Outcomes of Tricuspid Regurgitation After Lead Extraction

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Abstract

Background: Transvenous leads have been implicated in tricuspid valve (TV) dysfunction, but limited data are available regarding the effect of extracting leads across the TV on valve regurgitation. **Objective:** The aim of this study is to quantify tricuspid regurgitation (TR) before and after lead extraction and identify predictors of worsening TR. **Methods:** We studied 321 patients who had echocardiographic data before and after lead extraction. TR was graded on a scale (0=none/trivial, 1=mild, 2=moderate, 3=severe). A change of > 1 grade following extraction was considered significant. **Results:** A total of 321 patients underwent extraction of a total of 338 leads across the TV (1.05 ± 0.31 leads across the TV per patient). There was no significant difference in average TR grade pre- and post-extraction (1.18 ± 0.91 vs. 1.15 ± 0.87; p=0.79). TR severity increased after extraction in 84 patients, but was classified as significantly worse (i.e. > 1 grade change in severity) in only 8 patients (2.5%). Use of laser lead extraction was associated with a higher rate of worsening TR post-extraction (44.0% vs. 31.6%, p=0.04). **Conclusion:** In our single-center analysis, extraction of leads across the TV did not significantly affect the extent of TR in most patients. Laser lead extraction was associated with a higher rate of worsening TR after extraction.

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Statements and Declarations:

Dr. Lloyd is a consultant for Biosense Webster, Medtronic, and Boston Scientific. Dr. El-Chami is a consultant for Boston Scientific and Medtronic. Dr. Shah has received honoraria from Baylis Medical. Dr. Bhatia has received honoraria from Medtronic. All other authors have reported they do not have any conflicts relevant.

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Results:

A total of 321 patients underwent extraction of a total of 338 leads across the TV (1.05 ± 0.31 leads across the TV per patient). There was no significant difference in average TR grade pre- and post-extraction (1.18 ± 0.91 vs. 1.15 ± 0.87; p=0.79). TR severity increased after extraction in 84 patients, but was classified as significantly worse (i.e. >1 grade change in severity) in only 8 patients (2.5%). Use of laser lead extraction was associated with a higher rate of worsening TR post-extraction (44.0% vs. 31.6%, p=0.04).

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Keywords : lead extraction, tricuspid regurgitation, extraction tools

Introduction :

Transvenous lead extraction (TLE) remains a critical part of lead management in patients with cardiac implantable electronic devices (CIED).[1,2] TLE is an effective procedure for removal of cardiac implantable leads with a high rate of success and a low risk of major complications.[3] While transvenous leads have been implicated as a cause of tricuspid regurgitation (TR), the incidence of TR attributable to leads and the impact of lead extraction on the extent of TR are poorly defined. Although lead removal has been proposed as a way to treat TR, TLE often will not improve the degree of regurgitation and in some cases, may worsen TR by injuring the tricuspid valve (TV) or sub-valvular apparatus.[4] Additionally, the association between TR and worse outcomes in patients with heart failure has resulted in a proliferation of percutaneous therapies to address regurgitation.[5] For patients who are being considered for percutaneous tricuspid interventions who have existing leads across the TV, the role, timing and impact of TLE on TR prior to percutaneous intervention is also an area of uncertainty.

In light of the uncertainties regarding the impact of TLE on TR, we sought to quantify TR before and after TLE.

Methods:

Ethics Approval Statement :

This study was approved by the Institutional Review Board at Emory University.

Patient Selection :

We performed a retrospective analysis of patients referred for TLE of lead(s) across the TV from January 2014 to October 2021 at Emory Healthcare. TLE was defined as either removal of right ventricular (RV) lead(s) implanted for > 1 year or lead removal requiring specialized extraction equipment, per the 2017 Heart Rhythm Society consensus statement on CIED management.[6] Patients included in this analysis were those with paired echocardiograms (either transthoracic or transesophageal) within 3 years prior to extraction and within 1 year after extraction. Patients were excluded if the severity of TR could not be adequately assessed on either echocardiogram, if additional interventions to treat TR were performed (i.e. surgical or percutaneous TV replacement or repair) or if mechanical circulatory support was utilized at any time between the baseline and follow-up echocardiograms.

Extraction Procedure Details

The indication for each type of lead extraction across the TV was recorded. Indications were divided into broad categories: 1) infection (bacteremia, endocarditis, lead vegetation and/or pocket infection); 2) lead dysfunction (lead failure, dislodgement, recall, perforation or elevated capture threshold); 3) device upgrade (leads extracted either due to ipsilateral venous occlusion or to avoid redundant hardware); 4) TR as primary indication for TLE; and 5) other indications. All patients underwent lead extraction in either the electrophysiology lab or a hybrid operating room. Cardiothoracic surgical back-up and perfusion teams were available in selected cases based on institutional protocol, typically for lead dwell time > 5 years or if felt to be high-risk for complications based on operator discretion.

