Clinical Trials and Regulatory Science in Cardiology 7 (2015) 1–6

Contents lists available at ScienceDirect

Clinical Trials and Regulatory Science in Cardiology

journal homepage: http://www.elsevier.com/locate/ctrsc

Three-dimensional binding sites volume assessment during cardiac pacing lead extraction☆,☆☆,★

Bich Lien Nguyen [a,b,*,1], Alessandro Persi [a,1], Eli S. Gang [c,1], Fabrizio Fattorini [a,1], Alessandra Oliva [e,1], Antonio Vitarelli [a,1], Nicola Alessandri [b,1], Robert J. Siegel [d,1], Antonio Ciccaglioni [a,1], Carlo Gaudio [a,1]

[a] Electrophysiology Section, Cardiology Department, Umberto I Hospital, Sapienza University of Rome, Italy
[b] ICOT Latina, Polo Pontino, Sapienza University of Rome, Italy
[c] Electrophysiology Section, Division of Cardiology, Department of Medicine, Cedars-Sinai Medical Center Los Angeles, CA, USA
[d] Echocardiography Section, Division of Cardiology, Department of Medicine, Cedars-Sinai Medical Center Los Angeles, CA, USA
[e] Infectious Disease Department, Umberto I Hospital, Sapienza University of Rome, Italy

ARTICLE INFO

Article history:
Received 15 July 2015
Accepted 21 August 2015
Available online 28 August 2015

Keywords:
Pacing lead extraction
Electro-anatomical mapping system
Intracardiac echocardiography
Binding sites volume
Imaging

ABSTRACT

Background/objectives: Binding sites are the principal cause of failed lead removal and complications, and are not directly visualized by fluoroscopy. We aimed to assess binding sites between permanent cardiac pacing leads and cardiovascular structures using CartoSound™ three-dimensional (3D) imaging technology (Biosense Webster Inc., Diamond Bar, CA) during transvenous lead extraction, and compared outcomes to standard approach.
Methods: We recruited 291 patients undergoing percutaneous lead extraction, and 3D CartoSound anatomical mapping of the superior vena cava, right atrium (RA), coronary sinus, right ventricle (RV), pacing leads, and binding sites before, during, and after lead removal was randomly performed in 46 of them (38 men; mean age 73.7 ± 10.5 years; 1.96 leads/patient; mean time-from-implant of 62.7 ± 51.8 months) using a 10-Fr 3D SoundStar™ catheter and integrated into the Carto® mapping system.
Results: CartoSound was able to detect more intracardiac binding sites compared to fluoroscopy (RA 17.4% vs. 4.3%, $p = 0.04$; RV 43.5% vs. 21.7%, $p = 0.04$), but was unable to assess the subclavian/innominate veins. Binding sites volume correlated positively with time-from-implant ($r = 0.38$, $p < 0.05$), and powered-sheath use ($r = 0.39$, $p < 0.05$), and negatively with procedural success ($r = -0.37$, $p < 0.05$). When compared to standard approach, CartoSound use was characterized by a significantly lower mean procedure time ($p = 0.0001$), major complications ($p = 0.03$), and greater procedure success rates ($p = 0.03$).
Conclusions: Real-time 3D binding sites assessment is feasible and improves transvenous lead extraction outcomes. Its role as a complementary information requires extensive validation, and might be beneficial for a tailored strategy.

1. Introduction

Cardiac permanent pacing lead extraction procedures are increasingly performed [1–3], but only when benefits of removal outweigh significant procedural risks [4]. Binding sites between leads and the cardiovascular structures are the principal cause of partial or failed removal and complications. Determining the degree of fibrosis could help stratify perioperative challenges. Transvenous manipulation and extracting tools may disrupt scarred binding sites along the lead and tear it off the cardiovascular wall under X-ray monitoring. However, fluoroscopic imaging is unable to visualize binding sites other than by absent lead movement during manual traction throughout the procedure and to detect in a timely manner major complications [5]. There is currently a lack of routinely used imaging modality to stratify challenging procedures.

Recently, turbulent flow in the superior vena cava (SVC) using color-Doppler echocardiography demonstrated to be a noninvasive method to identify lead fibrosis and complex lead extraction procedures [6].

Two-dimensional (2D) intracardiac echocardiography (ICE) proved to be an effective alternative real-time modality to assist lead removal and improve procedure efficacy and safety by its ability to visualize fibrotic binding sites [7]. Three-dimensional (3D) CartoSound™ Module integrates real-time 2D ICE imaging into the Carto® electroanatomic

Abbreviations: 2D, two-dimensional; 3D, three-dimensional; ECG, electrocardiogram; ICE, intracardiac echography; MR, magnetic resonance; RA, right atrium; RV, right ventricle; SVC, superior vena cava; TEE, transesophageal echocardiogram.

