Predictors and Outcomes of Transvenous Lead Extraction Requiring Femoral Bailout

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Abstract

INTRODUCTION: Transvenous Lead Extraction (TLE) is usually performed via a superior approach. Predictors and outcomes of TLE requiring femoral vein bailout are poorly defined. We aimed to analyze predictors and consequences of TLE requiring femoral bailout. **METHODS:** A single tertiary center cohort of 421 consecutive patients who underwent TLE between May 2010 and February 2020 were analyzed. Venography was routinely performed before system upgrade to identify occluded veins. Patients were divided into 2 groups according to their need for femoral bailout extraction. **RESULTS:** A total of 928 leads were extracted with femoral bailout approach was needed in 71 leads(7.7%) among 49 patients(11.6%). A higher proportion of right ventricular(RV) leads required femoral bailout approach compared with right atrial(RA) leads[51/499(10.2%) vs 18/326(5.5%);p=0.02]. Femoral bailout was more common among younger patients, longer lead dwell time, more pocket entries, higher number of extracted leads, presence of abandoned leads and among patients with vascular occlusion. Following multivariate analysis, presence of abandoned leads, vascular occlusion and younger age remained a significant predictor for femoral bailout. Femoral bailout resulted in higher rates of major complications [5/49(10.2%) vs 12/372(3.2%);p=0.05] without intra-procedural mortality and no additional 30-day mortality[2/49(4.1%) vs 33/377(8.8%);p=0.39]. **CONCLUSION:** TLE of abandoned leads, occluded veins and younger age were found to be predictors of femoral bailout requirement. Despite higher rates of major complications in femoral TLE bailout, mortality was not increased. Venography prior to TLE should be considered for procedure planning.

INTRODUCTION

Cardiovascular Implantable Electronic Device (CIED) implantations have increased over the past 2 decades because of expanded indications. Following this increase there has been a parallel increase in the need to extract CIED leads for infectious and non-infectious etiologies. Nowadays, extractions of implanted leads are performed via transvenous lead extraction (TLE) procedures usually through a superior approach via the subclavian vein (SCV) [1] [2].

Extraction tools can be categorized into mechanical non-powered sheaths and powered sheaths. The latter can be divided into those that deploy a source of energy in order to dissect encapsulating fibrous tissue (laser and radiofrequency (RF) energy) and those that use handled triggered rotational dissecting tip to achieve that goal. Overall, tool development has made TLE a relatively safe and successful procedure[3].

The once commonly used femoral approach, which compared to the superior approach is associated with higher complication rates in the ELECTRa prospective registry [1], has now become mainly a bailout procedure in cases where superior TLE approach has failed and thus familiarity with its use has decreased as well [24] . However, albeit the inferior's approach reduced application, each approach for TLE has its downgrades:

While the femoral approach may be associated with cardiac avulsions [5], superior vena cava (SVC) tear remains a dreaded complication of the superior approach [6]. A combined superior and inferior TLE approach has been suggested in order to gain the advantage of each approach and avoid the caveats of the other [7].

Elaborating and refining predictors for femoral support or bailout should help optimize the synergy between different approaches and translate into an overall reduction in complications eventually providing better procedural outcomes.

Previously, femoral TLE bailout was found to be associated with prolonged lead dwell time and number of leads extracted in two relatively large clinical cohorts, while infection as a predictor was reported in one of these studies [8,9].

In the current study, we aimed to determine the predictors and outcomes for TLE requiring a femoral bailout, including those procedures performed in the presence of occluded veins, compared to procedures performed solely by a superior approach.

METHODS

STUDY PATIENTS AND DESIGN

Our cohort included all 421 consecutive patients undergoing TLE between May 2010 and February 2020 at Sheba Medical Center, a large tertiary university medical center in Israel. The clinical and procedural data of all TLE procedures were collected prospectively. Lead extraction was defined as any lead removal in which at least one lead required the assistance of equipment not typically used during implantation or at least one lead implanted for more than one year [10].

