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Long-term reliability of the defibrillator lead inserted by the extrathoracic subclavian puncture

Masaya Watanabe MD, PhD[1] | Hisashi Yokoshiki MD, PhD[1,2] | Hirofumi Mitsuyama MD, PhD[1] | Kazuya Mizukami MD, PhD[1] | Taro Tenma MD, PhD[1] | Rui Kamada MD, PhD[1] | Masayuki Takahashi MD[1] | Yoshiro Matsui MD, PhD[3] | Toshihisa Anzai MD, PhD[1]

[1]Department of Cardiovascular Medicine, Hokkaido University Graduate School of Medicine, Sapporo, Japan

[2]Department of Cardiovascular Medicine, Sapporo City General Hospital, Sapporo, Japan

[3]Department of Cardiovascular Surgery, Hokkaido University Graduate School of Medicine, Sapporo, Japan

Correspondence: Hisashi Yokoshiki, Department of Cardiovascular Medicine, Sapporo City General Hospital, Kita-11, Nishi-13, Chuo-ku, Sapporo 060-8604, Japan (hisashi.yokoshiki@doc.city.sapporo.jp).

Abstract

Background: As the transvenous defibrillator lead is fragile and its failure may cause a life-threatening event, reliable insertion techniques are required. While the extrathoracic puncture has been introduced to avoid subclavian crush syndrome, the reports on the long-term defibrillator lead survival using this approach, especially the comparison with the cephalic cutdown (CD), remain scarce. We aimed to evaluate the long-term survival of the transvenous defibrillator lead inserted by the extrathoracic subclavian puncture (ESCP) compared with CD.

Methods: Between 1998 and 2011, 324 consecutive patients who underwent an implantable cardioverter-defibrillator (ICD) implantation in Hokkaido University Hospital were included. ICD leads were inserted by CD from 1998 to 2003 and by contrast venography-guided ESCP thereafter. Lead failure was defined as a non-physiologic high-rate oversensing with abnormal lead impedance or highly elevated sensing and pacing threshold.

Results: Of 324 patients, CD was used in 37 (11%) and ESCP in 287 patients (89%). During the median follow-up of 6.2 years (IQR:3.2-8.3), 7 leads (2 in CD and 5 leads in ESCP group) failed. All patients with lead failure in ESCP group were implanted with either SJM Riata (n = 1) or Medtronic Fidelis lead (n = 4). Five-year lead survival was 93.8% (CI95%:77.3-98.4%) in CD compared with 99.1% (CI95%:96.6-99.8%) in ESCP group (P = 0.903). Univariate Cox regression analysis showed that the use of Fidelis or Riata lead was the strong predictor of the ICD lead failure (HR 13.8, CI95%:2.9-96.5; P = 0.001).

Conclusions: Contrast venography-guided extrathoracic puncture ensures the reliable long-term survival in the transvenous defibrillator leads.

KEYWORDS

cephalic cutdown, defibrillator lead, extrathoracic puncture, lead failure, subclavian crush syndrome

1 | INTRODUCTION

Implantable cardioverter-defibrillator (ICD) is an effective therapy for life-threatening ventricular arrhythmias.[1] Numerous clinical trials proved its efficacy, and the indication of the ICD therapy has been expanding.[2-4] At the same time, complications associated with the ICD leads, the most fragile component, have been recognized.[5]

Cephalic vein cutdown has been used for transvenous lead insertion since the early period of the device implantation.[6] While the cephalic approach is recognized as the most favorable to reduce the mechanical stress related to the insertion procedures,[7-9] it requires experience and longer procedure time.[10] Subclavian puncture, instead, is performed easily and briefly, whereas this method has the potential long-term risk of conductor fractures and insulation defects developed by compression of a lead between the first rib and clavicle.[11] To avoid these serious complications and provide an easier procedure, the extrathoracic approach, guided by fluoroscopic landmark,[12,13] venography[14,15] or ultrasound,[16] has been introduced. While the success rate in lead insertion was preferable with a low incidence of acute complications, the report of the long-term lead survival using the extrathoracic approach is quite limited, especially for ICD leads which are structurally complicated and therefore fragile.[5,17]

In this study, we aimed to evaluate the long-term survival of transvenous ICD leads inserted by the venography-guided extrathoracic subclavian puncture compared with that by the cephalic vein cutdown.