☆ Conflicts of interests: None.
☆☆ Disclosures: None.
★ Grant support: None.

* Corresponding author at: Electrophysiology Section, Cardiology Department, Umberto I Hospital, Sapienza University of Rome, Viale del Policlinico 155, 00161 Rome, Italy.
E-mail address: epbbnguyen@gmail.com (B.L. Nguyen).

[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

http://dx.doi.org/10.1016/j.ctrsc.2015.08.006

Table 1
Patient clinical and lead characteristics.

	CartoSound	Fluoroscopy	p
Patients	46	245	NA
Pacing leads	90	409	NA
Leads per patient	1.96	1.67	0.009
Mean age, y-o ± SD	73.7 ± 10.5	72.4 ± 11.9	0.4
Men, %	82.6 (38/46)	68.7 (169/245)	0.07
Mean time-from-implant, months ± SD	62.7 ± 51.8	52.3 ± 106.1	0.5
Lead location, %			
• right atrium	44.4 (40/90)	42.1 (172/409)	0.7
• right ventricle	48.9 (44/90)	50.9 (208/409)	0.8
• coronary sinus	6.7 (6/90)	7.1 (29/409)	1
High voltage coil, %	13.3 (12/90)	16.1 (66/409)	0.6
Lead fixation, %			
• active	42.2 (38/90)	37.9 (155/409)	0.4
• passive	57.8 (52/90)	62.1 (254/409)	0.4

NA: not applicable.

mapping system environment (Biosense Webster Inc, Diamond Bar, CA), enhancing visualization and confidence during electrophysiology procedures for cardiac arrhythmias [8].

We hypothesized that a 3D imaging of binding sites, and knowing their volume and relationships to pacing leads and cardiovascular structures during lead extraction would help procedural outcomes. We sought to assess the feasibility and safety of this technique and compared it to standard approach.

2. Methods

2.1. Study population

We recruited a total of 291 patients undergoing percutaneous lead extraction at our Institution between September 2011 and May 2015. Forty-six of them were blindly and randomly (1:6) assigned to undergo 3D CartoSound anatomical mapping during the procedure. Patients were referred for pacemaker and implantable cardioverter-defibrillator lead removal class IB indication (all cardiac device infections) and pre-operatively examined according to current guidelines [9]. The research protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki and was approved by the Institutional Review Board, and written informed consent was obtained from all patients before removal.

2.2. Pre-procedural examination and preparation

Cardiac implantable electronic device removal was performed in the cardiac electrophysiology laboratory under local anesthesia or sedation. Cardiothoracic surgery stand-by was available. Surface 12-lead electrocardiogram (ECG) was monitored, cutaneous defibrillation pads were applied, transvenous temporary pacing was placed in the right ventricular (RV) apex (RVA) through a femoral vein when required, and arterial blood pressure with pulse oximetry monitoring was available during the procedure.

2.3. CartoSound registration

The 3D CartoSound Module and 10-Fr 3D SoundStar™ catheter integrate real-time 2D ICE imaging into the Carto system environment. The latter is a non-fluoroscopic cardiac mapping system that ensures precise real-time tracking of catheter tip location by means of a tipped miniature magnetic field sensor, electrode patches attached to the body surface with magnetic sensors, and an external ultra-low magnetic field emitter under the catheterization table. A processing unit receives data from the sensors on the amplitude, frequency and phase of the magnetic fields emitted allowing determination of the precise location and orientation of the catheter tip, as previously described [8]. The SoundStar probe tip 3D location and direction is established by the incorporated tipped miniature magnetic field sensor and an ultrasound linear phased-array AcuNav™ ICE catheter platform (multifrequency 5–10 MHz, 64-element, pulsed and colorDoppler ultrasound, tissue penetration ≤10 cm, 4-way head articulation). Real-time 90° cross-sectional images (30 frames/s) were recorded by a dedicated console (ACUSON Cypress™, Siemens AG, Malvern, PA). Three-second segments of 2D ultrasound images were acquired during ECG gating and displayed within the Carto coordinate workspace. Complete integrated 3D CartoSound anatomical maps were created immediately before, during, and shortly after lead removal.

