Comparison of Acute and Long-term Outcomes of Evolution® and TightRail Mechanical Dilator Sheaths during Transvenous Lead Extraction

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Abstract

Background: Powered transvenous lead extraction (TLE) tools are commonly required to remove the leads that have long implant duration due to fibrotic adhesions. However, comparative data are lacking among different types of TLE tools. Aim: To compare the efficacy and safety of two different rotational mechanical dilator sheaths in retrospectively analyzed patients who underwent TLE. Methods and results: A total of 566 lead extractions from 302 patients using TightRailTM (333 lead extractions from 169 patients) and Evolution® (233 lead extractions from 133 patients) mechanical dilator sheaths were performed between July 2009 and June 2018. Acute and long term outcomes of study groups were compared. There is no statistically significant difference between Evolution® and TightRailTM groups in procedural success (93.9% vs. 94%), clinical success (99.2% vs. 98%) and major complications (3.8% vs. 1.2%), respectively ($p>0.05$). In multivariate regression analysis, lead dwell time, the number of extracted leads, and baseline leukocyte count was found as independent predictors of procedural success ($p<0.05$). During the median follow-up of 36.6 (0.2-118) months, all-cause mortality was observed in 73 patients (25.6% in the Evolution® vs. 23.1 in the TightRailTM group, $p>0.05$). Chronic renal disease, heart failure, and coagulopathy were shown as independent predictors of all-cause mortality in multivariate regression analysis ($p<0.05$). Conclusions: TLE using TightRailTM or Evoluation® mechanical dilator sheaths is a safe and effective therapeutic option. Both mechanical dilator sheaths showed similar efficacy, safety, and all-cause mortality at acute and long-term follow-up of patients who underwent TLE.

Condensed Abstract

In this observational cohort study, we compared the efficacy/safety and long-term mortality rates of the patients who underwent TLE procedure using the Evolution® vs. TightRail™mechanical dilator sheaths. Both groups showed similar procedural success and complication rates, in addition to all-cause mortality rates.

What is new?

- The Evolution® and TightRail™Mechanical Dilator Sheaths are two different tools with variable technical properties for the TLE procedure.
- To the best of our knowledge, this is the first large-scale observational report in the literature comparing the efficacy and safety of these two mechanical TLE system in chronically implanted PM/ICD leads in addition to long-term mortality outcomes.

- Both mechanical TLE systems showed similar procedural/clinical success and complication rates and all-cause mortality at long-term follow-up.

INTRODUCTION

In parallel to the increased use of cardiac implantable electronic devices (CIED), the electrophysiology society is faced with device-related problems like device upgrade, device-related infection, electrode dysfunction, and dislodgement, which should be managed with valid and reliable methods [1]. Despite significant improvement over the last decade in transvenous lead extraction (TLE) technology and low TLE related mortality at high-volume centers, the postprocedural and long-term mortality remain high in specific patient subgroups, including those undergoing TLE for infectious indications and device system upgrade [2].

After implantation, transvenous leads are often encapsulated with fibrotic capsules which adhere to vascular and intra-cardiac tissue by different humoral and cellular mechanisms [1]. Among various tools and methods, powered extraction devices are required to remove the chronically implanted leads [3]. Rotational mechanical dilator sheaths are acting by dissection of the fibrotic tissue in which the electrodes connected using the threaded end portion of the system [4]. Currently, two different mechanical dilator sheaths with variable technical properties are available in the market [Evolution$^{(r)}$ (Cook Medical, Bloomington, IN, USA) and TightRail^{TM} (Spectranetics Corp., Colorado Springs, Colorado, USA) mechanical dilator sheaths]. Both the TLE system revealed high efficacy rates and acceptable safety results[3,5]. However, the comparative data are scarce among different types of powered extraction tools. Previous studies have presented the data of single TLE device in general[5,6]. There is only one small study regarding the comparison of different rotational mechanical dilators[7].

Thus, we aimed to compare the safety and efficacy outcomes and all-cause mortality at long-term follow-up in a large-scale study population who underwent TLE using two different rotational mechanical dilators sheaths.

