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*Original Article*

# Snare sheath versus evolution sheath in transvenous lead extraction

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**Abstract:** Lead extraction remains a challenging procedure with significant success. Owing to the increasing use of cardiac implantable electronic devices, there is a growing need for effective techniques management, to avoid the occurrence of device-related complications and lead dysfunction. We made a comparison of Evolution sheath and Needles Eye Snare sheath (abbreviated to Snare sheath) by analyzed the results using two kind of the methods in the Cardiology Center of Peking University People's Hospital. In the retrospective study we evaluated patients who underwent lead extraction from July 2013 to July 2014. Those who underwent lead removal without using evolution or snare were excluded. Primary endpoints included total exposure time, operation time, and complications. Data on clinical characteristics, indications, and outcomes were prospectively collected and analyzed. A total of 76 patients were included in the study (65.8% male; aged 68.1±14.34 years old). Snare and Evolution were used in 59 and 17 patients, respectively. A total of 134 leads were removed with 103 leads (76.87%) extracted using the Snare sheath. Lead age was 10.8±7.0 years. Complete extraction was observed in 67 patients of 124 leads. Evolution sheath was associated with significantly lower complication even after adjustment of the number of leads, type of leads, and lead age, compared to the Snare group ($P<0.05$). In the Snare sheath group, mortality rate was 1.69% and minor complication rate was 3.39%. When compared to the Snare sheath, lead extraction with the Evolution sheath has less X-ray exposure time and less operation time ($P<0.05$), while with a higher success rate ($P<0.05$). Besides, the Evolution group has fewer major and minor complications.

**Keywords:** Lead extraction, pacemaker, snare, evolution

## Introduction

Since the first pacemaker was implanted in human body over 50 years ago, the indications for these devices for cardiac pacing and defibrillation have expanded significantly. However, the widespread application of the pacemaker has also led to an increasing number of device-related complications and consequently a growing need for lead removal. Since the late 1980s, transvenous techniques for the safe extraction of leads have evolved, from simple traction to the use of laser sheaths, with reported success rates exceeding 95% [1].

With small procedure failure, low morbidity and mortality, transvenous lead extraction is still the primary method of lead extraction nowadays. Furthermore, peration tools have been reported as a significant predictor of procedural outcome [2].

The aim of this study was to report our experience of using the two different extractions techniques in the removal of pacemaker and implantable cardioverter-defibrillator, by analysing the complications, X-ray exposure times, operation times, and success rates. In addition, we also compared the relative merits of the snare sheath and the evolution sheath in lead extraction [3-5].

## Methods

### *Population*

As the primary referral center for lead extraction in China, the Peking University People's Hospital is a 1400-bed teaching hospital. We perform an audit aiming to include all patients undergoing transvenous lead extraction by a single operator (J.G.) from inception of the lead extraction programme in our institution. Upon the approval of local ethics committee, records of all patients were examined and relevant data were entered into a dedicated database for evaluation [6-10].

**Table 1.** Patients' characteristics

| Patients | Snare group (n=59) | Evolution group (n=17) | *P* value |
|---|---|---|---|
| Demographics | | | |
| Age, year | 70.2±9.1 | 67.0±13.0 | 0.335 |
| Male/female | 40/19 | 10/7 | 0.566 |
| Ejection fraction, (%) | 62.7±6.8 | 65.1±9.6 | 0.344 |
| Time from implantation | 11.2±8.4 | 10.8±7.0 | 0.837 |
| Device | | | |
| Pacemaker | 53 (90) | 15 (15) | 0.032 |
| ICD | 2 (4) | 1 (2) | 0.51 |
| CRT | 3 (7) | 0 | 0.43 |
| CRTD | 1 (2) | 1 (4) | 0.65 |
| Main procedural indication | | | |
| Endocarditis | 7 (7) | 1 (2) | 0.023 |
| Pocket infection | 50 (94) | 16 (29) | 0.019 |
| Dysfunction or upgrade | 2 (2) | 0 (0) | 0.76 |

Note: Values are expressed as mean ± SD or numbers (%) of observations in corresponding group.

**Table 2.** Intraoperative data

| | Snare group | Evolution group | *P* value |
|---|---|---|---|
| Procedure time, (min) | 81±49 | 50±21 | 0.034 |
| Fluoroscopy time, (min) | 20±16 | 8±7 | 0.029 |

*Extraction technique*

Snare sheath extraction is defined as removal of the lead via femoral approach by using the Snare sheath (Cook Medical). The extirpation of lead via subclavian approach using evolution sheath is known as evolution sheath extraction (Cook Medical). No laser-assisted extractions were performed. Leads extraction via thoracotomy or sternotomy with cardiopulmonary bypass or not was referred to as open-chest lead extraction [11].