The SoundStar catheter was gently advanced from the inferior vena cava via a femoral vein under fluoroscopic monitoring. A “standard view” was obtained with the probe tip in the mid-right atrium (RA) facing anteriorly. In each patient, several 2D-slice sections of the SVC, RA, RV, coronary sinus, tricuspid valve, pacing leads, and binding sites were acquired from catheter manipulation to create the 3D CartoSound anatomical maps. Each 2D image was optimized by adjusting tissue resolution and penetration, and displayed on the system's “Ultrasound Viewer,” from which the endocardial surface contour was identified and traced automatically or overwritten by hand if necessary on the basis of echo-intensities at the blood-tissue interface. High echo-intense areas at blood-tissue interface were assigned as binding site areas by the operator. Each surface contour was stored to delineate planar-shaped series of anatomic mapping points. By repeating this process, a family of chamber contours were interpolated into a complete volume rendering, that were displayed on the Map Viewer within the Carto x, y, and z coordinates, that accurately showed a color-coded

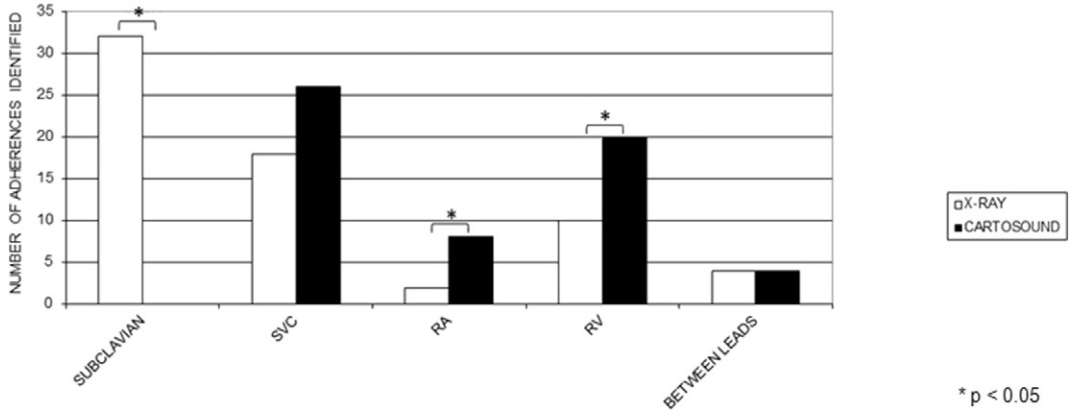

Fig. 1. Number of binding sites identified by fluoroscopy (X-ray) and CartoSound imaging at various cardiovascular locations. Between leads = between multiple pacing leads; RA = right atrium; RV = right ventricle; Subclavian = subclavian vein; SVC = superior vena cava.

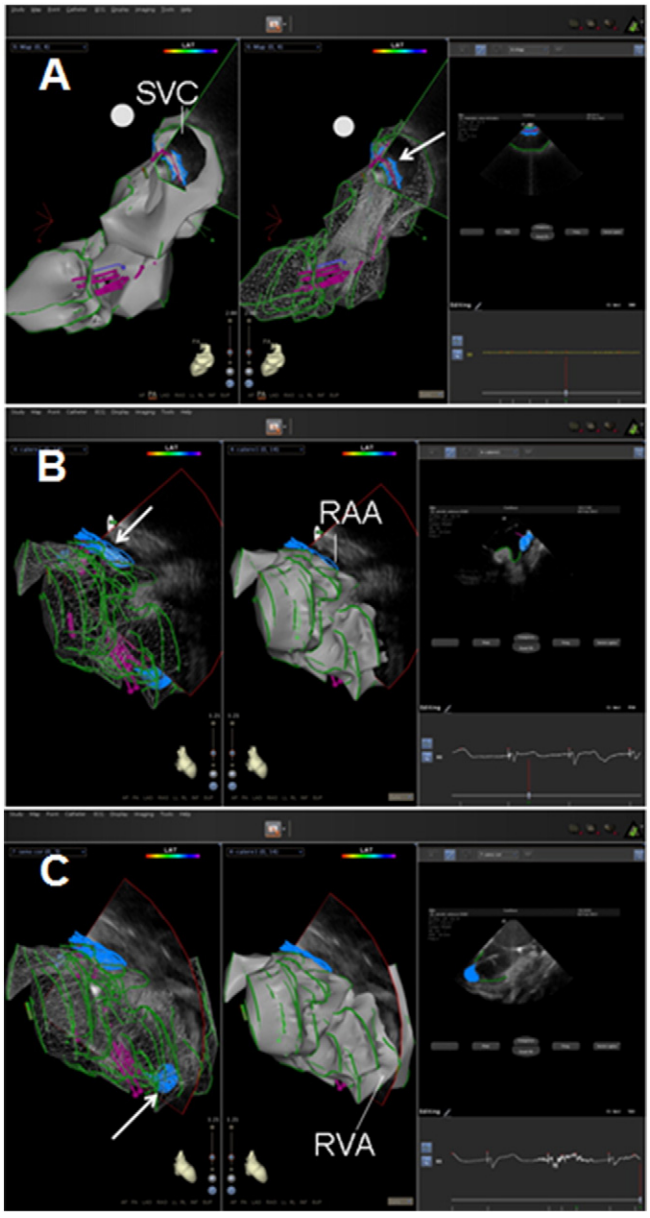

Fig. 2. CartoSound 3D anatomical mapping of the SVC, RA, and RV showed by the map viewer (left and mid panels) from real-time ICE images showed by the ultrasound viewer (right panels). Multiple endocardial contours (mesh) of the SVC, RA, RV borders (in green), catheters (multiple red lines), and binding sites (in blue, white arrows) are manually drawn. Panel A: PA view of binding sites located in the SVC; Panel B: RAO view of binding sites located at the SVC-RA junction/RAA roof; Panel C: RAO view of binding sites located at the RVA. ICE = intracardiac echocardiography; PA: posterior–anterior; RAA = right atrial appendage; RAO: right anterior oblique; RVA = right ventricular apex; RV = right ventricle; SVC = superior vena cava.