2 | METHODS

2.1 | Study cohort

Between 1998 and 2011, 324 consecutive patients who underwent an implantable cardioverter-defibrillator (ICD) implantation in Hokkaido University Hospital were included. All patients were treated according to the routine clinical protocol and have provided a written informed consent.

2.2 | Implantation techniques

After contrast venography, an ICD pocket was created in the left pectoral region unless the venous access was not available or the patient's preference. Thereafter, a transvenous ICD lead was inserted by either cephalic vein cutdown (CD) or contrast venography-guided extrathoracic subclavian puncture (ESCP) method.

Between 1998 and August 2003, implantation procedures were performed by a cardiovascular surgeon and an electrophysiologist. During this period, venous access with CD was obtained by a cardiovascular surgeon.

After September 2003, the procedures were performed only by the electrophysiologists and transvenous leads were inserted by ESCP. After a contrast venography, the skin incision was made perpendicular to the deltopectoral groove at the level of the coracoid process.[12] Once a pocket was created beneath the pectoral fascia, the puncture using a 21 G micropuncture needle (Micropuncture Introducer Set, Cook Medical, Inc., Bloomington, IN) aiming the extrathoracic subclavian vein as it crosses the first rib was conducted.[14] Coracoid process and deltopectoral groove were also used as the anatomical landmarks. The vein runs 1.5-2 cm medial and parallel to the deltopectoral groove and it crosses the deltopectoral muscle at the level of coracoid process.[12] To avoid pneumothorax and make the *gentle* angle between the needle and the subclavian vein, the needle was held tangential to the chest wall (Figure 1). If several attempts failed to achieve venous access, the additional injections of contrast were performed. If the vasospasm was observed, the puncture targeting the area without narrowing, normally toward lateral area, was performed, otherwise the experienced operator conducted the puncture.

After obtaining the venous access, a lead was gently handled to reduce the mechanical stress due to the contact with the venous and heart wall. When the lead tip came out of the sheath introducer, the lead stylet was withdrawn by 2-3 cm. Once the lead was advanced into the right ventricle (RV), active fixation was performed normally onto the RV apex.

In the measurement of ICD lead parameters, *R*-wave amplitude $\geq$ 5 mV and a pacing threshold $\leq$ 2.0 V with 0.5 or 0.4 ms pulse were considered acceptable. Defibrillation threshold tests were routinely performed twice, and successful defibrillation with more than 10 J as a safety margin was required.[18]

2.3 | Follow-up

After discharge, all patients were followed at the outpatient ICD clinic every 4 months. Extra visits were also planned in case of ICD shocks or the serious alerts from the remote monitoring system. Evaluation of the ICD clinic consisted of a patient history and interrogation of the device for arrhythmic events. Lead malfunction was examined by measurements of the lead impedance, pacing threshold, and intracardiac sensing amplitude.

2.4 | Definition of lead failure

Lead failure was classified into (a) conductor fracture, (b) insulation defect, or (c) other dysfunction by the following definitions.[5] Oversensing not related to cardiac cycle accompanied by either (a) the sudden increase in lead impedance >1500 Ohms or twice the number at last follow-up or (b) decrease < 200 ohms was defined as the conductor fracture or insulation defect, respectively. Other lead dysfunctions were defined as linear increase in lead impedance to >1500 Ohm, linear decrease in sensing R-wave amplitude < 2 mV, or increase in pacing threshold up to a level that the treating cardiologist considered inappropriate. Acute lead dislodgement was excluded from the analysis.