All lead extractions were performed in the electrophysiology laboratory, which is a hybrid theatre with the ability to accomplish the open-chest extraction. The cardiothoracic teams were informed of all extractions in advance and were on standby in the event of any major complications. The procedures were performed under sedation and continuous monitoring of arterial blood pressure and oxygen saturation. Temporary right ventricular pacing would established through the left femoral vein if the patient is pacemaker-dependent [12].

All patients using direct manual traction and locking stylet only were not successful. Using an aseptic technique, the pulse generator pocket was opened and leads were freed by surgical dissection down to the venous insertion site as far as possible. ~10 cm of the leads were left from the venous entry site if leads had not been previously severed. When using the evolution sheath, a locking stylet was inserted into the lead previously.

The success of extraction (i.e. complete extraction) was determined by means of radiographic criteria namely, the complete removal of all lead components. Partial success was defined as the removal of virtually all leads, or just few residues were left-usually a small portion of the lead such as the electrode, 4 cm or less of conductor coil and/or insulation, or the combination of the latter two [13-16]. Failure procedure refers to the abandonment of a significant length of lead (>4 cm) after attempting to remove it. Events were defined as major and minor complications or observations, according to previously published guidelines. Major complications were life-threatening or required a major treatment intervention, such as venous or myocardial perforation, pericardial tamponade, major tricuspid regurgitation, symptomatic pulmonary embolism, and lead migration. Minor complications included pericardial or thoracic effusion without further intervention, pocket hematoma, silent pulmonary embolism, and trivial tricuspid regurgitation. Lead extraction time refers to the duration from the initiation of gentle manual traction to the completion of lead removal.

*Statistical methods*

Data were presented as mean ± standard deviations. All date were analyzed with student t-test by Prism Graphpad version 6. All tests of significance were two sided, and the *P*-value of <0.05 was considered statistically significant.

## Results

From July 2013 to July 2014, 253 consecutive patients underwent procedures of the transvenous removal in our institution, extracting 557

**Table 3.** Results and complications

| Group | Snare group | Evolution group | *P* value |
|---|---|---|---|
| Extraction | | | |
| Complete | 51 (94) | 16 (30) | 0.024 |
| Partial | 6 (6) | 0 (0) | 0.036 |
| Failure | 2 (3) | 1 (1) | 0.32 |
| Number of treated patients | 59 | 17 | |
| Complications, n | | | |
| Death | 1 | 0 | 0.89 |
| Atrial perforation | 0 | 1 | 0.76 |
| Hematoma | 1 | 0 | 0.43 |
| Trivial tricuspid regurgitation | 1 | 0 | 0.58 |
| Total | 3 | 1 | 0.024 |

cardiac leads. Among them, 76 patients required removal of 134 leads by using the Snare sheath or the Evolution sheath and these latter constituted the study cohort [17].

*Patients and lead characteristics*

Patient characteristics are summarized in **Table 1**. There were no significant differences for the mean age, sex distribution, leads implantation duration, and indications for extraction in both groups (P>0.05).

However, the results also indicated that the pacemaker was significantly seldom used in the Evolution compared to the Snare group (**Table 1**, P<0.05). For the main procedural indications, the endocarditis and pocket infection were both significantly seldom occurred in Evolution group compared to the Snare group (**Table 1**, P<0.05).

*Evolution group illustrates better intraoperative data*

In order to evaluate the the intraoperative data of the Snare group and Evolution group, the intraoperative data, including procedure time and fluoroscopy time. The results indicated that the procedure time in the Evolution group was significantly shorter compared to the Snare group (**Table 2**, P<0.05). Furthermore, the fluoroscopy time in the Evolution group was also significantly shorter compared to the Snare group (**Table 2**, P<0.05).

*Complications and outcomes*

The complications, extractions and outcomes were given in **Table 3**. One patient died from pulmonary embolism in the Snare group. The procedural outcomes were similar in both groups and 30-day survival was 100% in the Evolution group.