METHODS

Study population

Our clinic is a high volume tertiary referral center for TLE procedure (>130/year) in our country. The study was designed as a single-center observational cohort study. The study included a total of 302 patients who underwent TLE procedure in our Electrophysiology Laboratory by using a hand-powered rotating mechanical dilator sheath marketed as the Evolution$^{(r)}$ (Cook Medical) and the TightRail^{TM} (Spectranetics Corp.) in between July 2009 and June 2018. Patients in whom the TLE has been performed by manual traction or with a locking stylet were excluded from the study. The indications for TLE were based on the recent European Heart Rhythm Association (EHRA) and Heart Rhythm Society (HRS) recommendations[1].

The study population was categorized into two as; the Evolution$^{(r)}$ group and the TightRail^{TM}group. First-generation Evolution$^{(r)}$ mechanical dilator sheath was used between July 2009 and September 2014, and TightRail^{TM} mechanical dilator sheath was used between September 2014 and June 2018 because of the availability and reimbursement policy of National Social Security System. There is no patient cross-over between the two groups. Laser-assisted sheaths or the second-generation Evolution$^{R/L}$ mechanical dilator sheath were unavailable and not reimbursed during the study period in our country. The study data were collected by using electronic medical records, files, and National Death Reporting System. The study complied with the principles outlined in the Declaration of Helsinki and approved by our local institutional ethics committee.

Lead extraction technique

The variable technical properties of both mechanical dilator sheaths were defined in Supplementary File 1. The TLE procedure was performed in the Electrophysiology Laboratory under deep sedation and local anesthesia with invasive blood pressure monitoring via femoral or radial route, non-invasive oxygen saturation monitoring, and a cardiothoracic surgery team standby. A thorough evaluation of pacemaker (PM/ICD) was

performed before the intervention, including assessing the degree of pacemaker dependency and temporary transvenous pacing was established if necessary. After the skin preparation, the generator pocket was opened, and the device generator was disconnected from the leads. The leads were separated from the scar tissue by blunt dissection. Simple manual traction via standard stylet was initially attempted. If manual traction was not successful, a systematic approach using locking stylet (Liberator Universal Locking Stylet in Evolution$^{(r)}$group, Cook Medical) (Lead Locking Device EZ in the TightRail^{TM} group, Spectranetics Corp.) for TLE. If this systematic approach was unsuccessful, mechanical dilator sheaths were used for both atrial, right ventricular, and coronary sinus leads.

The mechanical dilator sheath was then positioned over the targeted lead. The operator pulls the handle of the dilator sheath, which causes rotation of the cutting tip. The dilator sheath moves along the lead body by cutting fibrous adhesions via the distal metal tip or blade. In the Evolution$^{(r)}$ mechanical dilator sheath system, the outer polymer sheath covers the distal tip while advancing over the lead in the tracts free from adherences to protect the venous wall from damage and when fibrous attachments are met, the cutting tip uncovered from the outer sheath. In the TightRail^{TM} mechanical dilator sheath system, the shielded blade cuts the fibrous attachments by rotating 270**deg** clockwise and 270**deg** counterclockwise with each full trigger activation while extending the blade just 0.5 mm. Once the fibrous attachments are cut, the outer sheath is advanced until another area of attachment is encountered. After the release of leads from fibrous tissue, the leads were pulled back into the sheath and removed. In case of failure with an antegrade approach and presence of free-floating lead remnants, a femoral or jugular approach with Multisnare (Multi-Snare, PFM, Koln, Germany) was used to grasp the remaining part and to complete the procedure. For patients requiring replacement of their lead, a new lead system was implanted through the same vein in case of lead malfunction or upgrade to new technology. In the case of device infection, the subclavian vein on the opposite side was used after eradicating infectious microorganisms according to the recommendations of the recent guidelines [1]. In PM-dependent patients, re-implantation was performed in the same session if the extraction was due to non-infectious causes. In PM-dependent patients with cardiac device infection, a temporary PM was implanted through the contralateral jugular vein.

During the first 48 h after the procedure, continuous non-invasive blood pressure, oxygen saturation, and electrocardiographic monitoring were made, and echocardiographic evaluation just after the intervention and before discharge was performed. At each follow-up visit, a particular device interrogation was added to the patient assessment with clinical evaluation, electrocardiography, chest X-ray, and transthoracic echocardiography when necessary.

