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MINIREVIEWS

Influence of hospital volume and outcomes of adult structural heart procedures

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Abstract

Hospital volume is regarded amongst many in the medical community as an important quality metric. This is especially true in more complicated and less commonly performed procedures such as structural heart disease interventions. Seminal work on hospital volume relationships was done by Luft *et al* more than 4 decades ago, when they demonstrated that hospitals performing > 200 surgical procedures a year had 25%-41% lower mortality than those performing fewer procedures. Numerous volume-outcome studies have since been done for varied surgical procedures. An old adage "practice makes perfect" indicating superior operator and institutional experience at higher volume hospitals is believed to primarily contribute to the volume outcome relationship. Compelling evidence from a slew of recent publications has also highlighted the role of hospital volume in predicting superior post-procedural outcomes following structural heart disease interventions. These included transcatheter aortic valve repair, transcatheter mitral valve repair, septal ablation and septal myectomy for hypertrophic obstructive cardiomyopathy, left atrial appendage closure and atrial septal defect/patent foramen ovale closure. This is especially important since these structural heart interventions are relatively complex with evolving technology and a steep learning curve. The benefit was demonstrated both in lower mortality and complications as well as better economics in terms of lower length of stay and hospitalization costs seen at high volume centers. We present an overview of the available literature that underscores the importance of hospital volume in complex structural heart disease interventions.

Key words: Hospital volume; Transcatheter mitral valve repair; Septal ablation; Septal myectomy; Transcatheter aortic valve repair; Left atrial appendage closure

Core tip: Hospital volume is regarded amongst many in the medical community as an important quality metric. This is especially true in more complicated and less commonly performed procedures such as structural heart disease interventions. We present an overview of the available literature that underscores the importance of hospital volume in complex structural heart disease interventions including transcatheter aortic valve repair, transcatheter mitral valve repair, septal ablation and septal myectomy for hypertrophic obstructive cardiomyopathy, left atrial appendage closure and atrial septal defect/patent foramen ovale closure.

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INTRODUCTION

Hospital volume is regarded amongst many in the medical community as an important quality metric. The patients are unlikely to be in a position to choose between hospitals when it comes to emergent procedures. However, in case of non-emergent procedures, volume might be an important quality measure that could guide hospital selection by patients or referring physicians. This is especially true in more complicated and less commonly performed procedures such as structural heart disease interventions. Compelling evidence from a slew of recent publications has highlighted the role of hospital volume in predicting superior post-procedural outcomes following structural heart disease interventions[1,2]. This benefit was demonstrated both in lower mortality and complications as well as better economics in terms of lower length of stay (LOS) and hospitalization costs seen at high volume centers. To address this possible relationship of hospital volume and outcomes of structural heart disease procedures, we performed the search on PubMed and Medline with the following key words: Hospital volume, transcatheter aortic valve repair (TAVR), transcatheter mitral valve repair (TMVR), septal ablation (SA) and septal myectomy for hypertrophic obstructive cardiomyopathy (HOCM), left atrial appendage closure and atrial septal defect (ASD)/patent foramen ovale (PFO) closure and included all the studies with the above key words. We present an overview of the available literature that underscores the importance of hospital volume in complex structural heart disease interventions.

VOLUME-OUTCOME RELATIONSHIP

Seminal work on hospital volume relationships was done by Luft *et al*[3] more than 4 decades ago, when they demonstrated that hospitals performing > 200 surgical procedures a year 25%-41% lower mortality than those performing fewer procedures. Numerous volume-outcome studies have since been done for varied surgical procedures[4-7]. Certain agencies such as the Leapfrog group based in Washington DC have also made attempts to lay down minimal hospital volume requirements for various surgical procedures as a part of quality control[8]. The participating employers can use incentives to motivate their employees to get healthcare in institutions meeting these volume requirements[8]. Such standards for structural heart disease interventions are however not well defined partly because of the novelty of these procedures with lack of substantial evidence regarding volume-outcome relationship.

An old adage "practice makes perfect" indicating superior operator and institutional experience at higher volume hospitals is believed to primarily contribute to the volume outcome relationship[9]. This is further associated with evolution in the process of healthcare, with higher volume hospitals more likely to have better finances to develop more robust standards of care and infrastructure[8]. Hospital volume is thus believed by some to be a surrogate for possibly superior operator experience and availability of better ancillary support[9]. Selective referral with migration of lower risk patients to higher volume hospitals could also provide a healthier patient bias for such institutions[8]. Indeed, physicians might be inclined to refer their patients for elective procedures to larger hospitals with higher procedural volume leaving low volume institutions with more emergent procedures.