Specifically, complete extractions were achieved in 51 patients (86%) in the Snare group compared to 16 patients (94%) in the Evolution group (**Table 3**, P<0.05) [18]. Partial extractions were achieved in 6 patients (10%) in Snare group compared to 0 patient (0%) in Evolution group (**Table 3**, P<0.05), whereas the procedure was unsuccessful in 2 patients (3.38%) in Snare group compared to 1 patient (5.88%) in Evolution group. The unsuccessful extraction by Evolution sheaths was then completed by the femoral approach, although the unsuccessful extraction by femoral approach with Snare sheaths was not adequately completed by any other technique. Therefore, the ultimate complete extraction rates after rescue by other technique, were 100% to 86%, as the procedure began with the superior approach versus that initiated from the femoral approach. Furthermore, the ultimate partial extraction rates were 10% versus 0%, and the ultimate failure rates were 3.38% versus 0%, respectively (P<0.05, FET) [19].

Major complications were observed in 1 patient in the Snare group, and the patient was died from pulmonary embolism. 1 patient was observed with right atrial perforation in the Evolution group, requiring sternotomy. The reason for the perforation may probably be the strong adhesion of the atrial, leading to the attenuation of right atrial appendage and the atrial. After aspirated pericardial effusion, the atrial perforation was closed without opening chest surgery and other complications. One patient in the Snare group had a minor complication of pocket hematoma, requiring essential surgical operation, and one patient in the same group also suffered from trivial tricuspid regurgitation. Totally, the complications occurred significantly frequent in the Snare group compared to the Evolution group (**Table 3**, P<0.05). These differences in rates of major and minor complications were statistically significant.

*Duration of procedure and fluoroscopic exposure*

The procedural duration (50±21 versus 81±49) and total fluoroscopic exposure duration (8±7

versus 20±16 minutes) were significantly shortened (each P<0.01, Student t test) in Evolution group than in Snare group [20-25].

## Discussion

The major findings of our study are as follows: This study verified the clinical effect of Snare sheath and Evolution sheath in the transvenous lead extraction. CIED infected patients using Evolution sheath were associated with less X-ray exposure time. Likewise, the use of Evolution sheath among patients with CIED infection was associated with less operation time.

*Snare sheath versus evolution sheath*

This present study firstly compared the snare sheath technique with the evolution sheath technique in China. The evolution sheath has the advantages of shorter procedures and lower risk of major complications. In the meantime, the snare sheath via the femoral approach, was used for patients presenting with ruptured or floating leads [22, 26, 27].

This study was restricted own to the non-ruptured leads from patients, which were accessible from the proximal site and therefore amenable to both techniques. We observed significant between-group differences in mortality, major complications, and procedural success rates. Accordingly, for this kind of patients, operators can choose between these two techniques using their own experience.

In our own lead extraction experience with the Snare sheath, we had a rate of complete lead removal of 86% in 103 treated leads, while 94% in 31 Evolution treated leads. Complete and partial failure of Snare sheath extraction occurred by 3.39% and 10.17% respectively, with the proportion of 5.88% and 0 in Evolution sheath extraction. In previous published studies, success rates for complete lead removal using Snare sheaths have been described as about 88%. In these studies, failure of Snare sheath lead extraction was 12% [28]. Although it is difficult to compare those results with ours, due to the limited number of patients in our cohort, the results of Snare and Evolution sheath lead extraction yet indicate a promising perspective for procedural success.

Procedural duration and fluoroscopic exposure may seem less important than mortality, procedural success or complication rates. We found a significant difference in these two measurements in favor of Evolution extraction [29]. The fluoroscopic time observed during the Evolution procedure is concordant with previously published exposures. During a procedure from the femoral approach, ensnaring of the lead is time consuming and considerably increases the amount of radiation exposure.

Protection of the medical staff from radiation exposure is important. Therefore, the lesser radiation exposure associated with Evolution procedure is non-negligible advantage. This study represents an advantage in favor of Evolution procedure, in view of the identical success/complications ratio of the two approaches [30].

*Study limitations*

This study is a single-centre study carried out by experienced operators and therefore our results may not be widely applicable in less experienced centres. Lead extraction is with certain risk, which should only be performed in centres with skillful staff and essential equipment, also the access to onsite emergency surgery. This study is retrospective and therefore the results must be viewed with caution. Furthermore, this study has been a single-centre analysis including a relatively small number of patients. Therefore, in the future, larger prospective randomized trials are required to investigate the safety and efficacy of Evolution sheaths and Snare sheaths.

## Conclusion

When compared with Snare sheath, lead extraction with the Evolution sheath has less X-ray exposure time and operation time, howbeit with a higher success rate and fewer major and minor complications.

## Disclosure of conflict of interest

None.

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