Study Outcomes

Procedural/clinical success, failure, and complications

The success of TLE was determined through complete procedural and clinical criteria. Complete procedural success was defined as removing all targeted leads and lead material from the vascular space without permanently disabling complication or procedure-related mortality. Clinical success was defined as removing all targeted leads and lead material from the vascular space or retention of a small portion of the lead ($<$4 cm) that does not negatively impact the outcome goals of the procedure. This might be the tip of the lead or a small part of the lead when the remaining portion does not increase the risk of perforation, embolic events, the perpetuation of infection, or cause any undesired outcome. "Failure" was defined as the inability to achieve either complete procedural or clinical success or the development of any permanently disabling complication or procedural-related death. Complications were defined as major or minor, according to previously published guidelines [1].

Survival outcomes

All-cause mortality was defined as the mortality from all causes of death for our study population during the follow-up period. Mortality data were recorded for each patient from National Death Recording System.

Statistical analysis

Statistical analysis was performed using the NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA). Continuous variables were presented as mean ± standard deviation and median with interquartile ranges as appropriate and categorical variables as frequency and percentage. To test the normality of distribution, the Kolmogorov Smirnov test was used. Differences between the two groups were evaluated using Student's t-test for normally distributed variables and Mann-Whitney U test for variables without normal distribution. The Chi-square or Fisher's exact test was used to compare categorical variables as appropriate. The Wilcoxon Signed Ranks Test was used in the evaluation of hemoglobin measurements before and after the procedure. Survival analysis with a log-rank test was conducted for the combined end-point of death between the two groups, and Kaplan-Meier curves were created. Logistic regression analysis was used to evaluate the independent effects of the baseline variables on procedure failure and mortality. The odds ratios (OR) and 95% confidence intervals (CI) were calculated. A p-value <0.05 was considered significant.

RESULTS

Between July 2009 and June 2018, a total of 566 endovascular leads were extracted from 302 patients [Evolution® group (133 patients with 233 leads) and TightRail™ group (169 patients with 333 leads)]. The baseline demographic, clinical, and laboratory data of the study groups were represented in Table 1. Diabetes mellitus, hypertension, coronary artery disease, and HFrEF were more prevalent in the TightRail™ group ($p<0.05$).

The details of CIEDs and TLE procedures were shown in Table 2. The mean number of extracted leads per patient was 1.8±0.73, and the median lead dwell time was 5.0 (0.6-33) years. All ICD leads were of dual coils, and all coronary sinus electrodes have a passive fixation mechanism. Re-implantation was performed in 216 (71.5%) patients during the index TLE procedure. Leads with active fixation and coronary sinus leads were more common in the TightRail™ group ($p<0.05$). The most common TLE indications were lead malfunction (57.9%) in the TightRail™ group and CIED-related infection (49.1%) in the Evolution®group, respectively ($p<0.05$). Among different sheath sizes, 13F in the TightRail™ group and 9F in the Evolution® group were more frequently used ($p<0.05$).

Complete procedural and clinical success was achieved in 259 (85.8%) and 270 (89.4%) patients using mechanical dilator sheaths alone. There was no statistically significant difference between Evolution® and TightRail™ groups in complete procedural (86.9% vs. 84.2%, $p>0.05$) and clinical success (90.6% vs. 88%, $p>0.05$) (Figure 1). Rescue snaring system was used because of lead fracture in 29 patients (9.6%) (11.2% in Evolution® vs. 8.2% in TightRail™ group, $p=0.286$). Clinical success was achieved in 298 patients (98.6%) using both mechanical dilator sheath and snaring system (99.2% for Evolution® group vs. 98% for TightRail™ group). The rescue snaring system was only failed in one patient in the TightRail™group due to trapping of 3 electrodes in the right femoral vein that was extracted surgically. Three patients failed with mechanical dilator sheaths without using a rescue snaring system (n=2 in the TightRail™ group vs. n=1 in the Evolution® group). Among two patients in the TightRail™ group, the procedure was terminated in one patient due to the loss of consciousness during TLE in whom intracranial hemorrhage and subsequent death were observed, and in another patient, the electrode was left in the right ventricle due to failure with rescue tools. In one patient in the Evolution® group, a major vascular injury that required surgical intervention developed, and the one electrode was extracted completely by surgery. Major and minor complications were observed in 2.3% (n=7) and 9.3% (28) of patients which were similar among study groups ($p>0.05$) (Figure 2 & 3). The efficacy and safety outcome data of the study groups were shown in Table 3.