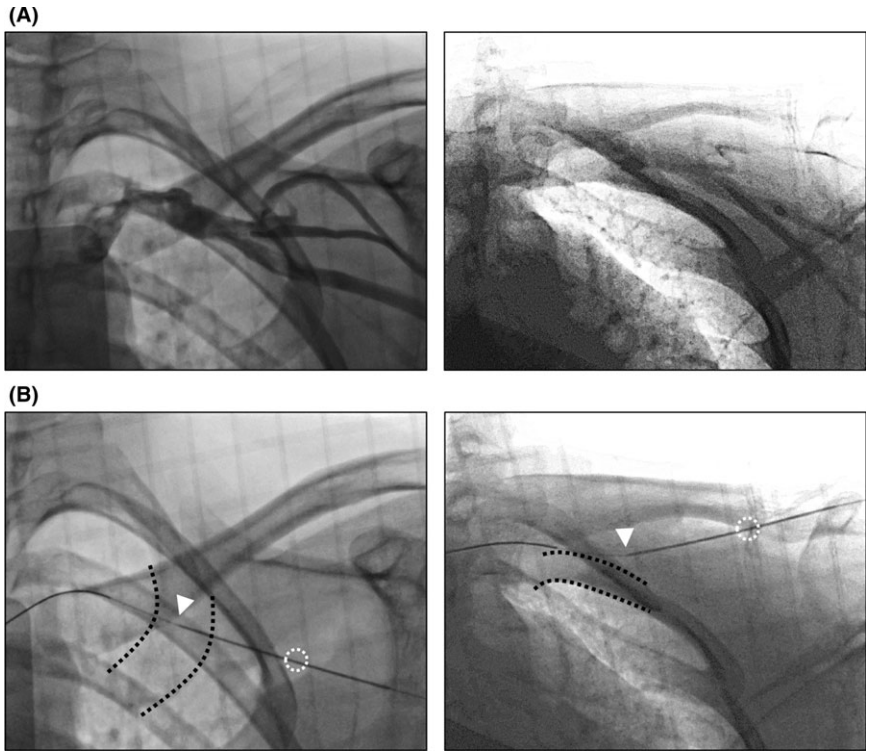

FIGURE 1 A representative case of the extrathoracic subclavian puncture (ESCP). (A) Anteroposterior (AP) (left panel) and caudal 40° views (right panel) of the contrast venography before the skin incision. (B) Radiographs demonstrating ESCP in the AP (left panel) and caudal 40° views (right panel). The circle and the arrowhead indicate the points where the needle entering the pectoral muscle and the subclavian vein as it crosses the first rib (highlighted by the dotted lines), respectively. Of note, the guide wire is advanced into the brachiocephalic vein through the needle tip with a *gentle* angle against the surface of the first rib

2.5 | Statistical analysis

Continuous variables are expressed as mean ± SD or medians with interquartile ranges (IQR) and compared using Student's t test or Mann-Whitney *U* test. Categorical variables are presented as numbers and percentages (%) and compared using chi-squared test. Freedom from lead failure was estimated by Kaplan-Meier method and compared by log-rank test between groups. Univariate Cox regression analysis was performed to identify risk factors for ICD lead failure. Multivariable analyses were not performed because of the limited number of patients and events. All tests were 2-sided, and a $P < 0.05$ was considered statistically significant. All statistical analyses were performed with JMP version 20.0.

3 | RESULTS

3.1 | Patient characteristics

Cephalic vein cutdown (CD) was used in 37 (11%) and the contrast venography-guided extrathoracic subclavian puncture (ESCP) in 287 patients (89%). Lead placement by either CD or ESCP was successfully performed in all of the study patients. None in both CD and ESCP groups received the subclavian puncture as a venous access.

Left ventricular ejection fraction (LVEF) was lower (49 ± 16% vs 43 ± 16%, $P = 0.032$), and primary prevention was more often the indication for ICD therapy (11% vs 28%, $P = 0.028$) in the patients treated by ESCP (ESCP group) compared to those by CD (CD group). Detail of the patient characteristics according to the lead insertion techniques is shown in Table 1.

3.2 | ICD device and lead characteristics

Biventricular ICD was more often used in ESCP group (single chamber, dual chamber, and biventricular ICD were 41%, 57%, and 3% in CD vs 33%, 43%, and 24% in ESCP group, $P = 0.002$; Table 1). Dual coil leads were more often used in ESCP group (73% vs 97%, $P < 0.001$). Medtronic 6949 Fidelis lead or SJM 1580 Riata lead was used in 34 (10%) and 10 (3%) patients in ESCA group, respectively. Detailed ICD lead characteristics in both groups are shown in Table 2.