The technical aspects of the lead extraction procedure were at operator discretion. Typically, leads which could not be removed with simple traction were prepped with locking stylets. The use of powered sheaths typically included the GlideLight Laser sheath (Spectranetics/Phillips, Colorado Springs, Colorado) or for mechanically-powered sheaths, either the TightRail Rotating Dilator Sheath (Spectranetics/Phillips) or the Cook Evolution RL (Cook Medical, Bloomington, IN). For the purposes of this study, the use of extraction tools was subdivided into laser-powered, mechanical-powered or a combination of both when multiple forms of powered sheaths were used. Femoral extraction tools were used when needed, at operator discretion.

Echocardiographic Assessment :

Severity of TR was assigned a grade of 0 to 3 (0=none/trivial TR, 1=mild TR, 2=moderate TR, 3=severe TR). For patients whose TR was reported as a range (i.e. mild to moderate), the less severe TR grade was recorded. Change in TR after TLE was considered clinically significant if the change was > 1 grade on the 0-3 scale.

Data Analysis :

Statistical analysis was performed using SPSS software (IBM, Armonk, NY). Categorical variables are given as numbers (percentages) and continuous variables are presented as means. Chi-square analysis was performed to compare changes in baseline clinical characteristics and extraction methods. A two-sample t-test was used to compare means between the two groups. A p value of < 0.05 was considered significant.

Results :

Patient Characteristics :

Out of 1813 patients who underwent TLE during the study period, 321 patients (17.7%) with echocardiograms before and after extraction were included in this analysis. Clinical characteristics of the study cohort are listed in Table 1.

A total of 338 leads were extracted across the TV (1.05 ± 0.31 leads across the TV per patient; Table 1). The RV leads extracted included 121 pacing leads (37.7%) and 200 defibrillator leads (62.3%). Indications for TLE included infection (n=186, 57.9%; 12 patients had evidence of TV endocarditis), lead dysfunction (n=65, 20.2%), device upgrade (n=58, 18.1%; 13 of these were extracted due to ipsilateral vein occlusion), TR (n=6, 1.9%) and other (n=6, 1.9%) (Table 1). There were no immediate procedural complications from RV lead extraction.

Changes in Tricuspid Regurgitation after Lead Extraction :

The average time between baseline echocardiogram and TLE was 80.7 ± 174.8 days, and the average time between TLE and follow-up echocardiogram was 78.3 ± 113.3 days. Of the 321 patients, 153 patients (47.7%) did not have any change in TR grade following lead extraction, while 84 patients (26.2%) had an improvement in TR grade following lead extraction (Fig. 1, 2). Worsening TR following lead extraction was observed in 84 patients (26.2%) (Fig. 1, 2). Overall, there was no significant difference in average TR grade pre- and post-extraction (1.18 ± 0.91 vs. 1.15 ± 0.87; p=0.79; Fig. 1).

Patients were stratified by those who developed worsening TR post-extraction (n=84, 26.2%) and those whose TR either stayed the same or improved post extraction (n=237, 73.8%). There was no difference in baseline clinical characteristics, type (pacing vs. ICD lead) or number of leads extracted, or indication for extraction between the two groups (Table 1). Endocarditis with involvement of the TV did not significantly influence the change in TR post-extraction (Table 1).

Only 8 patients (2.5%) had significant worsening of TR (> 1 grade): 4 patients had TR increase from mild to severe post-extraction, and the other 4 had an increase from none/trivial at baseline to moderate TR post-extraction (Fig. 2, Table 3). Improvement in TR was observed in 84 patients, of whom 16 patients had significant improvement in TR: 10 patients had TR decrease from moderate to none/trivial post-extraction, and 6 had TR decrease from severe to mild post-extraction (Fig. 2, Table 3). There was no difference in mean dwell time of leads between patients in whom TR worsened post-extraction compared to those in whom TR stayed the same or improved post-extraction (6.9 years ± 13.1 years vs. 6.0 years ± 11.2 years, p=0.55; Table 2).