At median 36.6 (0.2-117.5) months follow-up duration [74.6 (0.6-117.5) months for Evolution® group vs. 25.8 (0.2-63.5) months for TightRail™ group, $p=0.001$], all-cause mortality was observed in 73 patients (25.6% in Evolution®group vs. 23.1 in TightRail™ group, $p=0.616$). When the survival curves of both groups are evaluated with log-rank test, there was a statistically significant difference between Evolution® and TightRail™ groups which were thought to be due to a sicker population with more hypertension, diabetes mellitus, CAD, HFrEF, NYHA class II-IV, and lower LVEF of TightRail™ group compared to Evolution® group ($p<0.001$) (Figure 4).

Baseline demographic, clinical, laboratory and procedural characteristics of patients according to the procedural failure and all-cause mortality were shown in Supplementary File 2 and 3, respectively. In multivariable logistic regression analysis, the presence of HFrEF (OR: 5.73, 95% C.I.: 1.49-22.0, p=0.011), increased baseline aPTT level (OR: 1.09, 95% C.I.: 1.03-1.17, p=0.006) and baseline GFR level <60 ml/min/1.73m^2 (OR: 2.81, 95% C.I.: 1.12-7.08, p=0.028) were associated with a higher risk of all-cause mortality. Furthermore, baseline leukocyte count (OR: 1.20, 95% C.I.: 1.02-1.42, p=0.028), number of extracted leads (OR: 2.91, 95% C.I.: 1.45-5.86, p=0.003) and lead dwell time (OR: 1.08, 95% C.I.: 1.003-1.162, p=0.041) were found as independent predictors of TLE procedural failure.

DISCUSSION

The significant findings of our single-center large-scale cohort study were as follows; (1) the TLE using either Evolution®or TightRail™ hand-powered rotational mechanical dilator sheaths was associated with high efficacy and acceptable complication rates. Both procedural/clinical success and major/minor complication rates were similar between Evolution® or TightRail™ groups. Additionally, there was no difference in all-cause mortality rates at long-term follow-up between each group. The presence of heart failure, baseline coagulopathy, and impaired renal functions was associated with an increased risk of all-cause mortality.

Among various available TLE tools, hand-powered rotating mechanical dilator sheaths are preferred by many operators during the extraction of chronically implanted leads with fibrotic adhesions to the vascular and endocardial surfaces [8,9]. In our study, the TLE has been performed in patients with median lead dwell time of five years by using either first-generation Evolution® or TightRail™ systems at different time intervals because of the availability and governmental reimbursement policy. Evolution® system has been associated with excellent clinical and procedural success with low complication rates in previous studies [9-11]. In our study, complete clinical success and procedural successes were 99.2% and 94.0%, respectively, as in other studies, complete clinical and procedural success rates have been mostly >95% [8,11]. The clinical and procedural success rates were 88.0% and 84.2% without using rescue methods in our study. In previous studies, complete success rate without using rescue methods and tools was in the range of 69%-94.5%, and these studies major and minor complication rate was reported as 0%-4.2% and 0%-12%, respectively [4,6,10]. In our Evolution® group, major and minor complication rates were 3.8% and 10.5%, respectively, with compatible low complication rates as studies in the literature. The data about the TightRail™ system is limited in the literature. In a small observational study, the complete procedural and clinical success rates without rescue methods were 96% and 100%, respectively[5]. In a larger retrospective multi-center study, chronically implanted 147 leads in 100 patients were extracted using TightRail™ mechanical dilator sheath; complete success rate was 91%, and the major complication rate was 2%[12]. In our study, the complete procedural and clinical success rates were 86.9% and 90.5% using the TightRail™ system without rescue methods. Complete clinical success was increased to 98.2% with the use of a rescue snaring system. Major and minor complication rates were 1.2% and 8.2%, respectively, per studies in the literature.