3.3 | Complications associated with the lead insertion

Pneumothorax occurred in two patients (0.7%) in ESCP group while none in CD group ($P = 0.259$).

3.4 | Follow-up

Patients in CD group were followed for the longer period, as compared with ESCP group (median 8 [IQR 5.7-13.6] vs 5.9 years [IQR 2.8-8.0], $P < 0.001$).

3.5 | Lead survival

During the median follow-up period of 6.2 years (IQR 3.2-8.3), 7 ICD leads (two leads in CD and five leads in ESCP group) failed. Median time to the failure was 4.8 years (range 1.5-8.4). The Kaplan-Meier curve of the ICD lead survival according to the venous access is

TABLE 1 Patient and ICD lead characteristics

	CD (n = 37)	ESCP (n = 287)	*P*
Age	57 ± 14	58 ± 15	0.725
Female sex, n (%)	9 (24%)	58 (20%)	0.561
Structural heart disease			
Ischemic, n (%)	11 (30%)	83 (29%)	0.420
No ischemic, n (%)	22 (59%)	148 (52%)	
None, n (%)	4 (11%)	56 (20%)	
LVEF (%)	49 ± 16	43 ± 16	0.032
ICD indication			
Primary, n (%)	4 (11%)	79 (28%)	0.028
Secondary, n (%)	33 (89%)	208 (72%)	
ICD type			
Single chamber, n (%)	15 (41%)	94 (33%)	0.002
Dual chamber, n (%)	21 (57%)	123 (43%)	
Biventricular, n (%)	1 (3%)	70 (24%)	
Lead design			
Active lead fixation, n (%)	37 (100%)	287 (100%)	
Dual coil, n (%)	27 (73%)	277 (97%)	< 0.001
Medtronic 6949 (Fidelis), n (%)	0	34 (10%)	0.027
SJM Riata, n (%)	0	10 (3%)	0.249

CD, indicates cutdown; ESCP, extrathoracic subclavian puncture; LVEF, left ventricular ejection fraction; ICD, implantable cardioverter-defibrillator.

shown in Figure 2. Lead survival at 5 years was 93.8% (95% confidence interval [CI]: 77.3-98.4%) in CD vs 99.1% (95% CI: 96.6-99.8%) in ESCP group (*P* = 0.903).

Figure 3 shows the Kaplan-Meier curve of the ICD lead survival within the ESCP group according to the use of the recalled leads (i.e, Medtronic Fidelis and SJM Riata leads). Lead survival in the recalled leads was 94.7% and 80.7% (90.4% and 75.9% in 6949 Fidelis leads) at 5 and 10 years since implantation.

3.6 | Clinical presentation and failed lead characteristics

Clinical and lead characteristics in seven patients with failed ICD lead are shown in Table 3. All but one patient had structural heart disease and mean LVEF was 47 ± 25%.

Of note, all patients with ICD lead failure in ESCP group were treated with either SJM Riata or Medtronic Fidelis lead. In one patient with Fidelis lead failure (case 6), transvenous lead extraction was performed and a conductor fracture at the distal portion was confirmed. In all but one patient, oversensing of noise was documented. Inappropriate shocks were delivered to four patients. In one patient (case 3), unacceptable R-wave reduction and elevation of pacing threshold were detected 2.5 years after implantation.

3.7 | Risk factor for ICD lead failure

Table 4 shows the risk factors for ICD lead failure by univariate Cox regression analysis. Lead insertion by ESCP was not related to the lead failure (HR 0.46, CI 95% 0.10-3.22; *P* = 0.383). The use of the recalled lead was a strong risk factor for the ICD lead failure (HR 13.8, CI 95% 2.92-96.5, *P* = 0.001). In contrast to a prior study,[19] higher age was a modest risk of the failure (HR 1.07, CI 95% 1.01-1.14, *P* = 0.046).