TAVR

Following its approval, TAVR has rapidly evolved into a sought-after service with an increasing number of centers offering this structural intervention. However, TAVR program entails extensive resource utilization in terms of physician and ancillary manpower and other operational needs that newer lower volume centers might struggle with. A complex procedure such as TAVR should be per-

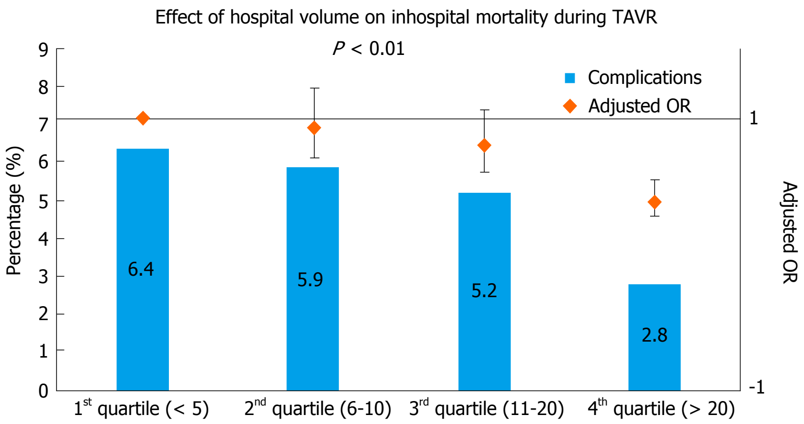

Figure 1 Effect of annual hospital volume on in-hospital mortality and procedural complication during transcatheter aortic valve repair. TAVR: Transcatheter aortic valve repair; OR: Odds ratio.

formed in specialty valvular heart disease centers lead by multidisciplinary heart valve teams. As of today, there is paucity of any evidence-based data to formulate clinical competency guidelines for TAVR. As per a sole consensus document[10], TAVR procedures can be introduced in centers that perform > 1000 catheterizations/400 percutaneous coronary interventions (PCIs) annually with TAVR interventionalists who have performed 100 structural procedures over their lifetime or at least 30 left-sided structural procedures per year. Likewise for surgical support, a minimum institutional annual volume of 50 aortic-valve replacements is recommended with surgeons who have completed 100 valve replacements over their career, with at least 10 considered high risk[10].

Previous literature on surgical valve replacement has highlighted the importance of institutional volume in predicting post-procedural outcomes[11]. Intuitively, one can reason that a similarly complex, percutaneous valve replacement procedure would also have superior results in higher volume institutions. In a recent analysis from Nationwide Inpatient Sample (NIS), we found hospital volume to be significantly predictive of lower in-hospital mortality following TAVR[12] (Table 1 and Figure 1). When compared to patients treated in lowest quartile of hospital volume, adjusted OR of in-hospital mortality in the highest quartile of hospital volume was 0.38 (0.27-0.54, $P \leqslant 0.001$). Increasing hospital volume was also independently predictive of shorter LOS and lower hospitalization costs (Table 1 and Figure 2). A separate spline analysis confirmed the significant hospital volume and outcome relationship with the predicted probability of in-hospital mortality dropping with increasing hospital volume.

TMVR/MITRACLIP

The Centers for Medicare and Medicaid (CMS) in their proposal to cover reimbursement for TMVR/Mitra-clip have laid down some operator and institutional requirements. The institution must have had ≥ 25 total mitral valve procedures in the previous year of which at least 10 must be mitral valve repairs. In addition, there should have been ≥ 1000 catheterizations per year performed in that institution, including ≥ 400 PCIs per year. The individual operator should have had ≥ 50 structural procedures per year including ASD and PFO and trans-septal punctures. Besides, it also mandates a comprehensive multi-disciplinary heart team comprised of various cardiologists, surgeons and strong ancillary support along with device-specific training as required by the manufacturer.

The National Institutes of Health in United Kingdom have minimal volume requirements for surgical mitral valve repair[13]. This is considered especially vital due to low volume of this procedure and many low volume centers perform mitral valve replacement more frequently in degenerative MR where mitral valve repair is strongly recommended[13]. Again, TMVR is a relatively new procedure with a steep learning curve and will need further studies to appraise specific volume requirements for involved operators and institutions. A more detailed competency guideline is expected in the forthcoming SCAI/AATS/ACC/STS Multisocietal Consensus Statement: Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement: Part 3: Mitral Valve[13]. In another analysis from NIS (Abstract presented as poster presentation at American Heart Association Scientific Sessions 2014, Chicago, IL), we noted the highest hospital volume tertile to be significantly predictive of lower in-hospital mortality and post-procedural complications following TMVR compared to the lowest volume tertile (OR = 0.12, 95%CI: 0.06-0.23, $P < 0.001$) (Table 2 and Figure 3A). The predicted probability of mortality and complications was noted to decrease with increasing hospital volume on an additional spline analysis.