In the literature, the need for rescue tools during TLE with mechanical dilator sheaths was highly variable (range of 2.4-27.1%) due to the used technique, extraction tool, patient, and lead characteristics[7,9,13]. In our study, the need for rescue tools was observed in 11.2% of the Evolution® group and 8.2% of the TightRail™ group (p>0.05). Higher lead dwell time, and the lead burden was associated with an increased need for rescue tools and major complication rates [14]. Involved leads in the lead fracture or infection categories were also more prevalent than other categories of TLE indications in patients with lead breakage, incomplete lead extraction, and need for rescue snaring tools [9]. As in line with previous studies, the lead dwell time, lead burden, leads with passive fixation, and infection parameters were significantly higher in patients with procedural failure who required a rescue snaring tool in our study.

In our study, major complications were observed in 7 patients (2.3%). Additionally, procedure-related death was seen in 2 patients (0.66%), which was due to intracranial hemorrhage (n=1) in the TightRail™ group and haemothorax (n=1) in the Evolution® group. Besides these deaths, major complications included cardiac tamponade in one patient in the TightRail™ group, major vascular lacerations in 3 patients by 0.99% in the Evolution® group, a cerebrovascular accident by 0.33% in Evolution®group. In the ELECTRa registry,

procedure-related death was seen in the range of 0.3-0.8% rates, and our study data is similar to this registry. In the ELECTRa registry, the cerebrovascular accident and vascular laceration were followed by 0.06% and 0.4-0.9%, respectively, and our data was similar to this registry [8]. Patients with cardiac tamponade had both atrial and ventricular PM electrodes with a passive fixation mechanism in which lead dwell time was ten years. We thought that the lead dwell time of ten years was likely the relevant clinical factor for such a critical life-threatening complication. The myocardial avulsion was thought to be during the extraction of the atrial electrode, which was successfully repaired surgically. In previous studies, massive pericardial effusion was reported by 0.25-0.59%, which was 0.33% in our study accordingly. In the ELECTRa registry analysis, 84.5% of major complications were cardiovascular avulsion [15]. In our study, 71% of major complications were cardiovascular complications, and cardiac avulsion was observed in two patients by 28.5%. In the ELECTRa registry, the minor complication rate was reported as 5% (range 4.3-5.7%), which was 9.2% in our study. The majority of minor complications in our study was pocket hematoma by 60%, but the drainage was only required in 2 (0.6%) of the patients In previous studies, the rate of hematoma requiring drainage was in the range of 0.9-1.6%[16,17]. In our study, the minor complication rate was higher than the ELECTRa registry. However, most of these cases were pocket hematoma requiring no drainage which did not cause any clinical problems.

There was no difference between TightRail^{TM} and Evolution® groups regarding the all-cause mortality rate at long-term follow-up in our study. If the TightRail^{TM} group was followed for the same duration as the Evolution® group, it is likely higher all-cause mortality would be seen in the TightRail^{TM} population. Moreover, there was a significant separation of the survival curves of both groups with the log-rank test, which was thought to be due to a sicker population with more hypertension, diabetes mellitus, CAD, HFrEF, NYHA class II-IV, and lower LVEF of TightRail^{TM} group compared to Evolution® group. To the best of our knowledge, our study is unique, with its largest sample size of the TightRail^{TM} group in the literature, in addition to long-term mortality outcomes of both device technology. Higher leukocyte count, lead burden, and lead dwell time were associated with a higher risk of procedural failure, and presence of heart failure, coagulopathy, and chronic renal disease was associated with a higher risk of all-cause mortality in our study. In previous studies, it was observed that the lead burden associated with a 3.5 fold increased risk of any complication. Moreover, TLE for infection and high CRP levels were found to be associated with all-cause mortality [18,19]. In a large-scale study with extracted 5521 leads that evaluated risk factors of procedural failure, major complications, and all-cause mortality, low platelet counts and higher INR levels (>1.2) were associated with major complications and 30-day death[20]. Furthermore, heart failure and renal dysfunction increased the 30-day mortality by 1.3-8.5 and 4.8 fold, respectively[21,22].

Our study results have important clinical implications. The TLE using either TightRail^{TM} or Evolution®mechanical dilator sheaths can be performed with an excellent clinical/procedural success and acceptable complication rates. These findings suggest that these extraction tools should be used by experienced operators with a cardiothoracic surgery team on standby to cope with any complication.