The superior approach group comprised all patients in whom the subclavian / axillary vein was the only approach used for lead extraction. Femoral approach was only used as a bailout solution in cases of unsuccessful superior TLE approach, and included all TLE patients in whom at least one of the leads was extracted through the femoral vein.

Venography is routinely performed before a system upgrade, and when the access vein is found to be occluded we recommend that an older lead be removed to gain venous access. We also perform venography on a case by case basis before substituting broken or malfunctioning leads.

The study and TLE registry was approved by the Institutional Review Board.

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EXTRACTION PROCEDURE

All TLE procedures were performed by experienced cardiac electrophysiologists with a cardiothoracic surgeon immediately available on-site and chest and abdomen prepared for emergency sternotomy. Patients underwent general anesthesia with hemodynamic monitoring, and a transesophageal echocardiography probe was available in the room. A large-bore femoral venous access was inserted in all patients in case a diversion to femoral setting extraction will be needed.

A stepwise approach was used in all patients as follows: in the pre laser era (July 2010 -December 2011) simple traction was applied to the lead from the pocket, usually after introduction of locking stylet. If still unsuccessful, at least one of the following mechanical tools was used: Evolution RL Controlled-Rotation

Dilator Sheat, Teflon or Polypropylene Byrd Dilator (both from Cook Medical, Bloomington ,IN), stainless steel dilator, and electrosurgical dissection (EDS) sheath (Cook Vascular Incorporated, Vandergrift, PA, USA). When laser sheaths (GlideLight Laser Sheath - Spectranetics, Colorado Springs, CO) were introduced at our institution it became a second option after simple traction. Tight Rail (Spectranetics, Phillips, Colorado Springs, CO), was later introduced during 2016 and became an alternative second option.

In cases where the superior approach was not fully successful and no major complication had occurred, femoral approach was attempted during the same procedure. In these cases, using the femoral vein access acquired earlier, a Needle's Eye Snare Retrieval (Cook Medical, Leechburg, Pennsylvania), a Gooseneck snare (ev3, Europe SAS, Paris ,France) or a deflectable ablation catheter were deployed to catch the lead or remanents and extract from the femoral vein. Femoral approach was not implemented as a combined technique with the superior approach, nor was it used to rail the lead in case of laser and power tools usage.

The TLE procedure was terminated after complete removal of the leads; when lead fragments could not be further removed or in the event of a major complication.

SUCCESS AND OUTCOMES

The Heart Rhythm Society 2017 consensus document was used to define procedural success and outcome [10]. Complete procedural success was defined as removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complication or procedure related death. Clinical success was regarded as removal of all targeted leads and lead material from the vascular space with the exception of small portion (<4 cm) retention of the lead that does not negatively impact the outcome goals of the procedure including perforation, embolic events or infection perpetuation, etc. Partial success was defined as clinical success when most of the lead was removed, leaving at the most 4 cm of coil and/or insulation and/or lead tip.

Complications were classified using the 2017 HRS conventional criteria[10] and were attributed to the extraction method used at the time the complication was observed. Complications were continuously recorded until hospital discharge. Major complications were those that imposed immediate life threat and included procedure-related death, need for pericardiocentesis, vascular tear, severe tricuspid regurgitation (TR) (defined as either TR requiring intervention, or TR resulting in lifelong disability), stroke or requirement of urgent surgery occurring during the TLE procedure. Complications that did not meet the major complication criteria were classified as minor complications.

All-cause mortality and current patient status were updated from Israel's national population registry updated on a regular basis.

