



Predictive Risk Factors for Fracture at Catheter of Totally Implantable Venous Access Devices via Subclavian Vein Insertion

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Background: Fracture of totally implantable venous access devices (TIVAD) is a rare but potential serious complication. We aimed to explore the risk factors for fracture at catheter of TIVAD via subclavian vein insertion. **Materials and Methods:** From January 2008 to July 2010 the records of 34 patients with fractured TIVAD were retrospectively reviewed. The comparison group included 170 randomly selected cases (5 for every patient with a fractured catheter) from 3919 cases of TIVAD implantations without catheter fracture. Variables associated with catheter implantation and the relationship between the catheter and the clavicle were analyzed. **Results:** Statistical analysis revealed implantation method, duration of implantation, brand of device, and port-clavicle distance were predictive risk factors for catheter fracture on univariate analysis. Duration of implantation >200 days and port-clavicle distance <2.5 cm were independent risk factors for catheter fracture on multivariate analysis. Stratified analysis indicated that a port-clavicle distance <2.5 cm in patients with duration of TIVAD implantation >200 days was associated with a significantly increased risk of catheter fracture. **Conclusions:** We suggested that TIVAD with a port-clavicle distance <2.5 cm could be removed to prevent catheter fracture when the implantation duration is more than 200 days.

Key words: Venous access device, implantable, fracture

INTRODUCTION

Totally implantable venous access devices (TIVAD) are commonly used for delivery of chemotherapy. The early and late complications of TIVAD implantation including pneumothorax, infection, obstruction, and catheter fracture are well-described in the literature.¹ Catheter fracture is a rare and had potential serious complication after TIVAD implantation. A fragmented catheter lodged in the heart may induce arrhythmias or embolization to the pulmonary artery and should be retrieved immediately when recognized.² Catheter fracture may be preceded by constant compression of the catheter between the clavicle and first rib (the “pinch-off sign” on chest radiograph).³ In the literature, there are few reports describing the possible mechanisms of TIVAD fracture.^{2,4,5} We aimed to analysis the risk factors of TIVAD fracture.

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MATERIALS AND METHODS

We conducted a retrospective analysis of 34 patients in whom TIVAD occurred between January 2008 and July 2010. The comparison group with 170 cases (5 cases for every patient with TIVAD fracture) were randomly selected by Statistical Package for Social Sciences version 15.0 (SPSS, Inc., Chicago, IL, USA) from 3919 patients with TIVAD without fracture during the same period. All patients received TIVAD via subclavian vein implantation for administration of chemotherapy. The study was approved by the Institutional Review Board and Ethics Committee.

The variables included in the study were the demographic (age, sex, primary malignancy, method and duration of implantation) and radiological characteristics (location of the fracture, presence/absence of the pinch-off sign, side, brand of device implanted, angle and distance between the clavicle and port). Exclusion criteria were as follows: Implantation of the TIVAD through the jugular vein or femoral vein; no posteroanterior (PA) view chest radiograph performed after implantation (variation in measuring the port-clavicle distance and angle present on other chest radiography views); implantation the TIVAD for parenteral or venous access; and malposition of the TIVAD (tip of the TIVAD was not positioned in the superior vena cava).

Totally implantable venous access devices implantation by cut-down or the puncture method was performed in the same fashion.⁶ Three brands of TIVAD were implanted in this study:

- BardPort (Bard Access Systems, Salt Lake City, UT, USA),
- Arrow (Arrow international, Reading, PA, USA), and
- Port-A-Cath (SIMS, Deltec, Inc., St. Paul, MN, USA).