map, with multiple lead lines assigned as "floating" colored in red, the binding sites colored in blue, and manually delimitated for volume calculation. Shortly after lead removal, possible sites of pericardial effusion, and tricuspid valve morphology and function were assessed using the color-Doppler function. Possible pulmonary embolism was assessed using pulse oximetry and Computed Tomography scan.

CartoSound evaluation time was defined as the time since 3D map creation to the 3D assessment of binding sites.

2.4. Lead extraction procedure

Leads were removed mainly via the implant vein, none were removed using the jugular approach [5]. Leads were freed from adhesions down to the insertion site, secured with ties of silk suture around the insulation, and visually examined by fluoroscopy in their intravascular segment. Fluoroscopic identification of intracardiac binding sites was defined as absent lead movement during manual traction throughout the procedure. Transvenous lead extraction was performed manually with or without the assistance of traction devices and other devices used to disrupt fibrous tissue from the lead [10]. Gentle manual traction of the lead was first attempted. Subsequently, locking stylets were introduced into the central lumen of the inner coil and anchored in its most distal part as far as possible (Lead Locking Device 1, 2, and EZ LLD™, Spectranetics®, Colorado Springs, CO) to uniformly increase lead body tensile strength and aid traction near the tip. Non-powered and powered telescoping dissecting sheaths were also used to dissect binding sites [11]. Mechanical sheaths (7-Fr or 11-Fr polypropylene or Teflon, Byrd, Cook® Medical Inc, Bloomington, IN) allowed blunt dissection through adhesions to free the lead body from the vascular wall. Laser sheaths used an energy source to break down adhesions (12-Fr, 14-Fr or 16-Fr Laser Sheath SLS® II, Spectranetics Corp). At its distal tip, the layer of spirally wrapped optical fibers produce a single ring of pulsed excimer laser light, and was activated as fibrotic binding sites were encountered. Maneuvers and safety precautions were adopted as previously described [5,11,12]. Femoral extraction tools and snares were adopted in case the lead was no longer accessible from the original venous entry site or for lead fractures or fragments. In the CartoSound group, the 3D imaging results of the binding sites were used to modify the lead extraction technique. Laser sheaths were used when at least one binding site volume was above 1.0 cm^3. Procedural outcomes and complications were defined according to recommendations [4,9]. Extraction time was defined as the time since the start of traction or dilation to lead removal. Procedure time was defined as the time since local anesthesia to lead removal including 3D CartoSound assessment.

2.5. Statistical analysis

Continuous variables were expressed as mean ± standard deviation. Categorical data were expressed as percentages. Possible relationships between continuous variables were determined using a Pearson correlation coefficient whereas categorical variables were correlated using Wilcoxon rank-sum test (SPSS software v13, SPSS Inc., Chicago, IL). Student paired *t* test was used to evaluate the clinical significance where p values <0.05 were considered statistically significant.

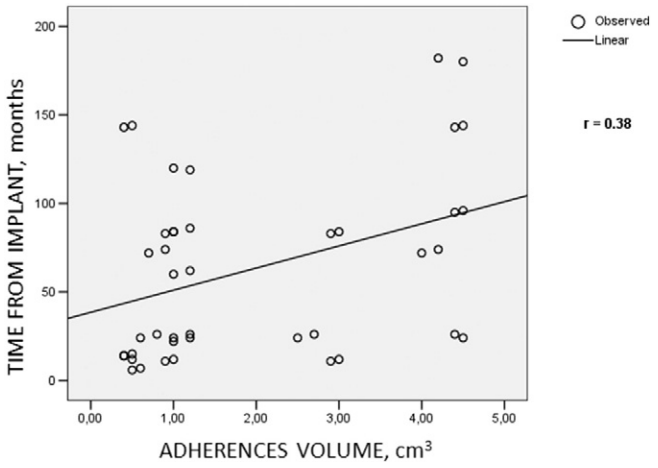

Fig. 3. Correlation between binding sites volume and time from implant of pacing leads. The scatter diagram shows the relation between the binding sites volume at the time of CartoSound evaluation during lead extraction and the time from implant of the leads. As shown, the volume of binding sites quantified by CartoSound imaging is associated with the time from lead implantation.