HOCM: SA, SEPTAL MYECTOMY

ACCF/AHA HOCM guideline recommends that an operator be labeled experienced in SA only after he/she has performed > 20 procedures in a facility with a cumulative volume of > 50 procedures[14]. However, given the low overall volume of SA, the maintenance of competency requires an annual operator volume of only 5 ablations with no comment on institutional volume[14].

Table 1 Multivariate regression for different outcomes during transcatheter aortic valve repair

Variable	Multivariate simple logistic regression for mortality		Multivariate simple logistic regression for any complications and mortality		Multivariate simple logistic regression for LOS (LOS ≥ 6 d)		Multivariate simple logistic regression for disposition of transfer to short-term hospital/other facilities/home health care	
	OR (95%CI)	*P*-value	OR (95%CI)	*P*-value	OR (95%CI)	*P*-value	OR (95%CI)	*P*-value
Hospital volume quartile								
1st quartile	1	Referent	1	Referent	1	Referent	1	Referent
2nd quartile	0.92 (0.70-1.21)	0.550	0.86 (0.76-0.99)	0.029	0.82 (0.71-0.94)	0.004	1.06 (0.91-1.23)	0.451
3rd quartile	0.80 (0.60-1.06)	0.114	0.70 (0.61-0.80)	< 0.001	0.91 (0.80-1.05)	0.194	0.65 (0.56-0.75)	< 0.001
4th quartile	0.38 (0.27-0.54)	< 0.001	0.71 (0.62-0.82)	< 0.001	0.85 (0.74-0.98)	0.024	0.77 (0.66-0.90)	0.001
Access								
Transfemoral	1	Referent	1	Referent	1	Referent	1	Referent
Trans-apical	1.54 (1.17-2.03)	0.002	1.44 (1.26-1.64)	< 0.001	2.27 (1.96-2.63)	< 0.001	1.37 (1.18-1.60)	< 0.001
Age (10-yr increment)	1.26 (1.07-1.47)	0.005	0.97 (0.91-1.03)	0.316	1.07 (1.00-1.14)	0.051	1.57 (1.46-1.69)	< 0.001
Gender								
Male	1	Referent	1	Referent	1	Referent	1	Referent
Female	1.09 (0.89-1.36)	0.392	1.21 (1.11-1.33)	< 0.001	1.43 (1.30-1.57)	< 0.001	1.99 (1.79-2.21)	< 0.001
Charlson score								
0	1	Referent	1	Referent	1	Referent	1	Referent
1	1.29 (0.78-2.14)	0.321	1.13 (0.92-1.38)	0.236	1.23 (1.01-1.50)	0.038	1.40 (1.14-1.72)	0.002
≥ 2	1.60 (1.01-2.55)	0.047	1.73 (1.44-2.08)	< 0.001	2.02 (1.69-2.42)	< 0.001	1.72 (1.42-2.07)	< 0.001
Bed size of hospital								
Small	1	Referent	1	Referent	1	Referent	1	Referent
Medium	0.43 (0.28-0.67)	< 0.001	0.89 (0.70-1.15)	0.386	1.18 (0.91-1.52)	0.215	1.17 (0.88-1.56)	0.279
Large	0.42 (0.29-0.61)	< 0.001	0.73 (0.58-0.91)	0.005	1.36 (1.09-1.71)	0.007	1.23 (0.96-1.58)	0.103
Model 2								
Hospital volume quartile (5 procedures increment)	0.88 (0.83-0.93)	< 0.001	0.94 (0.92-0.95)	< 0.001	0.93 (0.91-0.95)	< 0.001	0.95 (0.94-0.97)	< 0.001
Model 3								
Hospital volume quartile (10 procedures increment)	0.77 (0.69-0.86)	< 0.001	0.87 (0.84-0.91)	< 0.001	0.87 (0.84-0.90)	< 0.001	0.91 (0.87-0.95)	< 0.001

LOS: Length of stay; OR: Odds ratio.

Nonetheless, volume remains one of the many factors required to achieve satisfactory post-procedural outcomes. In a retrospective analysis from NIS, we noted highest hospital volume tertile to be significantly predictive of lower post-procedural complications following SA upon multivariate adjustment (OR = 0.51, 95%CI: 0.26-0.98, P = 0.04). Parallel to septal myectomy, which has been shown to have excellent outcomes when performed at centers of excellence, SA is more likely to be better performed at centers with volume and resources to care for this unique patient population. Indeed, a recent study showed a higher overall in-hospital mortality and post-procedural complication rate following septal myectomy in the real world clinical practice than that reported from selected referral centers[15]. Although, a trend was seen towards higher institutional volume being associated with better outcomes, the final results were non-significant indicating a need for further studies (Table 3).