In all patients, postoperative chest radiograph was performed for identifying the location of the TIVAD. The port-clavicle distance was determined by measuring the minimum distance between clavicle and port of the TIVAD [Figure 1]. The port-clavicle angle of the TIVAD was measured on the PA chest radiograph [Figure 2]. All patients diagnosed with catheter fracture were immediately referred to cardiovascular physicians for removal of the fractured catheter. The SPSS version 15.0 was used for all analyses. The characteristics of the cases and control subjects were compared and tested for significant differences using Student's *t*-test for linear variables and a Pearson's Chi-squared test for categorical variables. Receiver operating characteristic (ROC) curves were constructed to determine the optimal cut-off point for continuous significant variables. The variables found to be significant on univariate analysis were included in the multivariate model to evaluate the risk of catheter fracture. Stratified analysis was used to test whether identical regression models were appropriate for different groups. Values were expressed as mean $\pm$ standard deviation, and estimated odds ratios (ORs) and 95% confidence intervals (CIs) for the association between the potential risk factors and catheter fracture risk were calculated. A value of $P < 0.05$ was considered to indicate statistical significance.

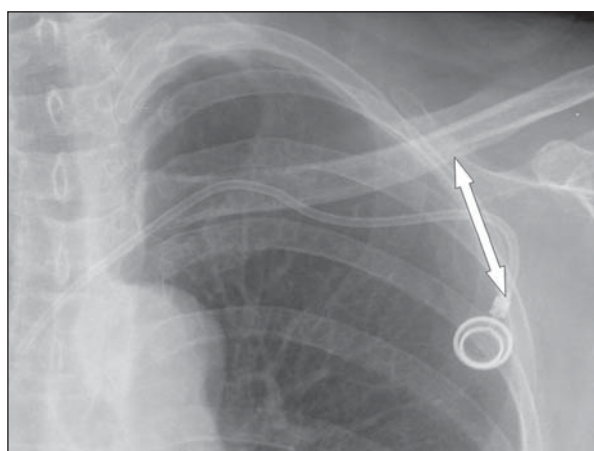


Figure 1. Measurement of the minimum distance between the clavicle and port of the totally implantable venous access devices (white arrow)

RESULTS

A total of 204 cases was included in the analysis, and the demographic and clinical characteristics of the patients are presented in Table 1. The most common location of catheter fracture was the port-catheter junction 88% (30/34), and the other four cases of fracture were located at the level of the

Table 1. Patient characteristics

Factor	Fractured (<i>n</i> = 34)	Not fractured (<i>n</i> = 170)	<i>P</i> value
Sex (male/female)	18/16	106/64	0.339
Age (years)	52.9 $\pm$ 12.5	52.6 $\pm$ 15.2	0.132
Site of primary malignancy			
Gastrointestinal tract	12	36	
Breast	7	17	
Lung	4	23	
Female reproductive	3	8	
Genitourinary	0	7	
Soft tissue	0	7	
Head/neck	4	46	
Hematological	4	26	
Method (puncture/cut-down)	34/0	139/31	0.003
Side (right/left)	5/29	41/129	0.269
Brand (A/B/C)	15/0/19	93/36/41	<0.001
Pinch-off syndrome	1	1	0.306
Duration of implantation (days)	757.5 $\pm$ 445.3	397.1 $\pm$ 236.4	<0.001
Port-clavicle distance (cm)	2.55 $\pm$ 1.18	4.95 $\pm$ 1.81	0.001
Port-clavicle angle ($^{\circ}$)	33.4 $\pm$ 15.2	36 $\pm$ 15.3	0.48

Brand: (A) BardPort (Bard Access Systems, Salt Lake City, UT, USA), (B) Arrow (Arrow international, Reading, PA, USA), and (C) PORT-A-CATH (SIMS, Deltec, Inc., St. Paul, MN, USA)

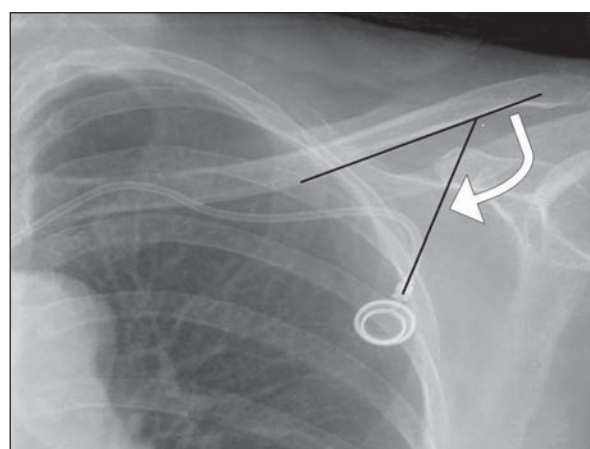


Figure 2. Measurement of the angle between the port and the clavicle (white arrow)