STATISTICAL ANALYSIS

The study cohort was divided into two groups according to the TLE approach (superior versus femoral bailout). All statistical tests were 2-sided, and a p-value of less than 0.05 was considered significant. Categorical variables are reported in frequencies and percentages. The significance of categorical variables between groups was assessed using the chi-square test or Fisher's exact test, as appropriate We tested all variables for normal distribution by the Kolmogorov-Smirnov test and by visualizing the QQ-plot, plotting the distribution and variance of the residuals. Normally distributed continuous variables were reported as mean and standard deviation values, and differences between groups were assessed using the student's t-test. Continuous variables not normally distributed were reported as median and interquartile range (IQR, 25th-75th percentiles) values, and significance was assessed using the Mann-Whitney U test. Differences between groups were tested using the Wilcoxon or Kruskal-Wallis tests. A multivariate logistic regression model was constructed for prediction of need to switch over to a femoral approach. The model consisted of variables that were statistically significant in univariate tests and of clinically relevant indices. Statistical analysis was performed using the SPSS statistical software 25.0.0 (IBM, Armonk, NY, USA), and the R foundation statistical computing and graphics software (version 4.0.0).

RESULTS

BASELINE CHARACTERISTICS AND PREDICTORS OF FEMORAL BAILOUT

A total of 421 patients underwent extraction from May 2010 to February 2020. 49 patients(11.6%) required a femoral bailout approach. Of the total 928 lead extracted, 71(7.7%) needed a femoral bailout following a failed superior approach attempt.

Patients in the femoral bailout group were younger(age 58±19 vs 67±15;p<0.01) and had less vascular disease(37% vs 58%;p=0.04)(Table 1). The two groups were comparable in all other comorbidities. Patients requiring femoral bailout had an increased number of extracted leads(3[2,3] vs 2[1,3]), longer lead dwell time (years from first lead implantation to extraction)(9.5[5.05, 13.94] vs 5.62[2.52, 8.94], had at least one abandoned lead present (53% vs 15%;p<0.01) and experienced more previous entries into pocket(71% vs 49%;p=0.01).

For both approaches, the most common indication for TLE was CIED infection(71% vs 79%, p=0.3). Occluded veins found during routine venography before system upgrade were the second most common indication for the femoral bailout group, whereas this indication was less prevalent among TLE achieved by a superior approach[8/49(16%) vs 5/372(1%);p<0.01]. Vascular occlusion was overall identified in 34 patients by the following division: 13 by routine venography before system upgrade; case by case decision to perform venography before non-infectious procedures in 9 patients; known SVC syndrome or occluded veins as the driving reason for TLE in 7 patients; and finally in 5 patients occluded veins was identified on day of operation. Extraction in the presence of occluded veins via superior approach without femoral bailout was achieved in only 19 out of 34 procedures(56%).

Patients older than 60 comprised a large proportion[294/421 (69.8%)] of our cohort, and infectious TLE etiologies[251/294, (85.4%)] were the primary causes for extraction in this population. Femoral bailout rates due to infectious etiologies varied significantly between older and younger patients, as an exceptionally low percentage of femoral supports were required for elderly patients in comparison to younger patients[16/251 (6.4%) vs 19/78 (24.4%) respectively;p<0.01]. Conversion rates for femoral bailout due to non-infectious reasons were similar between older and younger patients[7/43 (16.3%) vs 7/49 (14%);p=0.79]. Finally, the younger TLE patients (age<60) had longer lead dwelling time in comparison to older patients[7.31 (3.8-11) vs 5.32 (2.42-9.17);p=0.002].

Multivariable analysis revealed that older age was associated with a lower rate of femoral bailout[0.97 (95% CI 0.95-0.98);p=0.009], presence of an abandoned lead[4.99 (95% CI 1.48-10.95);p=0.006] and vascular occlusion[7.88 (95% CI 3.21-20.1);p<0.01] remained significant predictors for need of femoral bailout, while other baseline parameters did not(Table 2).

PROCEDURAL OUTCOMES

Clinical and radiological success between approach groups was not compared as femoral bailout group represents extraction failure of superior approach methods. Only 7 patients who hadn't suffered major complication or death[7/421 (1.7%)] had superior approach clinical\radiological failure without a femoral attempt.

