beyond 30 days, respectively. The median re-occlusion free period after successful mechanical recanalization was 100.5 days (range: 6–859 days). Except for three cases that required repetitive recanalization, the median re-occlusion free period after successful mechanical recanalization was 113 days (range: 6–859 days). The Kaplan-Meier curve method was performed for re-occlusion free survival of TIVAPs that underwent successful mechanical recanalization (Figure 3). The re-occlusion free survival rates after successful mechanical recanalization were 95% ± 9% (1 month), 84% ± 16% (3 months), 67% ± 25% (6 months), and 57% ± 28% (1 year). The re-occlusion free survival after first successful mechanical recanalization were 95% ± 10% (1 month), 88% ± 16% (3 months), 79% ± 22% (6 months), and 68% ± 28% (1 year). The causes of last follow-up in 24 successful cases of mechanical recanalization were death ($n = 9$), lost to follow-up ($n = 2$), port removal after cessation of chemotherapy ($n = 6$), re-occlusion ($n = 6$), and last follow up day ($n = 1$).

Discussion

Among the 29 cases of intraluminal occlusion, 24 cases (82.7%) were recanalized by mechanical saline pressure via the indeflator. Previous studies demonstrated that thrombolytic treatment was effective in restoring patency

to TIVAP catheters with an intraluminal occlusion.[6] The rate of patency restoration in TIVAPs with mechanical recanalization in this study was reasonable in comparison with the average rates after 30 min of drug administration with reteplase (69.8%), alteplase (52.1%), recombinant urokinase (59.8%), tenecteplase (51.5%), and alfimeprase (60%). The overall patency restoration rates after about 120 min of drug administration were as follows: reteplase (95.2%), alteplase (86.5%), recombinant urokinase (72.5%), tenecteplase (82.7%), and alfimeprase (80%).[7–18] Two cases in the present study revealed leakage of contrast media from broken catheters without evidence of catheter migration or catheter embolization on linograms after mechanical recanalization. Catheters can be injured by various mechanical stresses as a result of the pinch-off syndrome, forceful flushing with small syringes, or for no obvious reason.[3,19–21] In cases of a broken catheter, it is assumed that the various mechanical stresses mentioned above continued to act on the catheter, so that a part of the catheter was weakened. Although the catheter had broken in two of our cases, we considered this complication as tolerable for two reasons. First, in absence of an available thrombolytic agent, mechanical recanalization provides an opportunity for recanalization before removal of a TIVAP due to dysfunction. Second, although the catheters had broken, neither underwent distal embolization. Most embolized fragment are completely asymptomatic, but a linogram should follow mechanical recanalization.

The 1-, 3-, 6-, and 12-month re-occlusion free survival rates in this study were 95%, 84%, 67%, and 57%, respectively. For cases of first mechanical recanalization, the re-occlusion free survival rates were 95%, 88%, 79%, and 68% (Figure 3), and the data showed that the patency of the catheter was relatively well preserved after mechanical recanalization.

Mechanical recanalization has several advantages over the commonly performed thrombolysis. First, mechanical recanalization would work when the lumen of a catheter is occluded by clots and also by drug precipitates or lipids. Second, in the case of a thrombolytic agent, the indwelling time is long (minimum, 30 min).[4,6] On the other hand, in the case of mechanical recanalization, the procedure time is relatively short (about 10 min). Third, thrombolytic agents are generally expensive.[6] Mechanical recanalization with saline using only an indeflator may be less expensive than thrombolytic protocols.

This study has several limitations. First, intraluminal occlusion was defined as complete inability to both infuse fluid into the TIVAP and withdraw blood from the TIVAP. However, venous thrombosis, intraluminal clot, and precipitations of drug or parenteral nutrition could present as an intraluminal occlusion. Because proper management of TIVAP dysfunction depends on the accurate diagnosis of the occlusion mechanism, this study is limited because we did not consider the various causes of intraluminal occlusion. Second, this study retrospectively collected data about TIVAP dysfunction. In addition, we assumed that a well-trained practitioner locked the TIVAP after use. These could have introduced bias in the real clinical field. Third, this study did not compare thrombolytic agents with mechanical recanalization regarding restoration rate and period of patency. To provide accurate and reliable results, further prospective and systematic research is required. Fourth, several risk factors are associated with the development of catheter occlusion, including the size and material of the catheter.[6] The scope of this study was limited to only 6.5F and silicone catheters.

Finally, in the absence of an available thrombolytic agent, mechanical injection of saline was considered a tolerable alternative method for restoring occluded catheters and sustaining the function of catheters. A linogram should follow mechanical recanalization since breakage of the catheter can occur during mechanical recanalization of a TIVAP.

Declaration of conflicting interests

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IRB approval

The study protocol was approved by the Institutional Review Board of the Korea University Guro Hospital (IRB approval number 2020GR0449).

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