Powered extraction sheaths were used in 202 procedures (81 mechanical, 78 laser, 34 combination of mechanical and laser; Table 2). The use of extraction tools was associated with a numerically higher rate of worsening TR compared to extraction with simple traction, although this difference was not significant (70.2% vs. 60.3%, p=0.11; Table 2). The use of laser lead extraction (laser or combination) was associated with a higher rate of worsening TR post-extraction (44.0% vs. 31.6%, p=0.04) compared to mechanical extractions (25.0% vs. 25.3%, p=0.95) (Table 2). Of note, extractions that required laser-powered sheaths had longer average lead dwell times (10.1 ± 15.1 years vs. 4.2 ± 8.9 years; p<0.01; Fig. 3).

Discussion :

In this large cohort of patients undergoing TLE, we found that the risk of significant worsening TR after lead extraction is low (2.5%). In addition, we found that most patients (73.8%) had unchanged TR or improved TR after lead extraction.

TLE remains an important procedure in the management of CIED-related problems.[7] While the overall major complication rate of TLE remains low at 0.2-3.4%,[3] damage to the TV during lead extraction remains a concern. Increased TR after lead extraction has been reported to occur in 3.5-15% of cases.[8-10] Variation in reported TR after lead extraction could be related to the definition of TR, extraction methods or timing of imaging. For instance, Park et al[9]reported that significant acute TR occurred in 11.5% of their cohort, with one requiring emergency TV replacement. A significant TR increase was defined as an increase of at least 1 grade. In addition, evaluation of valvular function pre and post extraction was performed via intra-procedural transesophageal echocardiogram (TEE) in all cases. Administration of general anesthesia, volume status, and RV function during the procedure can affect the assessment of TR and may not accurately affect long-term TV function.[11] By comparison, Polewczyk et al[12] conducted a multi-center post hoc analysis of 2631 patients and found that in 90.31% of procedures, TLE had no negative influence on TV function. A significant increase in TR was defined by 2 grades or more, similar to our study.

While risk factors for TLE-related TV damage (TVD) have not been clearly identified, various risk factors have been proposed for TVD following lead extraction. These include both younger[10, 12] and older patient age,[8] higher left ventricular ejection fraction,[12] extraction of pacemaker rather than defibrillator leads,[9] removal of [?] 2 leads and female sex[13]. In our cohort, we did not identify any significant differences in patient or procedural characteristics between those with worsened TR after TLE compared to those with unchanged or improved TR.

Longer dwell time is associated with the development of scar tissue, fibrosis and calcification encapsulating intravascular leads and thus often necessitates the use of powered sheaths.[14]Similarly, long dwell time is also associated with more fibrosis and scar tissue around the lead and the leaflet. Therefore, excessive traction on the lead during TLE could result in flail leaflets and worsening TR.

Several studies showed that a longer dwell time prior to TLE corresponded to a higher rate of TLE-related TR.[9, 12]While our study did not show any association between average dwell time and TLE-related TR, the use of laser-powered sheaths, which was associated with longer dwell time, was associated with worsened TR.

Our study has several limitations. Importantly, we only included patients with echocardiograms before and after lead extraction, which resulted in inclusion of only a minority of patients undergoing TLE. While this certainly has the potential to introduce selection bias, it is likely that patients in whom there is greatest clinical concern for tricuspid valve dysfunction or right heart failure would be most likely to have echocardiograms performed. Additionally, we included patients with an echocardiogram performed up to one year following TLE to assess for change in TR. Acute peri-procedural changes may have resolved by the time the echocardiogram was performed. However, in contrast to prior studies which have assessed change in TR solely based on intra-procedural TEE before and after extraction, our data likely provide a better assessment of long-term TR beyond the impact of acute procedural loading conditions.

Conclusion :

In our single-center analysis, extraction of leads across the TV did not significantly alter the extent of TR. Laser lead extraction was associated with a higher rate of worsening TR after extraction, although this may be the result of a longer dwell time for the leads requiring laser-powered sheaths. Further studies are needed to determine if certain TLE strategies predispose to worsening TR.

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Figures/Tables :

Table 1: Baseline Clinical Characteristics

	Worsening TR Post-Extraction (n=84)	Same or Improved TR Post-Extraction (n=237)	P value
Demographics			
Age (years), mean ± SD	62.1 ± 14.2	61.9 ± 15.5	0.92
Body mass index, mean ± SD	29.5 ± 6.3	29.1 ± 7.1	0.64
Women, n (%)	39 (46.4)	96 (40.5)	0.34
Comorbidities and Risk Factors			
Systemic hypertension, n (%)	69 (82.1)	178 (75.1)	0.19
Congestive heart failure, n (%)	69 (82.1)	188 (79.3)	0.58
Baseline LVEF (%), mean ± SD	37.9 ± 17.0	35.2 ± 16.9	0.21
Chronic kidney disease, n (%)	33 (39.3)	92 (38.8)	0.94
Pulmonary hypertension, n (% of known)	32 (46.4)	123 (59.4)	0.06
Atrial fibrillation/Atrial flutter, n (%)	46 (54.8)	117 (49.4)	0.40