A total of 928 leads were extracted in our cohort with 71 via a femoral position. The operator decision to switchover to femoral bailout intra-procedurally was carried out when the superior approach was not fully successful for the following reasons: 37 of the 71 leads were extracted via femoral bailout because of lead breakage(unrelated to known vascular obstruction) occurring during the procedure itself. 19 leads were extracted via a femoral bailout because of vascular occlusion causing either inability to pass and deploy tools or lead breakage. Finally, in 15 leads femoral bailout was deployed due to inability to extract the lead from the superior approach without causing lead breakage.

RV leads comprised most[499/928 (53.8%)] of leads extracted(Figure 1). A higher proportion of RV leads had to be extracted from a femoral approach compared with RA leads[51/499(10.2%) vs 18/326(5.5%);p=0.02]. A small fraction of left ventricular(LV) leads [2/103(1.9%)] were extracted via the femoral access.

Abandoned leads comprised roughly 10 percent [91/928 (9.8%)] of the extracted leads in our cohort. One third

[30/91 (33%)] of them were extracted transfemorally. The overall clinical success rates of transfemoral abandoned leads extraction were much lower than non-abandoned leads[22/30(73.3%) vs 40/41(97.6%);p<0.01].

Femoral bailout had a higher overall[18/18 (100%)] clinical success of RA leads compared to RV leads[43/51(84.3%)](Figure 2). The 2 LV leads requiring femoral bailout were extracted successfully. Clinical[18/25(72%)] and radiological[11/25 (44%)] success rates of femoral bailout extraction of RV abandoned leads was exceptionally low.

All leads which were extracted via femoral approach due to vascular occlusion had full radiological success[19/19(100%)], while only roughly half of patients with femoral bailout due to lead breakage that occurred during the procedure achieved radiological success[19/37(51.3%)](figure 3).

PERIPROCEDURAL COMPLICATIONS

Table 3 summarizes overall periprocedural complications. 3 intra-procedural deaths occurred, all of which underwent laser extraction from a superior approach. The femoral group experienced lower 30-day mortality, although not statistically significant[2/49(4%) vs 33/372(9%);p=0.39].

Major complications(without intraprocedural death) were observed in 3% of patients undergoing TLE(14/421). Femoral bailout was associated with a higher percentage of major complications without intraprocedural mortality[5/49(10.2%) vs 9/369(2.4%);p=0.015]. We experienced 9 vascular and cardiac tears of which 4 were directly related to femoral approach tool deployment(none resulted in fatalities). Serious TR complications as a result of extraction occurred in 7 patients of whom only one patient required femoral TLE. Five minor complications(including pocket hematoma, femoral vein tear, pulmonary emboli, and minor TR) were encountered: 4 of which were associated with the femoral bailout group, compared to one in the superior approach group[4/49(8.2%) vs 1/372(0.3%);p<0.01].

Femoral bailout patients required more blood transfusion peri-procedurally[9/49 (18%) vs 14/372(3.8%);p<0.01], however, this did not translate into excess in mortality.

Extraction in occluded veins via a superior approach resulted in major complications in 16%[3/19(15.7%)] of the cases, while shifting to a femoral strategy in these patients did not result in additional major complications.

DISCUSSION

The current study revealed that age, occluded veins and abandoned leads are predictors for need to switch to a femoral bailout approach. A required switch to a femoral approach was not found to increase mortality, but does result in more procedural complications.

PREDICTORS FOR FEMORAL BAILOUT

In line with previous reports, lead dwell time and number of leads extracted [8] [9] were found as independent predictors for femoral bailout procedure in univariate analysis. Femoral approach may be needed for leads with longer dwelling time for the following reasons: Older leads tend to break during TLE making extraction from a different site mandatory [11], and in cases of leads with well-formed adhesions, mechanical support from inferior approach may be helpful [8]. Increased lead number adds to lead-lead and lead-vascular adhesions and TLE complexity, promoting the need for femoral support.