ASD/PFO CLOSURE

Some of the initial data suggested that ASD/PFO closure could be performed safely at low-volume hospitals[16]. Relative simplicity of ASD/PFO closure that shares some of the techniques with other, more commonly preformed percutaneous interventions[17] led some to believe that volume-outcome relationship might not hold true for this

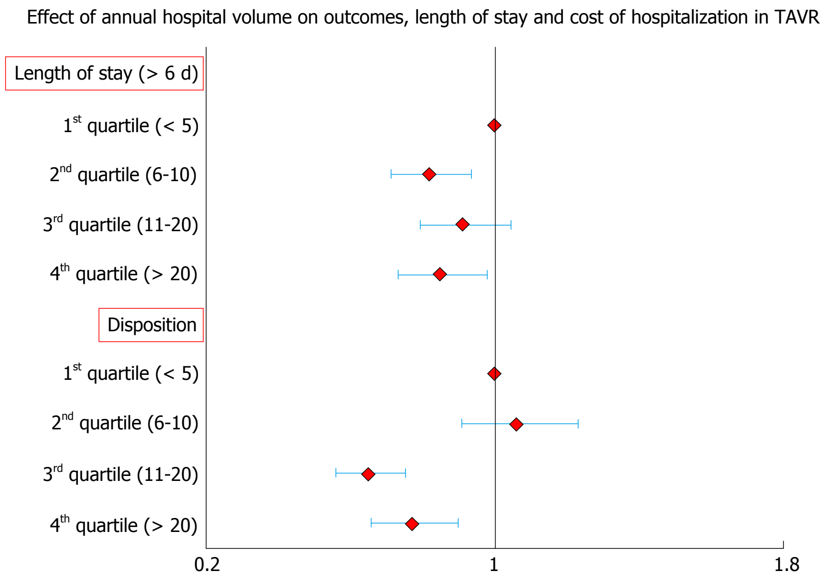

Figure 2 Effect of annual hospital volume on length of stay and cost of hospitalization in transcatheter aortic valve repair. TAVR: Transcatheter aortic valve repair.

Table 2 Multivariate predictors of primary and secondary outcomes for patients who underwent transcatheter mitral valve repair

Variable	OR (95%CI)	*P* value
Hospital volume tertile		
1st tertile	1	Referent
2nd tertile	0.23 (0.12-0.41)	0.177
3rd tertile	0.12 (0.06-0.23)	< 0.001

OR: Odds ratio.

procedure. The current ACC/AHA/SCAI guidelines recommend a minimal annual volume of > 10 ASD/PFO closure procedures for maintenance of catheterization laboratory proficiency. However, these guidelines also note the lack of sufficient evidence based data for this recommendation.

Opotowsky *et al*[18] showed the inverse hospital volume outcome relationship in an early study from the NIS database. In another study that included a larger sample size, an absolute risk reduction of 4.6% was noted when procedures were performed at hospitals with an annual procedural volume > 10[1]. An additional absolute risk reduction of 2.1% was further noticed if procedures were performed at hospitals with an annual volume > 25 indicating a need for possible revision of competency guidelines. Furthermore nearly 30% of the hospitals performing ASD/PFO closures were observed to be below the recommended threshold of 10 annual procedures (Figure 3B and C and Table 3).

LAA CLOSURE, ENDOVASCULAR STENTING OF ADULT COARCTATION

A recent study by Badheka *et al*[2] showed higher hospital volume to be inversely associated with better post-procedural outcomes as well as lower hospitalization costs and shorter LOS[2] (Figure 4 and Table 4). Hospitals with and annual volume cut-off of > 18 procedures had post-procedural complication rate, which compared favorably with trial data. This study added evidence to inverse operator volume-outcome relationship seen in the CAP registry[19]. Further studies are again needed to determine volume thresholds and lay down minimal competency requirements.

The use of stenting for adult aortic coarctation has been on the rise given the literature on favorable initial and intermediate outcomes. In a retrospective analysis, we observed significantly lower rate of post-procedural complications in hospitals performing more than 3 procedures annually (9.5% *vs* 23%, *P* = 0.002) including a lower rate of vascular complications (9.5% *vs* 20.6%) (Figure 5). Adjusted OR of post-procedural complications in hospitals with annual volume of 3 or more procedures was 0.40 (0.19-0.82, *P* = 0.013). These were further complemented by lower hospitalization costs at higher volume hospitals.