Diabetes Mellitus, n (%)	33 (39.3)	90 (38.0)	0.83
Coronary Artery Disease, n (%)	31 (36.9)	84 (35.4)	0.81
Prior cardiac surgery, n (%)	27 (32.1)	77 (32.5)	0.95
CABG, n (%)	14 (16.7)	36 (15.2)	0.75
Device			
Pacemaker, n (%)	29 (34.5)	92 (38.8)	0.49
ICD, n (%)	55 (65.5)	145 (61.2)	0.49
Leads across TV, mean ± SD	1.07 ± 0.40	1.05 ± 0.26	0.60
Abandoned leads across TV, mean ± SD	0.06 ± 0.24	0.05 ± 0.24	0.74
Echocardiograms			
Pre-extraction echocardiogram (days), mean ± SD	98.5 ± 201.2	74.5 ± 164.5	0.28
Post-extraction echocardiogram (days), mean ± SD	92.5 ± 120.1	73.3 ± 110.6	0.18
Indication for Extraction			
Infection, n (%)	50 (59.5)	136 (57.4)	0.73
Tricuspid valve endocarditis, n (%)	5 (6.0)	7 (3.0)	0.21
Lead dysfunction, n (%)	18 (21.4)	47 (19.8)	0.86
Device upgrade, n (%)	12 (14.3)	46 (19.4)	0.29
Upgraded due to Ipsilateral vein occlusion	2 (16.7)	11 (23.9)	0.28
Upgraded to avoid redundant hardware	10 (83.3)	35 (76.1)	0.28
TR, n (%)	2 (2.4)	4 (1.7)	0.69
Other+, n (%)	2 (2.4)	4 (1.7)	0.69

+Other included hematoma, right upper extremity deep venous thrombosis, superior vena cava baffle stenosis, superior vena cava syndrome, pre-operative removal for lymph node dissection, and left ventricular assist device pain

Table 2: Effect of Extraction Method and Dwell Time on Degree of TR Post-Extraction

	Number of Cases of Worsening TR Post-Extraction (n=84)	*Number of Cases of S*
Extraction Method	*Extraction Method*	*Extraction Method*
Simple traction, n (%)	25 (29.8)	94 (39.7)
Extraction tools required, n (%)	59 (70.2)	143 (60.3)
Mechanical, n (%)	21 (25.0)	60 (25.3)
Laser, n (%)	31 (36.9)	47 (19.8)
Combination, n (%)	6 (7.1)	28 (11.8)
Laser + Combination, n (%)	37 (44.0)	75 (31.6)

Mechanical + Combination, n (%)	27 (32.1)	88 (37.1)
Unknown, n (%)	1 (1.2)	8 (3.4)
Average Dwell Time (Pre-extraction)	*Average Dwell Time (Pre-extraction)*	*Average Dwell Time (*
Duration (years), mean ± SD	6.9 ± 13.1	6.0 ± 11.2

Table 3: Analysis of Changes in the Degree of Tricuspid Regurgitation After Lead Extraction

	TR Before Extraction	TR After Extraction	N
All patients with same or improved TV function (n, %)	0-3	0-3	23
No change in TV function (153, 47.7%)	0	0	38
	1	1	74
	2	2	28
	3	3	13
Non-significant (for 1 degree) improvement of TV function (68, 21.2%)	3	2	9
	2	1	34
	1	0	27
Significant (for 2 or 3 degrees) improvement of TV function (16, 5.0%)	3	1	6
	2	0	10
All patients with worsening TV function	0-3	1-3	84
Non-significant (for 1 degree) worsening of TV function (76, 23.7%)	0	1	39
	1	2	27
	2	3	10
Significant (for 2 or 3 degrees) worsening of TV function (8, 2.5%)	0	2	4
	1	3	4