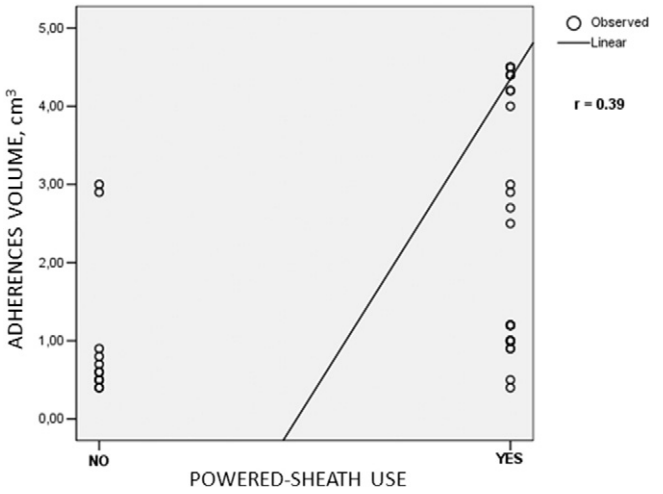

Fig. 4. Correlation between powered-sheath use and binding sites volume. The scatter diagram shows the relation between powered-sheath use during transvenous lead extraction and the binding sites volume at the time of CartoSound evaluation. As shown, the use of powered-sheaths is associated with the volume of binding sites quantified by CartoSound imaging.

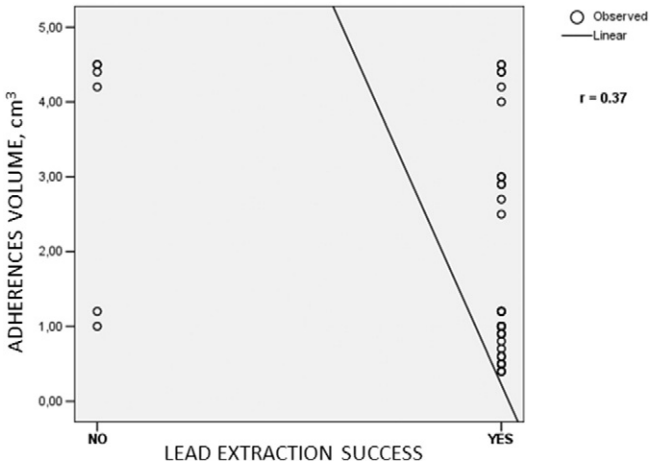

Fig. 5. Correlation between lead extraction success and binding sites volume. The scatter diagram shows the relation between procedural lead extraction success and the binding sites volume at the time of CartoSound evaluation indicating a negative correlation. As shown, the procedural success is inversely associated with the volume of binding sites quantified by CartoSound imaging.

3. Results

3.1. Patient clinical and lead characteristics

Data are summarized in Table 1. Over a cohort of 291 patients, 245 underwent lead extraction using a standard approach, and 46 (38 men, mean age 73.7 ± 10.5 years) underwent the procedure using CartoSound 3D binding sites volume assessment. Leads had been implanted for a mean period of 62.7 ± 51.8 months (median 60 months, range 7–180 months). A total of 90 leads (1.96 leads/patient) were explanted during 3D binding sites volume evaluation.

3.2. Procedural lead extraction and CartoSound characteristics

The number of 2D CartoSound slices acquired for anatomical map reconstruction were 5.2 ± 1.8 for the SVC, 7.9 ± 2.1 for the RA, and 9.9 ± 2.3 for the RV. CartoSound 3D maps were completed in all patients, providing qualitative, quantitative, and localization information on the binding sites of leads to anatomical structures.

3.3. Pacing lead assessment

Pacing leads were visualized in all patients as circular (transversal view) or linear (longitudinal view) depending on the probe position and lead direction, and color-coded in red. The system was also able to easily distinguish between free-floating leads or leads adherent to the venous wall or to the endocardium. Lead course was followed clearly to the myocardial insertion site of its tip.

Table 2
Procedural outcomes.

	CartoSound	Fluoroscopy	p
In-hospital major complications, %	0 (0/46)	2 (5/245)	0.03
Success, %	93.5 (43/46)	80.4 (197/245)	0.03
Procedure time (min), mean ± SD	30.1 ± 23.2	90 ± 34	0.0001
X-ray exposure time (min), mean ± SD	15.6 ± 19.3	24.2 ± 10	0.0001
2D ICE imaging acquisition time (s), mean ± SD	17.6 ± 11.2	NA	NA
3D CartoSound imaging evaluation time (min), mean ± SD	4.9 ± 2.3	NA	NA

NA: not applicable.

3.4. 3D binding sites assessment

Binding sites location assessment using CartoSound and fluoroscopy are summarized in Fig. 1.