Our study results should be interpreted with some limitations. First, the study groups were non-randomized, and the data were collected retrospectively in this cohort study. Second, the impact of the learning curve on the outcomes of the Evolution® group, which was available at first, could not be ignored. Third, data for procedure and fluoroscopy time as markers of the case complexity were not available for all participants. Fourth, second-generation Evolution$^{R/L}$ mechanical dilator sheath could not be used during the study period. At last, the availability of TLE devices mainly depends on the reimbursement policy of our National Social Security System, which limits the randomization. Thus, the study compared two non-contemporaneous periods where the different devices were available rather than a direct comparison. Furthermore, non-rotational dissection tools and laser sheath were not available in our country.

In conclusion, our results showed that the TLE by using either TightRail^{TM} or Evolution®hand-powered rotational mechanical dilator sheath systems was highly effective with acceptable safety results. However, rescue extraction tools and backup cardiothoracic surgery support should be available on site. The selection of the TLE tool should be based on the operator preference/experience, availability, and reimbursement of

the devices. Continued investigation is required to compare safety, success, and complication rates with other techniques.

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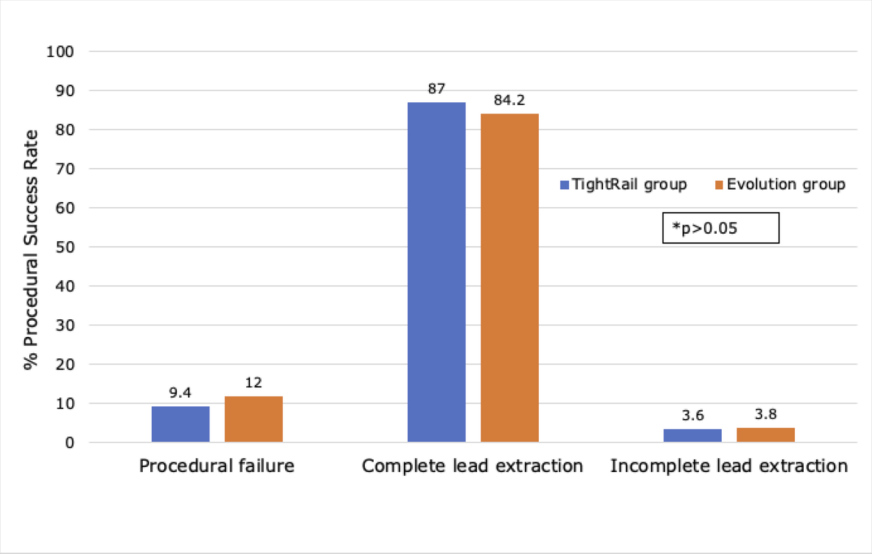
Figure Legends

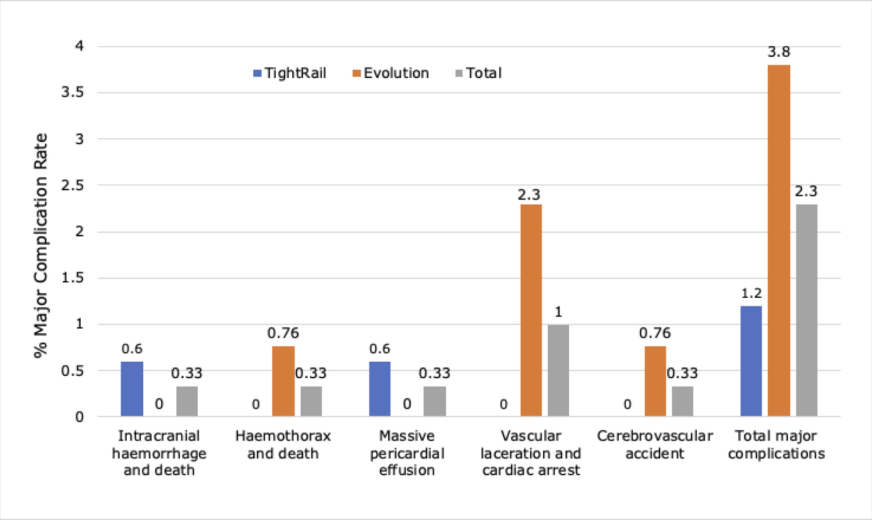
Figure 1 . The comparison of procedural success and failure rates without using rescue tools.