LIMITATIONS OF USING HOSPITAL VOLUME

A volume based referral strategy is not without its limitations. This could restrict the entry of newer hospitals in a highly competitive medical field, which might actually provide contractual leverage to bigger hospitals with potential cost inflation. A procedure-based strategy always has the danger of leading to inappropriate procedures by operators and institutions. Again, in order to keep up higher volumes, many institutions may forego quality improvement activities. Besides, low volume centers play an integral role in healthcare by catering to smaller communities especially in rural areas and in pre-tertiary care. The benefits of selective referral to high

Table 3 Hospital volume and primary outcome, length of hospital stay > 2 d, and predictor of highest quartile of cost of care (> $17160) following atrial septal defect/patent foramen ovale closure: Multivariate adjusted model

	Primary outcome		Length of stay		Cost of care	
	OR (95%CI)	*P* value	OR (95%CI)	*P* value	OR (95%CI)	*P* value
Hospital volume (*n* of procedure per yr)						
1st tertile (< 14)	Referent		Referent		Referent	
2nd tertile (14-37)	0.73 (0.57-0.93)	0.013	0.50 (0.36-0.69)	< 0.001	0.72 (0.49-1.07)	0.104
3rd tertile (> 37)	0.67 (0.48-0.94)	0.019	0.37 (0.24-0.57)	< 0.001	2.55 (1.54-4.20)	< 0.001

Three levels hierarchical mixed effects models were generated (patient level factors nested within hospital level factors) with the unique hospital identification number incorporated as random effects. Primary outcome (*n* = 6328) was adjusted for age, sex, Deyo's modification of Charlson Comorbidity Index, Median Household income, primary payer, hospital teaching status, emergent/urgent admission, weekend admission, Intracardiac Echocardiography use during procedure and hospital volume. In length of stay > 2 d (*n* = 6302) and predictors of highest quartile of cost (> 17160 $) (*n* = 5389), we included all variables in primary outcome. Hospital volume were calculated based on the unique hospital identification number on year to year basis. OR: Odds ratio.