first rib and clavicle. The rate of catheter fracture was 0.86% (34/3953) among all implanted TIVAD during this period, and all fractured catheters were successfully retrieved by a goose-neck snare device.

Analysis showed that the implantation method, brand of device, duration of implantation, and port-clavicle distance were significant factors associated with fracture on univariate analysis. The ROC curve showed the cut-off point for the duration of implantation was 200 days, and the port-clavicle distance was 2.5 cm. The variables of implantation method (cut-down or puncture), device brand (A, B, C), duration of implantation (>200 days or <200 days), and port-clavicle distance (>2.5 cm or <2.5 cm) were included in the multivariate analysis. The results of the multivariate analysis for the risk factors of catheter fracture are shown in Table 2. The factors that independently correlated with fracture of the TIVAD were duration of implantation >200 days and port-clavicle distance <2.5 cm. Stratified analysis confirmed that a port-clavicle distance <2.5 cm was associated with a significantly higher risk of catheter fracture (OR = 13.04, 95% CI: 4.16-40.87, $P < 0.001$) in patients with a duration of TIVAD implantation >200 days [Table 3].

DISCUSSION

A fractured catheter is a rare, but life-threatening complication, and the incidence of TIVAD fracture has been reported to range from 0.53% to 0.1%.^{1,6,7} The published cases and possible mechanism of catheter fracture were summarized in Table 4. Signs of catheter fracture include local swelling, pain or increased resistance during port flushing, and palpitations without physical exertion, but some fragmented catheters may remain asymptomatic for years.^{26,27}

Fracture of the middle part of the catheter may be induced by constant compression of the catheter between the first-rib and clavicle (the pinch-off syndrome).³ However, we found only a few (four cases) of fracture at the level of the first rib and clavicle, and only one case with the pinch-off sign in each group (i.e., fracture and not fractured groups). Lin *et al.*⁵ and Cheng *et al.*²⁷ also reported similar findings regarding the fracture site of TIVAD. The mechanism of catheter fracture over the port-catheter junction may be extrinsic compression near the port-catheter junction combined with material fatigue caused by repeating bending of the catheter with shoulder movement, not pinch-off syndrome.

In univariate analysis, TIVAD implantation method, brand of device, and duration and distance between the port and the clavicle were associated with increased risk of catheter fracture. The puncture method for TIVAD implantation was associated with an increased risk of catheter fracture, similar to

Table 2. Multivariate analysis of variables associated with risk factors of catheter fracture

Variables	Number of patients (%)	OR (95% CI)	<i>P</i> value
Method			
Puncture	173	NS	0.998
Cut-down	31		
Brand			
A	108	1.02 (0.38-2.77)	0.965
B	36		
C	60		
Duration of implantation			
<200 days	46	0.24 (0.058-0.98)	0.047
>200 days	158		
Port-clavicle distance			
<2.5 cm	53	12.57 (4.34-36.4)	<0.001
>2.5 cm	151		

OR = odds ratio; CI = confidence interval

Table 3. Stratified analysis by duration of implantation for risk factors of catheter fracture

Variables	<200 days		>200 days	
	OR (95% CI)	<i>P</i> value	OR (95% CI)	<i>P</i> value
Method (puncture/cut-down)	NS	0.999	NS	0.998
Brand (A/B/C)	NS	0.997	NS	0.923
Port-clavicle distance (<2.5 cm/>2.5 cm)	5.3 (0.3-82.8)	0.232	13 (4.2-40.9)	<0.001