Binding sites were visualized as echo-intense structures along the lead, often highlighted by a linear ultrasound shadow, and color-coded in blue. Scar tissue was usually present at the site of lead binding site to the venous wall or to the endocardium. CartoSound was able to detect binding sites in the SVC in 56.5% (Fig. 2, Panel A), RA in 17.4% (Fig. 2, Panel B), RV in 43.5% (Fig. 2, Panel C), and between leads in 8.7% of the cases. The subclavian/innominate venous region was not easily reachable with the currently available CartoSound probe and registration was not performed.

On the other hand, fluoroscopy assessment identified lead binding sites to the cardiovascular system by a reduced movement on X-ray during the cardiac cycle at the venous subclavian entry site in 69.6% ($p = 0.0001$), SVC in 39.1% ($p = 0.1$), RA in 4.3% ($p = 0.04$), RV in 21.7% ($p = 0.04$), and between leads in 8.7% ($p = 1$ vs. CartoSound, respectively) of the cases (Fig. 1).

The mean volume of binding sites was 2.0 ± 1.6 cm^3. Based on CartoSound findings, 3D binding sites volume correlated positively only with the time from implant as a clinical variable ($r = 0.38$, $p < 0.05$, Fig. 3).

3.5. Procedural lead extraction technical characteristics

Powered-sheath use correlated positively with 3D binding sites volume identified by CartoSound imaging ($r = 0.39$, $p < 0.05$, Fig. 4), and with the time from lead implantation ($r = 0.34$, $p < 0.05$).

3.6. Procedural outcomes

Data are summarized in Table 2. Procedural outcomes using 3D binding sites volume assessment are listed. Mean procedure time of 30.1 ± 23.2 min, and X-ray exposure time of 15.6 ± 19.3 min were all significantly lower compared to standard approach (90 ± 34 min, $p = 0.0001$; 24.2 ± 10 min, $p = 0.0001$, respectively). Mean 3D CartoSound evaluation time was 4.9 ± 2.3 min, with a mean time to obtain a 2D ICE image of 17.6 ± 11.2 s. Procedural success rate improved using 3D CartoSound imaging compared to standard approach (93.5% vs. 80.4%, $p = 0.03$, respectively), and correlated negatively with the volume of binding sites identified ($r = -0.37$, $p < 0.05$, Fig. 5).

No major procedure-related complications occurred, as opposed to standard approach (2%, p = 0.03, 3 deaths, 2 cardiovascular avulsions requiring drainage).

4. Discussion

To our knowledge, this is the first description of a 3D binding sites volume assessment using a cardiac mapping system during chronically implanted cardiac pacing lead extraction. The advancement of extracting tools under X-ray aims to disrupt scar tissue along the lead and tear it off the cardiovascular wall and is hampered by binding sites. Fluoroscopy is limited by the inability to: distinguish venous and myocardial walls and confirm that the sheath follows an intravascular course; detect dangerous venous and cardiac wall displacements during sheath advancement such as vessel torsion or myocardial invagination; visualize binding sites; promptly detect potential life-threatening complications [5]. With expanding indications for cardiac device implantation, dealing with the challenges of chronically implanted leads removal has also increased. Since there may be a correlation between the degree of fibrosis and procedure complexity, assessing binding sites could help stratify perioperative risk. There is currently a lack of routinely used imaging modality to stratify challenging procedures. Ultrasound imaging modalities have been evaluated to assist lead extraction. Turbulent flow in the SVC using color-Doppler echocardiography predicts lead fibrosis and complex lead extraction procedures [6].

Transesophageal echocardiogram (TEE) is logistically difficult as it requires the presence of an anaesthesiologist and an Echo operator [13]. A mechanical rotational 2D ICE 360° probe (Ultra ICE™, Boston Scientific Corp, Boston, MA) was successfully used to guide lead removal [6]. Two-D ICE is commonly used as an alternative to TEE for a number of cardiac interventional procedures [14], and monitor acute procedure-related complications. It requires additional 10-Fr sheath femoral venous access, and increased costs, offset by the use of local anesthesia, and shows several advantages in terms of fluoroscopy and procedure time, patient's discomfort, and hospital stay [15,16]. However, 2D ultrasound suffers from the known operator-dependent limitations, and from being a technology with a limited field-of-view, therefore not providing information on leads and binding sites in the 3D space. The introduction of non-fluoroscopic electro-anatomical mapping systems improved cardiac electrophysiology procedures efficacy and safety. Real-time 3D ultrasound-derived CartoSound geometries [8,17,18] benefit from the integration of 2D phased-array ultrasound images into the 3D electromagnetic database of a mapping system to improve spatial resolution, and real-time tracking. We used this 3D technology for the first time to carefully look for attachments to pacing leads and to different anatomical structures, and assess their volume.