4 | DISCUSSION

4.1 | Main findings

In the present study, we demonstrate a satisfactory long-term survival of ICD leads inserted by the contrast venography-guided extrathoracic subclavian puncture (ESCP). Five-year lead survival of 99.1% by ESCP was excellently comparable to that by cephalic vein cutdown (CD) of 93.8% (*P* = 0.903), considered as the safest venous approach.[8] Of note, during the median follow-up of 5.9 years, none in ESCP group implanted with leads other than the recalled ones had the defibrillator lead failure. These results may ensure ESCP as a reliable venous approach for the defibrillator lead insertion.

4.2 | Extrathoracic puncture as a first-line approach for lead insertion

Extrathoracic approach was introduced[15] to avoid the complication related to the subclavian puncture.[11,20] While several techniques based on anatomical landmarks,[12,13] guided by contrast venography[14,15] or real-time ultrasound,[16] have been reported with the satisfactory procedure success and short-term lead survival, the long-term efficacy of this approach remains controversial. Aizawa et al reported the increased risk of the lead failure in ESCP compared with CD.[7] In contrast, Chan et al reported that the risk of lead failure in the axially puncture was comparable with CD and significantly lower than subclavian puncture during the follow-up > 5 years.[10] Of note, in those reports, the choice of the venous accesses was at the discretion of the operator[10] or ESCP was only performed if CD was failed as a fist choice.[7] In addition, these reports did not only include the patients with an ICD but also those with a pacemaker. To the best of our knowledge, the present study, for the first time, demonstrated the long-term ICD lead survival inserted by ESCP in the consecutive patients.

In our patients, five-year lead survival treated by ESCP was 99.1%, comparable with that by CD of 93.8%. Chan et al reported, in consistent with our results, the *pacemaker* lead survival was 98.8% s and 97.7% with the axially puncture and CD during the follow-up of 73.6 months (*P* = 0.389). Prior studies reported that the ICD lead survival was 97.5% to 85% at 5 years,[21-24] although most of the studies did not provide the detail in the venous access. Although simple comparison might be difficult due to various conditions among different studies, the long-term ICD lead survival by

TABLE 2 Detailed ICD lead characteristics

Cutdown								
Maker	**Model**	**Model number**	**Fixation**	**Coil**	**Structure**	**Outer insulation**	**Inner insulation**	**Number**
Guidant	Endotak DSP	G 0125	active	dual	Multilumen	Silicone	Silicone	4
	Endotak Endurance	G 0154	active	dual	Multilumen	Silicone	Silicone	1
Medtronic	Sprint	M 6943	active	dual	Multilumen	Silicone	Silicone	10
	Sprint Quattro	M 6944	active	dual	Multilumen	Polyurethane	Silicone	8
	Sprint	M 6945	active	dual	Multilumen	Silicone	Silicone	14
							Total	37
Extrathoracic puncture								
Maker	**Model**	**Model number**	**Fixation**	**Coil**	**Structure**	**Outer insulation**	**Inner insulation**	**Number**
Guidant	Endotak Endurance	G 0154/55	active	dual	Multilumen	Silicone	Silicone	57
	Endotak Reliance	G 0180	active	single	Multilumen	Silicone	Silicone	3
	Endotak Reliance	G 0184/85	active	dual	Multilumen	Silicone	Silicone	34
	Endotak Reliance SG	G 0292	active	single	Multilumen	Silicone	Silicone	1
	Endotak Reliance SG	G 0295	active	dual	Multilumen	Silicone	Silicone	22
Medtronic	Sprint	M 6945	active	dual	Multilumen	Silicone	Silicone	29
	Sprint Quattro Secure	M 6947	active	dual	Multilumen	Silicone	Silicone	51
	Sprint Fidelis	M 6949	active	dual	Multilumen	Silicone	Silicone	34
SJM	Riata	S 1580	active	dual	Multilumen	Silicone	Silicone	9
	Riata ST	S 7030	active	dual	Multilumen	Optim	Silicone	1
	Durata	S 7120/21/30/31	active	dual	Multilumen	Optim	Silicone	40
	Durata	S 7122	active	single	Multilumen	Optim	Silicone	6
							Total	287