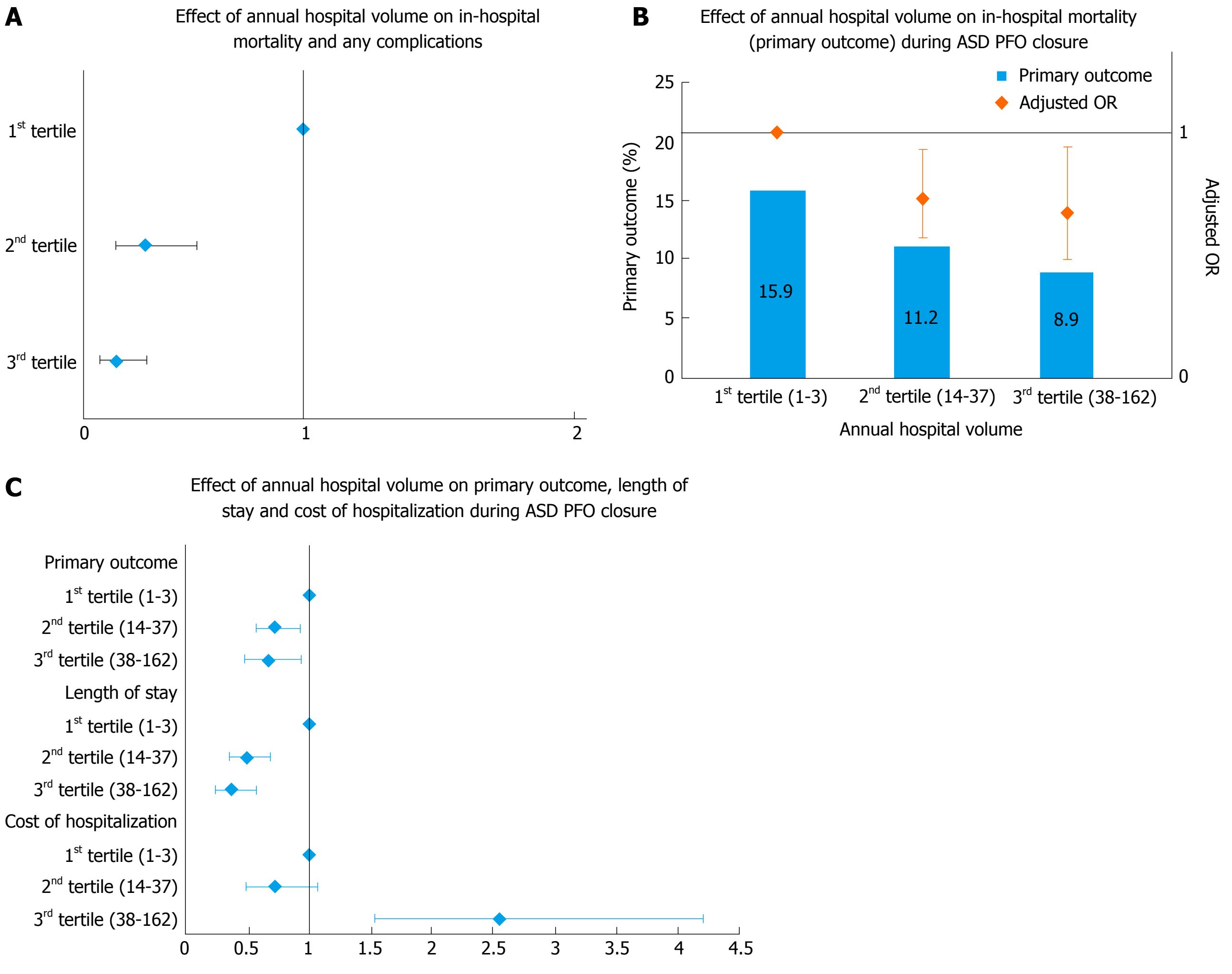

Figure 3 Effect of annual hospital volume. A: On primary and secondary outcome during transcatheter mitral valve repair; B: On in-hospital mortality (primary outcome) during atrial septal defect/patent foramen ovale closure; C: On primary outcome, length of stay and cost of hospitalization during atrial septal defect/patent foramen ovale closure. ASD: Atrial septal defect; PFO: Patent foramen ovale; OR: Odds ratio.

volume centers thus must be weighed against a potential lack of access to healthcare resulting from regionalization. However, most of the emerging structural heart disease interventions are elective procedures that could justify transfer to higher volume centers.

Some authors have also suggested the role of operator volume and experience in contributing towards effect of institutional volume on outcomes. Indeed, some studies studying outcomes of surgical procedures have shown that the institutional-volume relationship might be non-significant once operator volume is accounted for. Nonetheless, other studies have also demonstrated persistent hospital volume outcomes relationship even after adjusting for operator volume. Additionally, hospital

Table 4 Multivariate regression for different outcomes left atrial appendage closure

Any procedural complication or death (*n* = 264)	OR with 95%CI	*P* value
Hospital annual LAA closure volume (per unit increase)	0.89 (0.85-0.94)	< 0.001
Length of stay (*n* = 258)	HR	*P* value
Hospital annual LAA closure volume (per unit increase)	0.95 (0.92-0.98)	< 0.001
Cost of hospitalization (*n* = 250)	Estimate ($)	*P* value
Hospital annual LAA closure volume (per unit increase)	0.96 (0.93-0.98)	< 0.001

LAA: Left atrial appendage; OR: Odds ratio.

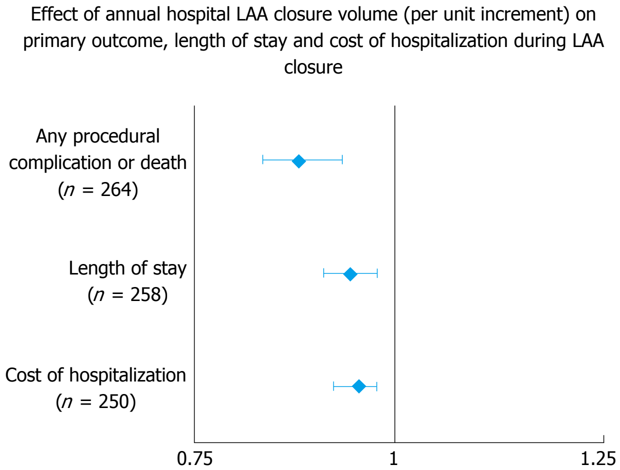

Figure 4 Effect of annual hospital left atrial appendage closure volume (per unit increment) on primary outcome, length of stay and cost of hospitalization during left atrial appendage closure. LAA: Left atrial appendage.