The decision whether to extract or abandon non-infected CIED leads during system upgrade, lead failures or other reasons, remains an operational decision based on case by case risk-benefit ratio[10]. Eventually the presence of abandoned leads, adds to the number of leads in the vasculature and intuitively, abandoned leads also have longer dwell time and increase crowding within the vein that may result in occlusion. Increased use of femoral bailout for abandoned lead extraction has been observed previously[12]. Recently, Segreti et al reported a high success rate for abandoned lead extraction using mechanical tools with relatively limited need to switch to femoral approach. However, the median dwelling time of the oldest abandoned leads in their cohort was shorter than ours[108 months(60–168) vs 132 months(84-196)][13], and could account for the difference observed in our cohort.

Patients in the femoral bailout group were found to be younger. One might argue that any TLE cohort study may suffer from younger age selection bias, as a more aggressive approach with possibly complicated course(often requiring femoral bailout) for non-mandatory TLE indications is potentially carried out for younger patients[10]. However, this age-driven selection bias is less straightforward for TLE performed due to infectious etiologies for which the operator doesn't have much leeway in the decision to abandon or extract a given lead. In accordance, our data shows that a large majority of our patients were elderly and extracted due to infectious etiologies and when compared with younger patients who were extracted due to similar indications the elderly group had less tendency for femoral bailout.

A partial explanation for femoral switchover tendency of younger patients, is that younger patients have longer lead dwell time in our cohort. This can be rationalized as younger patients have increased chance to have CIED implanted from a very young age due to diverse etiologies such as idiopathic dilated cardiomyopathy (DCM), channelopathies and hypertrophic cardiomyopathy (HCM)[14]. Our analysis reveals that younger age is an independent risk factors predisposing for a femoral bailout. It is possible that vascular calcifications and adhesions might be found in the overall younger patients population, resulting in reduced efficiency of mechanical and powered tools, eventually predisposing them for the need of a femoral bailout [15].

Venous occlusion after CIED implantation is quite common with a prevalence of up to 27% of all implantations [16], and site of occlusion is the subclavian vein in 60%, for 33% it is the brachiocephalic vein and for the remaining it is the SVC[17] . Venous occlusion by itself is not an indication for lead extraction, but rather a class 2a indication for patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead [10].

Presence of superior venous occlusion has been found to be a risk factor for major complications of TLE [6], although trials examining the outcomes of femoral support or bailout in the presence of superior occluded veins are lacking.

Sub analysis of the ELECTRa study found a correlation between the use of power sheaths for TLE of leads in occluded veins and vascular tears[6]. The authors recommended that venography should be considered preprocedurally for all patients undergoing extraction and that special precaution should be taken when using powered sheaths in the presence of occluded veins.

Recognition of the hazards of SVC tear during superior approach and the link between venous occlusion and the need for femoral support has been stressed by Isawa et al. [7], reporting a high prevalence of venous occlusion after routinely performing venography, and a low threshold for femoral support for patients with occluded veins, in order to avoid SVC tears. It has been previously suggested that when occluded veins are encountered during TLE, femoral support should be considered to stabilize the extracted lead[4].

Suspected mechanism linking power sheath use in the presence of vascular occlusion and resulting vascular tears is not known. We can speculate that when faced with vascular obstruction in the brachiocephalic-SVC junction, difficulty might rise to keep the sheath co-axial with the lead, forcing unwanted contact between the sheath head and the SVC wall potentially causing vascular tears.

Despite of all mentioned above, Sohal et al. reported high success rates using laser sheaths for TLE due to occluded veins. However, their site of occlusion was mainly the subclavian vein, which is less likely to injure during TLE, in contrast to the brachiocephalic-SVC–high RA area. Furthermore, their use of intraprocedural venography as part of their extraction protocol to confirm intravascular position of tools could have potentially minimized vascular injuries [1819].

Our results add and show that venous occlusion is associated with a higher complication rate of TLE in the superior approach group, however, when a femoral bailout approach was used to extract leads from occluded veins, radiological success was achieved in all cases.