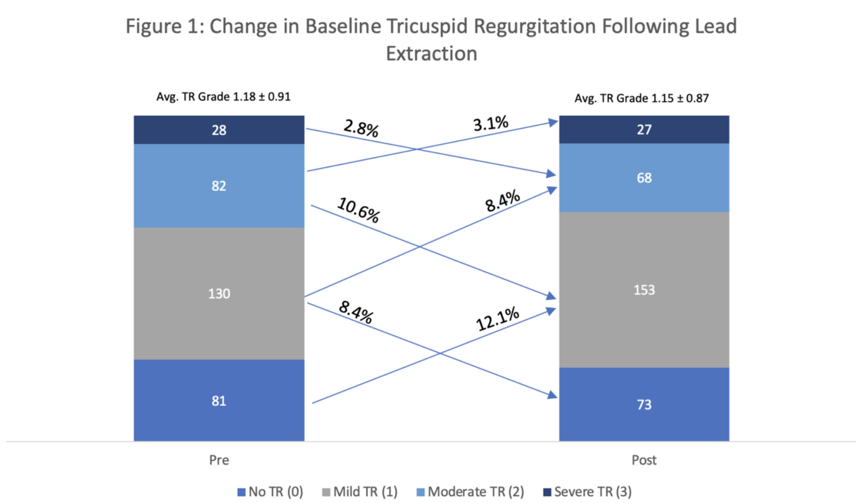

Figure 1: Change in Baseline Tricuspid Regurgitation Following Lead Extraction. This figure depicts the changes in TR grade following lead extraction. Arrows show individual changes in TR by 1 grade following lead extraction.

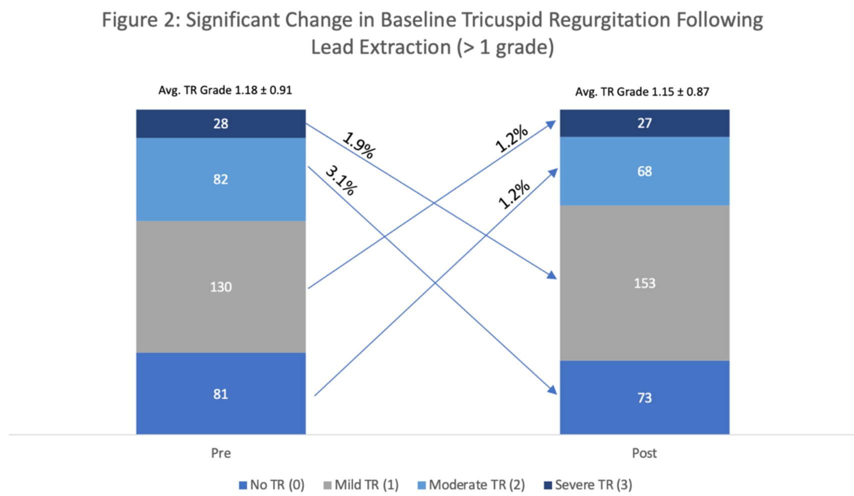

Figure 2: Significant Change in Baseline Tricuspid Regurgitation Following Lead Extraction (>1 grade). This figure depicts the changes in TR grade following lead extraction. Arrows show individual changes in TR by > 1 grade (significant changes) following lead extraction.

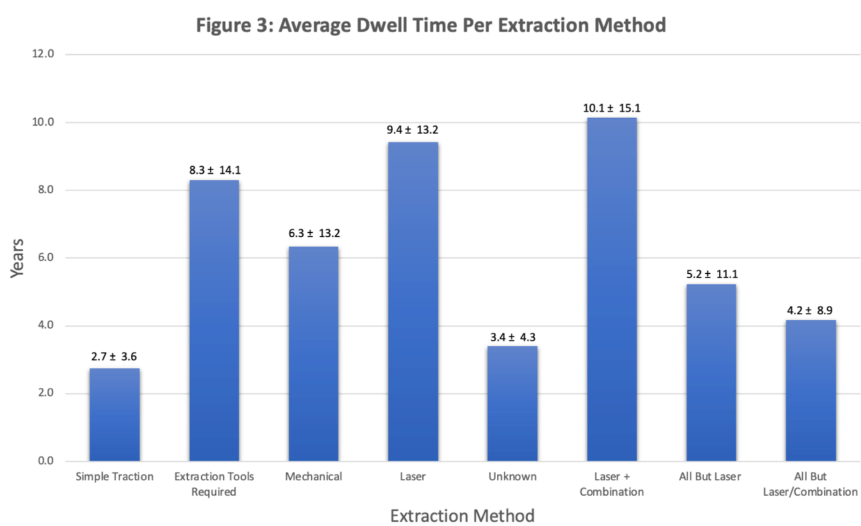

Figure 3: Average Dwell Time Per Extraction Method. This figure demonstrates the average dwell time in years based on type of extraction. Extractions that required use of powered extraction sheaths had longer average dwell times compared to extractions where simple traction was used alone. Extractions that required laser powered sheaths had the longest average dwell times.