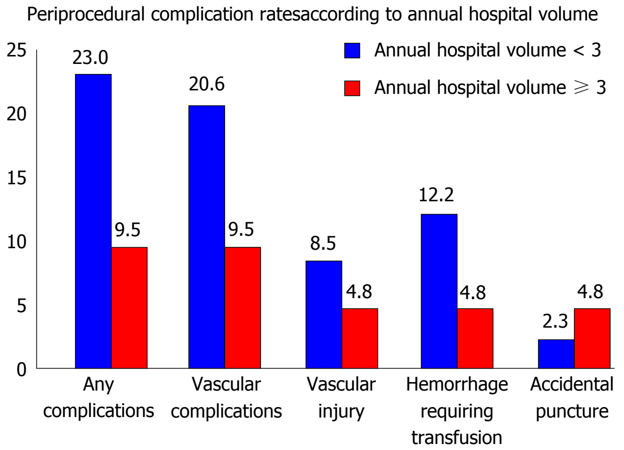

Figure 5 Peri-procedural complication rates according to annual hospital volume.

complexity in terms of range of services and technological provided can be responsible for improved outcomes as shown in a prior study by McCrum *et al*[20] and thus findings of retrospective studies should be interpreted with caution. But in the absence of detailed information on the quality of surgical procedures at a particular hospital, high hospital volume remains a valid contributor in reducing surgical mortality[21].

FUTURE DIRECTIONS

Hospital volume cannot be used as a sole quality metric since many low volume centers are known to provide safe and efficient healthcare. It is important to appraise the factors that result in superior outcomes in a subset of low-volume hospitals and further develop programs that allow other hospitals to adopt such practices. Development of newer structural heart programs with their multidisciplinary heart valve teams have lead to improved outcomes of surgical procedures in these hospital irrespective of annual procedural volume. This was demonstrated in recent analysis of improved outcomes of surgical aortic and mitral valve replacement in TAVR and TMVR capable centers respectively (abstract presented as poster presentation at SCAI 2015 Scientific Sessions, San Diego, CA). Risk-adjusted mortality rates, complication and readmission rates when considered together are some of the other important factors that can be used to assess quality of healthcare provided by different hospitals.

It has been previously demonstrated that a high coronary intervention volume does not translate into superior structural heart disease interventions outcomes[22]. Moreover, the procedural volume requirements are difficult to apply to structural disease interventions since these complex, highly specialized interventions are performed in much lower numbers. This further lends support for amendments in training requirements with a focus on procedure specific training with variable proctoring and use of simulators, in depth knowledge of the field besides annual volume recommendations. Additionally, a standardized process of certification and maintenance based on outcomes needs to be developed[20]. A plausible option is the evolution of umbrella training wherein trainees could have the opportunity to rotate through different hospitals and gain knowledge about best clinical practices.

CONCLUSION

Hospital volume is indeed a genuine predictor of post-procedural outcomes. This is important in the current era of expanding structural heart disease interventions, which are relatively complex with evolving technology and a steep learning curve. However, other quality metrics should also be accounted for in order to avoid labeling any good low-volume hospitals as underperformers. Further studies are mandatory to study the volume-outcome relationship for multiple emerging structural interventions since current data on many such interventions is either extrapolated from other procedures or based on consensus rather than evidence.

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MINIREVIEWS

Collateral findings during computed tomography scan for atrial fibrillation ablation: Let's take a look around

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Abstract

The growing number of atrial fibrillation catheter ablation procedures warranted the development of advanced cardiac mapping techniques, such as image integration between electroanatomical map and cardiac computed tomography. While scanning the chest before catheter ablation, it is frequent to detect cardiac and extracardiac collateral findings. Most collateral findings are promptly recognized as benign and do not require further attention. However, sometimes clinically relevant collateral findings are detected, which often warrant extra diagnostic examinations or even invasive procedure, and sometimes need to be followed-up over time. Even though reporting and further investigating collateral findings has not shown a clear survival benefit, almost all the working groups providing data on collateral findings reported some collateral findings eventually coming out to be malignancies, sometimes at an early stage. Therefore, there is currently no clear agreement about the right strategy to be followed.

Key words: Collateral findings; Incidental findings; Incidentalomas; Cardiac computed tomography; Image integration

Core tip: Several cardiac computed tomography (CT) scans are performed worldwide in order to better delineate left atrial anatomy before atrial fibrillation (AF) ablation. A thorough examination of the entire field of view often discovers cardiac or extra-cardiac collateral findings, which might represent potentially malignant diseases. Early detection of such diseases may guarantee a curative treatment. Our objective is to consolidate the current literature about collateral findings detected at cardiac CT before AF ablation and to highlight the potential implications of systematically reporting and following up such findings.