FEMORAL BAILOUT - PROCEDURAL COMPLICATIONS AND FAILURES

Our practice was to deploy femoral extraction only as a last resort and as such reserved for the most challenging cases. Under these circumstances, a relatively high proportion of major complications and procedure failures in comparison to non-femoral extraction group would be expected. However, although there was a statistical difference in major complications between the superior and femoral bailout groups, there were only 5 major complications directly linked to femoral extraction, with no reported fatalities and lower 30-day mortality.

El-Chami et al. previously reported a low procedural success rate (58%) of femoral TLE [9], yet the reason for femoral bailout procedural outcomes according to the reason for femoral transition were not provided.

A high proportion of TLE failures and major complications were linked to abandoned leads and especially RV abandoned leads. On the other hand, we observed a higher success rate of both abandoned and non-abandoned atrial leads via the femoral approach. In accordance with our findings, previous reports have stressed the superior results of femoral TLE of RA leads over RV leads. Possible explanations for this observation are that sheaths are better aligned with atrial and coronary sinus leads; Ventricular leads cannot be easily freed from the myocardium before the proximal body of ventricular leads has to be pulled down and that scar tissue engulfing the lead is more abundant in the ventricle[20].

LIMITATIONS

Several limitations are acknowledged: This is a retrospective single center study with no control group and with different operators and different thresholds for a power tool usage and strategy used during femoral bailout.

Relatively few patients in our cohort were diagnosed with occluded veins. In our institution the only absolute indication for venography before extraction is system upgrade and thus was performed in a limited number of patients. The real number of patients with upper thoracic vein occlusion is probably higher. Intuitively, since only a relatively small percentage of our cohort underwent venography, some additional major complications documented in the superior approach group could have resulted from underdiagnosed occluded veins.

The risks of femoral extraction are likely to be biased by the fact that it was only used as a bailout procedure for the most challenging cases. As a consequence, drawing conclusions about the difference in complication rates between the femoral and non femoral extraction when not strictly used for their bailout is not warranted.

CONCLUSIONS

Presence of younger age, abandoned leads and venous occlusion were found to be significant predictors of femoral bailout TLE. Our findings are in accordance with reports finding upper thoracic occluded veins to be predictors for catastrophic vascular tears, especially when using power tools. Therefore, upper extremity venography should be considered routinely prior to TLE.

Extraction failure of abandoned leads was prevalently observed even via femoral bailout, signifying the unique challenge these leads pose.

Despite the predictors listed above for femoral bailout TLE, our results suggest that femoral extraction is a relatively safe procedure and proper synergy of its use along with other approaches may optimize extraction procedural outcomes.

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The study and TLE registry was approved by the Institutional Review Board

Figure Legends

FIGURE 1 - Femoral extraction approach according to lead type.X axis – lead type, Y axis – number of leads extracted (yellow -total group, red - transfemorally extracted leads)**;**

Abbreviations: RV, Right ventricular; RA, Right atrial; LV, Left ventricular.

FIGURE 2 - Femoral extraction procedural outcomes according to lead type. X axis - lead type, Y axis - number of leads extracted transfemorally per each group (green – complete success, yellow- partial success, red - failure).

Abbreviations: RV, Right ventricular; RA, Right atrial; LV, Left ventricular.

FIGURE 3 – Femoral bailout procedural outcomes according to femoral switchover cause. X axis –femoral bailout switchover cause, Y axis – number of leads extracted (green – complete success, yellow – partial success, red – failure).