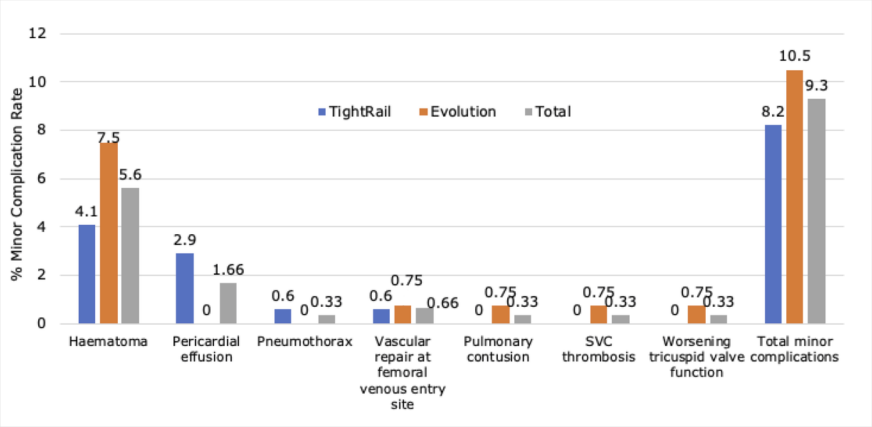
Figure 2 . The distribution and comparison of major complications according to the mechanical dilator sheath types.

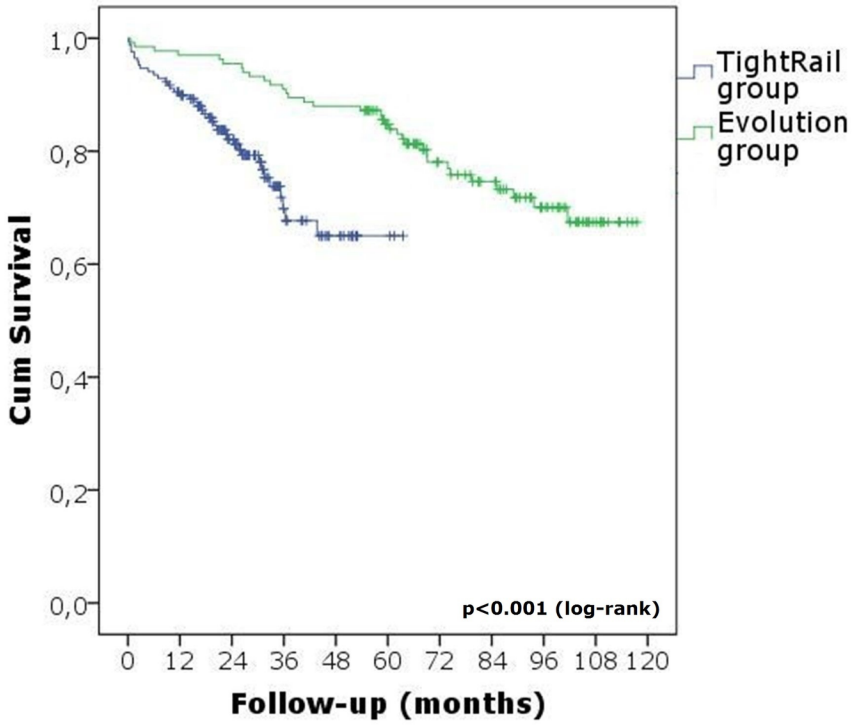
Figure 3 . The distribution and comparison of minor complications according to the mechanical dilator sheath types.

Figure 4 . Kaplan-Meier curve illustrating the cum survival of TightRail^{TM} and Evolution$^{(r)}$ groups during long-term follow-up ($p<0.001$, log-rank).









	Total no of patients	Mortality (+)	Mortality (-)	Survival rate	Mean Survival Duration (month)	95% C.I. Lower-Upper
TightRail™	169	39	130	%76.9	49.04±2.01	45.10-52.98
Evolution®	133	34	99	%74.4	97.86±2.98	92.02-103.70

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