NS = not significant; OR = odds ratio; CI = confidence interval

the findings in our previous report.⁶ We believe that the reason of device brand and implantation duration are associated with catheter fracture is related to the composition of the catheter and material fatigue due to repeated loading and unloading force. No catheter fracture was found on brand B of TIVAD in our study. The design of catheter connection to port (Cath-Lock system) may be an important cause for catheter fracture.⁵ The Cath-Lock system with flexible and soft design may decrease the risk of catheter fracture by reducing the bending force during shoulder movement. The route of catheter was beneath the clavicle through subclavian vein and all ports were fixed in the upper chest near the clavicle. The relationship of port and clavicle with short distance may increase damage of the catheter by constant rubbing at the edge of the clavicle.

Materials science has shown that the shape of the structure significantly affects its fatigue life; a sharp angle may lead to increased local pressure and initiate fatigue cracks. Eventually, the cracks will reach a critical size, and the material will fail.²⁸

Table 4. The published cases and possible mechanism of catheter fracture

Author/year	Total cases	Fractured cases	Percentage of fracture (%)	Possible cause of fracture
Rebahi <i>et al.</i> ⁸	4	4	Case report	Pinch-off syndrome
Nagasawa <i>et al.</i> ⁹	1	1	Case report	Material failure
Cortés-Flores <i>et al.</i> ¹⁰	156	1	0.64	No comment
Doley <i>et al.</i> ¹¹	1	1	Case report	Design of Port-A Site of placement Type of chemotherapy Duration of catheter use
Kim <i>et al.</i> ¹²	442	1	0.23	Pinch-off syndrome
Shimizu <i>et al.</i> ¹³	1	1	Case report	Material failure
Nishinari <i>et al.</i> ¹⁴	350	1	0.29	No comment
Lin <i>et al.</i> ⁵	3358	73	2.17	Pinch-off syndrome Design of Port-A
Wang <i>et al.</i> ¹⁵	1	1	Case report	No comment
Ghayyda <i>et al.</i> ¹⁶	1	1	Case report	Trauma
Chang <i>et al.</i> ⁶	1131	6	0.53	Pinch-off syndrome Catheter damage Increased pressure within catheter
Kapadia <i>et al.</i> ⁷	1	1	Case report	Pinch-off syndrome
Gowda <i>et al.</i> ¹⁷	1	1	Case report	No comment
Schummer <i>et al.</i> ¹⁸	2	2	Case report	No comment
Denny and Frank ¹⁹	1	1	Case report	Pinch-off syndrome
Iannelli <i>et al.</i> ²⁰	1	1	Case report	Trauma
Ferrari <i>et al.</i> ²¹	1	1	Case report	Pinch-off syndrome
Kock <i>et al.</i> ²²	1500	2	0.13	No comment
Klotz <i>et al.</i> ²	2	2	Case report	Pinch-off syndrome
Raungaard and Thuesen ²³	1	1	Case report	No comment
Lorenz <i>et al.</i> ²⁴	1	1	Case report	No comment
Noyen <i>et al.</i> ²⁵	1	1	Case report	Pinch-off syndrome

We thought that the shape of a TIVAD could be represented by measuring the port-clavicle angle; however, the results of our analysis showed that the port-clavicle angle did not increase the risk of catheter fracture.

Our findings are consistent with material fatigue theory that structural fractures are due to long duration of use and more extrinsic compressive force. The better design of TIVAD, the use cut-down method, shorter duration of implantation and longer port-clavicle distance could avoid catheter fracture.

CONCLUSION

In this study, we investigated the risk factors of TIVAD fracture, and the results showed implantation more than 200 days and a port-clavicle distance <2.5 cm were independent factor for fracture of TIVAD on multivariate analysis, and a port-clavicle distance <2.5 cm was associated with a

significantly higher risk of catheter fracture in patients with a duration of TIVAD implantation more than 200 days on stratified analysis. We suggested that TIVAD with a port-clavicle distance <2.5 cm could be removed to prevent catheter fracture when the implantation duration more than 200 days.

DISCLOSURE

The authors declare that this study has no conflict of interest and financial support.

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