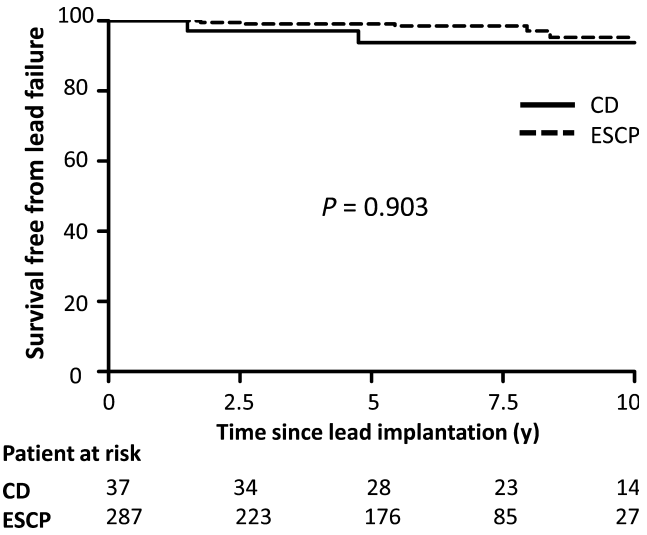

FIGURE 2 Kaplan-Meier survival curves of transvenous defibrillator leads inserted by cephalic cutdown (CD) and the extrathoracic subclavian puncture (ESCP)

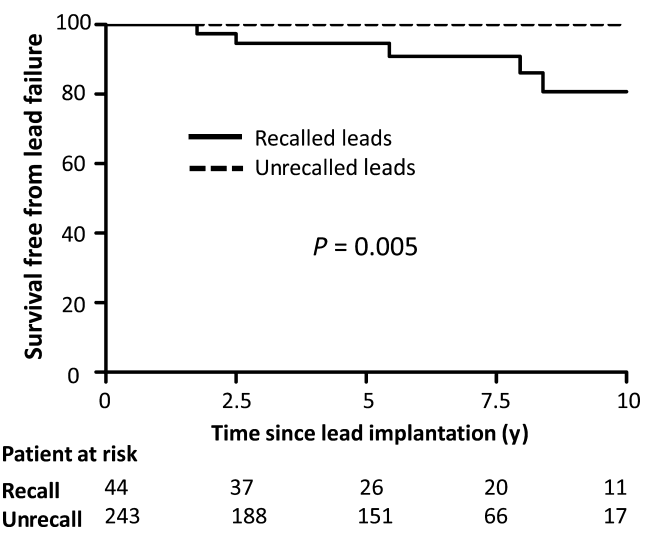

FIGURE 3 Kaplan-Meier survival curves of the recalled and unrecalled defibrillator leads in the patients for whom the extrathoracic subclavian puncture was used

ESCP in the present study seems satisfactory and has never been inferior to that in prior reports using any venous approach. In addition, our results and the literature guaranteed high success rate of the procedural achievement of ESCP.[10,14] We expect that our results accumulate an evidence of the efficacy of ESCP as a first-line venous access for ICD lead implantation.

4.3 | Lead failure in the recalled ICD leads

In consistent with the previous reports,[19,25] the use of the recalled lead was a risk of the lead failure in our population (Table 4). Lead survival in these fragile leads was 94.7% and 80.7% (90.4% and

TABLE 3 Patient and lead data in the patients with ICD lead failure

Case No.	Age at implant	Sex	Diagnosis	LVEF (%)	Indication	Venous access	Lead type	Years since implant	Clinical presentation	Inappropriate shock	Cause of failure
1	66	M	HCM	70	Secondary	CD	Medtronic 6943	4.8	oversensing	yes	Unknown
2	70	F	Myo	52	Secondary	CD	Medtronic 6945	1.5	oversensing	yes	Unknown
3	54	M	CSA	68	Secondary	ESCP	SJM 1580, Riata	2.5	Pacing & sensing disorder	no	Conductor fracture?
4	57	F	DCM	16	Primary	ESCP	Medtronic Fidelis	8.0	oversensing, high impedance	no	Conductor fracture
5	71	M	OMI	42	Secondary	ESCP	Medtronic Fidelis	8.4	oversensing, high impedance	no	Conductor fracture
6	74	F	OMI	67	Secondary	ESCP	Medtronic Fidelis	1.8	oversensing	yes	Conductor fracture[a]
7	71	M	DCM	11	Primary	ESCP	Medtronic Fidelis	5.5	oversensing, high impedance	yes	Conductor fracture