Our findings suggest that CartoSound 3D anatomical mapping is feasible during chronically implanted pacing lead extraction. This technology better identifies intracardiac binding sites compared to fluoroscopy, and was able to assess their volume, that correlates positively with time from implant and powered-sheath use, and negatively with procedural success. We also confirmed a positive correlation between the use of powered-sheaths and time from implant, as previously reported [19]. Since binding sites are not directly detectable by fluoroscopy other than absent lead movement during manual traction throughout the procedure, information provided by 3D anatomical mapping, in addition to clinical data [20], might be helpful in stratifying procedural risks and planning the most appropriate procedural approach.

In our limited experience, 3D binding sites volume assessment improved procedural outcomes compared to standard approach, in terms of lower procedure time, X-ray exposure time, major complications and greater procedure success despite the lead/patient ratio was significantly greater in these subjects. CartoSound assessment did not affect procedure time and X-ray exposure time that were similar to prior reports [12]. We suspect that this imaging technique could potentially decrease overall surgery and X-ray time with experience, but further studies are warranted to prove these benefits. Cardiac pacing lead extraction is considered a high-risk procedure. Risk reduction depends primarily on avoidance and early identification of potentially life-threatening cardiovascular complications, such as severe local bleeding, cardiac dysfunction, and embolization. Technological efforts to overcome these limitations are warranted.

4.1. Study limitations

This is a single-center experience. Multi-center studies are required to better define the role of 3D binding sites assessment during lead extraction. Possible correlations, such as between binding sites volume and patient or lead characteristics, were beyond the scope of our study and remain to be done. In addition, we did not compare this method with other ultrasound imaging techniques, nor did we compare it for adhesions detection with magnetic resonance (MR), since it was beyond the scope of this study, and the explanted devices were not MR-conditional. Further studies are needed to compare this new technique with other technologies, especially with the recently implanted MR-conditional devices.

This method is potentially limited by its operator-dependency as the high echo-intense areas are manually assigned, and by the inability to screen the subclavian/innominate venous region, common binding sites and difficult areas to cross the transvenous sheaths. In fact, as opposed to the intracardiac locations, ICE imaging of the lead-scar-tissue interface at venous sites is often confounding and difficult to accurately characterize and trace bindings sites because: 1) the layer of fibrous scar binding the lead to the vascular wall is usually very thin, 2) the images quality immediately adjacent to the leads is very poor due to the metal-induced artifact from lead conductors and high-voltage coils, especially in the opposite side from the ICE transducer.

Several other technologies, such as 3D ICE and 3D TEE [21,22], as well as 4D ICE [23] are under evaluation and may provide new clinical information not possible with current 2D imaging catheters. Because of the imaging challenges at the lead-scar-tissue interface, technology improvements might allow the assessment of these venous regions so important for frequent occlusion and difficulty of crossing with extraction sheaths. Moreover, future extracting tools might have ring electrodes on them to be visualized and tracked on the 3D mapping system and help direct the manipulation over the identified binding sites.

5. Conclusions

Real-time 3D binding sites volume assessment using CartoSound anatomical mapping is feasible and may provide incremental information during chronically implanted pacing lead extraction. Its role as a complementary imaging tool to increase challenging procedures outcomes requires extensive validation. Knowing more about binding sites volume and morphology might be beneficial for a tailored strategy and could help stratify perioperative risk. Large multi-center randomized controlled trials are required to allow a change in routine clinical practice.

Acknowledgments

We thank Fabrizio Piergentili for his assistance.

Authors substantial contributions

Bich Lien Nguyen, MD, PhD: research concept/design, data analysis/interpretation, manuscript drafting, approval of the final manuscript version.

Alessandro Persi, MD: data analysis/interpretation, drafting the paper, approval of the final manuscript version.

Eli S Gang, MD: analysis or interpretation of data, critical revision and approval of the final manuscript version.

Fabrizio Fattorini, MD: data collection/interpretation, drafting the paper, approval of the final manuscript version.

Alessandra Oliva, MD: data collection/interpretation, drafting the paper, approval of the final manuscript version.

Antonio Vitarelli, MD: research design, drafting the paper, approval of the final manuscript version.

Nicola Alessandri, MD: research design, critical revision and approval of the final manuscript version.

Robert J Siegel, MD: research design, critical revision and approval of the final manuscript version.

Antonio Ciccaglioni, MD: research design, data acquisition, critical revision and approval of the final manuscript version.

Carlo Gaudio, MD: data interpretation, fundings, critical revision of the manuscript, approval of the final manuscript version.

References

[1] Baddour LM, Epstein AE, Erickson CC, et al. Update on cardiovascular implantable electronic device infections and their management: a scientific statement from the American Heart Association. Circulation 2010;121:458–77.

[2] Maytin M, Love CJ, Fischer A, et al. Multicenter experience with extraction of the Sprint Fidelis implantable cardioverter defibrillator lead. J Am Coll Cardiol 2010;56:646–50.