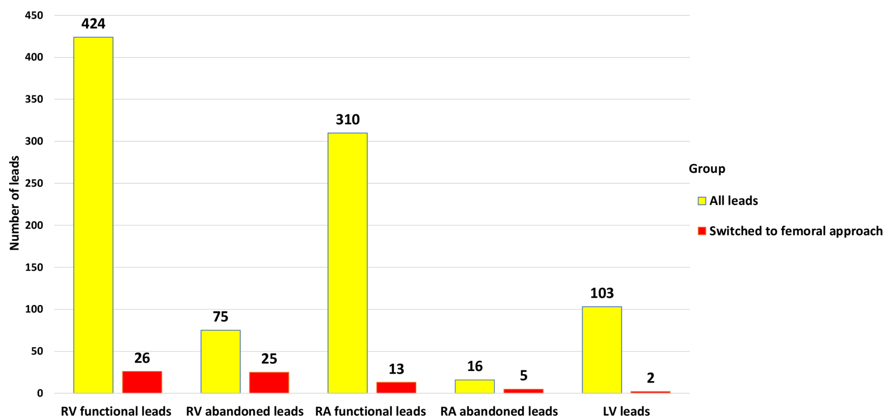

Figure 1 **Femoral extraction approach according to lead type**

X axis – lead type, Y axis – number of leads extracted (yellow -total group, red - transfemorally extracted leads)**;**

Abbreviations: RV, Right ventricular; RA, Right atrial; LV, Left ventricular.

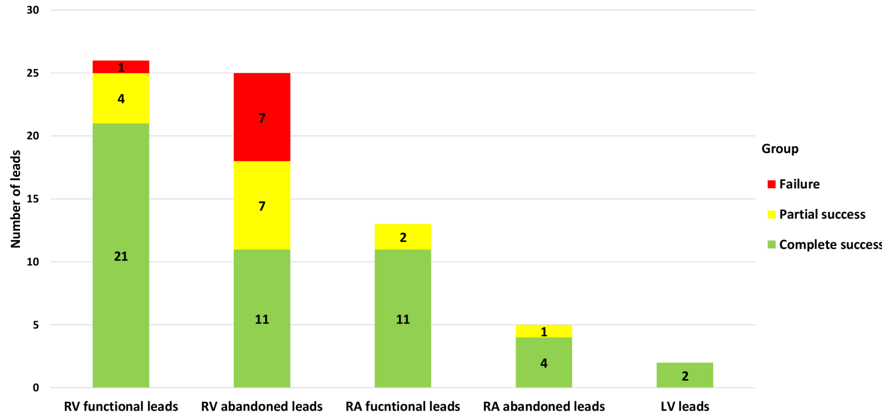

Figure 2 **Femoral extraction procedural outcomes according to lead type**

X axis - lead type, Y axis - number of leads extracted transfemorally per each group (green – complete success, yellow- partial success, red - failure).

Abbreviations: RV, Right ventricular; RA, Right atrial; LV, Left ventricular

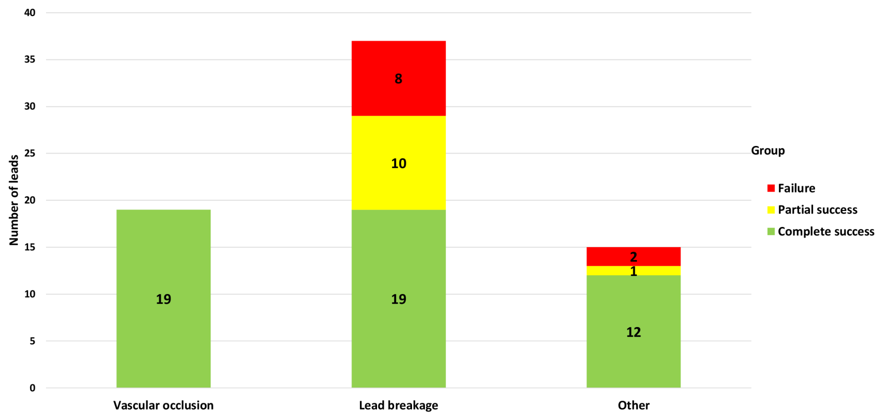

Figure 3 **Femoral bailout procedural outcomes according to femoral switchover cause**

X axis –femoral bailout switchover cause, Y axis – number of leads extracted (green – complete success, yellow – partial success, red – failure).

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