HCM indicates hypertrophic cardiomyopathy; Myo, myocarditis; CSA, coronary spastic angina; CD, cutdown; ESCP, extrathoracic subclavian puncture; LVEF, left ventricular ejection fraction; DCM, dilated cardiomyopathy; OMI, old myocardial infarction.
[a]Analysis of the extracted lead confirmed a conductor fracture at the distal portion.

TABLE 4 Univariate analysis of predictors of ICD lead failures

Variable	HR	CI 95%	*P*
Age↑, per 1 year	1.07	1.01-1.14	0.046
Sex (Female)	2.48	0.49-11.29	0.254
Structural heart disease	1.98	0.34-37.59	0.494
Primary prevention	1.15	0.16-5.35	0.868
LVEF	1.00	0.96-1.05	0.957
ESCP	0.46	0.10-3.22	0.383
Dual Coil	0.42	0.07-7.92	0.468
Fidelis or Riata lead	13.80	2.92-96.5	0.001

HR indicates hazard ratio; CI, confidence interval; LVEF, left ventricular ejection fraction; ESCP, extrathoracic subclavian puncture.

75.9% in 6949 Fidelis leads) at 5 and 10 years since implantation, presenting the time-depending increase of the lead failure.[9] In a patient in whom a Fidelis lead was extracted after failure, the conductor fracture at the distal portion was confirmed. In other four patients with the failure in their recalled leads, at least, conductor fracture at the proximal portion was not observed by the X-ray examination.

Recent multicenter study in Canada on the Fidelis lead failure[9] reported that the lead failure rate in the axially vein access was higher compared with that in cutdown (23.1% vs 11.4% at 5 years). Interestingly, the failure rate in axially access was higher compared with subclavian puncture consistently from the early period since implantation (3.2% vs 1.9% and 23.1% vs 17.6% at 2 and 5 years; statistical significance was not shown), which conflicts with the previous studies reporting the lower failure rate of pacemaker leads in ESCP compared with the subclavian puncture.[10,26] Of importance, this lead has been reported extremely at risk, and the failure rate in this Canadian cohort[9] was higher compared with that reported by Medtronic based on the remote monitoring (16.4% vs 11.7% at 5 years since implantation). Further analyses are needed to identify whether the use of CD instead of the ESCP contributes to the decrease of the failure in this fragile lead.

4.4 | Predictor of lead failure

Older age, contrary to the prior studies,[27] was a modest risk of lead failure by univariate analysis in the present study. In addition, neither higher LVEF nor the absence of the structural heart disease indicating the higher physical activity was associated with the risk of the lead failure. While the difference in the patient or lead characteristics was a potential reason for the discrepancy with the prior studies, it may also be explained that the extrathoracic approach attenuated the mechanical stress of the defibrillator lead at the proximal portion and contributed to decrease the lead failure in those with higher physical activity.

4.5 | Limitations

We admit several limitations in our retrospective observational study conducted in a single center. Firstly, the number of the patients treated with CD was smaller and those patients were followed longer compared with the patients with ECSP approach. Secondly, patient characteristics were different between the two groups mainly because ESCP group included more patients underwent ICD therapy as a primary prevention. Thirdly, the ICD lead model was different between the two groups, which may have influenced the lead survival. Finally, the influence of the venous access on the recalled leads was not evaluated as all these recalled leads were inserted by ESCP.

5 | CONCLUSIONS

The present study demonstrated an excellent long-term survival of the transvenous ICD leads inserted by the contrast venography-

guided extrathoracic subclavian puncture in the consecutive patients, which was comparable with the cephalic vein cutdown. Further studies enrolling larger number of the patients are required to determine whether the extrathoracic puncture is eligible as a first-line venous access for ICD lead implantation.

CONFLICT OF INTEREST

Authors declare no conflict of interests for this article.

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