[3] Tracy CM, Epstein AE, Darbar D, et al, American College of Cardiology Foundation, American Heart Association Task Force on Practice Guidelines, Heart Rhythm Society. 2012 ACCF/AHA/HRS focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. Circulation 2012;126(14):1784–800.

[4] Wilkoff BL, Love CJ, Byrd CL, et al. Transvenous lead extraction: heart rhythm society expert consensus on facilities, training, indications, and patient management. Heart Rhythm 2009;6:1085–104.

[5] Wilkoff BL, Byrd CL, Love CJ, et al. Pacemaker lead extraction with the laser sheath: results of the pacing lead extraction with the excimer sheath (PLEXES) trial. J Am Coll Cardiol 1999;33:1671–6.

[6] Yakish SJ, Narula A, Foley R, Kohut A, Kutalek S. Superior vena cava echocardiography as a screening tool to predict cardiovascular implantable electronic device lead fibrosis. J Cardiovasc Ultrasound 2015;23(1):27–31.

[7] Bongiorni MG, Di Cori A, Soldati E, et al. Intracardiac echocardiography in patients with pacing and defibrillating leads: a feasibility study. Echocardiography 2008; 25(6):632–8.

[8] Okumura Y, Hens BD, Johnson SB, et al. Three-dimensional ultrasound for image-guided mapping and intervention. Circ Arrhythm Electrophysiol 2008;1:110–9.

[9] Love CJ, Wilkoff BL, Byrd CL, et al. Recommendations for extraction of chronically implanted transvenous pacing and defibrillator leads: indications, facilities, training. North American Society of Pacing and Electrophysiology Lead Extraction Conference Faculty. Pacing Clin Electrophysiol 2000;23:544–51.

[10] Kennergren C, Schaerf RH, Sellers TD, et al. Cardiac lead extraction with a novel locking stylet. J Interv Card Electrophysiol 2000;4:591–3.

[11] Wazni O, Epstein LM, Carillo RG, et al. Lead extraction in the contemporary setting: the Lexicon study. J Am Coll Cardiol 2010;55:579–86.

[12] Bordachar P, Defaye P, Peyrouse E, et al. Extraction of old pacemaker or cardioverter defibrillator leads by laser sheath versus femoral approach. Circ Arrhythm Electrophysiol 2010;2:319–23.

[13] Endo Y, O' Mara JE, Weiner S, et al. Clinical utility of intraprocedural transesophageal echocardiography during transvenous lead extraction. J Am Soc Echocardiogr 2008; 21(7):861–7.

[14] Ferguson JD, Helms A, Mangrum JM, et al. Catheter ablation of atrial fibrillation without fluoroscopy using intracardiac echocardiography and electroanatomic mapping. Circ Arrhythm Electrophysiol 2009;2:611–9.

[15] Ali S, George LK, Das P, Koshy SK. Intracardiac echocardiography: clinical utility and application. Echocardiography 2011;28:582–90.

[16] Stec S, Zaborska B, Sikora-Frac M, Kryński T, Kułakowski P. First experience with microprobe transoesophageal echocardiography in nonsedated adults undergoing atrial fibrillation ablation: feasibility study and comparison with intracardiac echocardiography. Europace 2011;13:51–6.

[17] Kautzner J, Peichl P. 3D and 4D echo-applications in EP laboratory procedures. J Interv Card Electrophysiol 2008;22:139–44.

[18] Dong J, Calkins H, Solomon S, et al. Integrated electroanatomic mapping with three-dimensional computed tomographic images for real-time guided ablations. Circulation 2006;113:186–94.

[19] Jones IV SO, Eckart RE, Albert CM, Epstein LM. Large, single-center, single-operator experience with transvenous lead extraction: outcomes and changing indications. Heart Rhythm 2008;5(4):520–5.

[20] Dalal A, Asirvatham SJ, Chandrasekaran F, Seward JB, Tajik AJ. Intracardiac echocardiography in the detection of pacemaker lead endocarditis. J Am Soc Echocardiogr 2002;15:1027–8.

[21] Gao G, Penney G, Ma Y, et al. Registration of 3D trans-esophageal echocardiography to X-ray fluoroscopy using image-based probe tracking. Med Image Anal 2012; 16(1):38–49.

[22] Koolwal AB, Barbagli F, Carlson CR, Liang DH. A fast slam approach to freehand 3-D ultrasound reconstruction for catheter ablation guidance in the left atrium. Ultrasound Med Biol 2011;37(12):2037–54.

[23] Lee W, Griffin W, Wildes D, et al. A 10-Fr ultrasound catheter with integrated micromotor for 4-D intracardiac echocardiography. IEEE Trans Ultrason Ferroelectr Freq Control 2011;58(7):1478–91.