Perna F, Casella M, Narducci ML, Dello Russo A, Bencardino G, Pontone G, Pelargonio G, Andreini D, Vitulano N, Pizzamiglio F, Conte E, Crea F, Tondo C. Collateral findings during computed tomography scan for atrial fibrillation ablation: Let's take a look around. *World J Cardiol* 2016; 8(4): 310-316 Available from: URL: http://www.wjgnet.com/1949-8462/full/v8/i4/310.htm DOI: http://dx.doi.org/10.4330/wjc.v8.i4.310

IMAGE INTEGRATION IN ATRIAL FIBRILLATION ABLATION

Cardiac computed tomography (CT) is being increasingly required for a large amount of indications, such as coronary artery disease, congenital heart disease, and detection of intracardiac thrombi[1]. It is also frequently performed among patients undergoing atrial fibrillation (AF) catheter ablation, in order to achieve three-dimensional reconstruction of the left atrium (LA), which is crucial for pre-procedural planning of the ablation strategy and accurate intra-procedural catheter navigation, especially in complex cardiac anatomies[2-4].

Pulmonary vein (PV) isolation has become a cornerstone in the treatment of AF, and may represent a first-line therapy in selected cases[5-8]. However, complicated LA or PV anatomy can make it extremely difficult to access some areas, thus contributing to suboptimal success rates and hindering the successful application of this technique[9,10]. Moreover, it has been ascertained that PV anatomic variations are fairly common[11-13]. Knowledge of the conventional pulmonary venous anatomy, as well as of anatomic variants, is crucial for preprocedural planning and safer catheter navigation. Fluoroscopy alone cannot differentiate between PVs, LA and surrounding structures. On this proposal, cardiac CT has gained acceptance, among cardiac electrophysiologists, as the preferred radiological investigation in order to precisely delineate LA and PV anatomy, because of its better diagnostic gain on intrathoracic organs and vessels as compared to other investigations, such as intracardiac echocardiography[14]; moreover, cardiac CT is more widely available than magnetic resonance, requires shorter scanning times and is better tolerated by patients[2-4,15]. These characteristics made cardiac CT the gold standard exam for image integration in AF ablation.

Cardiac CT performed for AF ablation is a chest CT angiography scan acquired using multidetector CT scanners with a field of view (FOV) which usually extends vertically from the level of the carina to the diaphragm. CT scan is generally not electrocardiographically (ECG)-gated, since a consistent part of the patients may be in AF during the examination. The absence of ECG-gating is the main difference between cardiac CT scan performed for AF ablation and for coronary artery disease, since synchronization with the ECG is necessary in order to investigate coronary arteries. Scan synchronization with the contrast medium is often performed with the bolus tracking technique, that is, injecting a bolus of radio-opaque contrast media into the patient *via* a peripheral vein, tracking the volume of contrast within a region of interest, and then following it with the CT scanner after it reaches that region. After imaging the left atrium, it is possible to build a volume rendering three-dimensional image of the structures of interest, which is imported in the electroanatomical mapping system workstation and segmented using an image processing software, in order to better distinguish the left atrium from the surrounding structures. Once the segmentation process is complete, the three-dimensional representation of the left atrium is displayed in the electroanatomical mapping system and is superimposed to the three-dimensional electroanatomical map created by the operator; the electroanatomical map and the CT image are aligned to each other in order to allow the operator to move the mapping catheter within the three-dimensional representation of the left atrium.

Image integration between the cardiac CT scan (performed before the ablation) and the electroanatomical LA map (obtained intraprocedurally), allows the operator to have a detailed roadmap of the actual patient's anatomy available during the ablation procedure. This is crucial for anatomic definition of ablation targets and precise catheter navigation throughout complex anatomies, as well as for limiting collateral damage to adjacent structures, such as the esophagus (lowering the risk of atrio-esophageal fistula)[16]. This technique is particularly useful while ablating difficult targets, such as the ridge of Marshall between the left-sided PVs and the left atrial appendage, in order to avoid ablating either inside the appendage (risk of perforation) or too deep inside the PVs (risk of PV stenosis) (Figure 1). Image integration systems have been shown to reduce procedural and fluoroscopy times, and even improve procedural outcomes, thus justifying their increased procedural costs[17-19].

COLLATERAL FINDINGS DETECTED BY CARDIAC CT FOR AF CATHETER ABLATION

Cardiac CT scan usually details only a small FOV strictly around the heart, although almost the entire chest is irradiated during image acquisition. A larger FOV is then available from the unprocessed data to examine the neighboring structures, such as lungs, breasts, mediastinum, spine, and upper abdomen, with no additional X-rays exposure. While examining the entire FOV of a cardiac CT, it is frequent to encounter cardiac or extra-cardiac collateral findings (CFs) during the imaging study (Figures 2 and 3). The term "collateral finding" reflects an incidentally discovered mass or lesion, detected by CT, magnetic resonance imaging, or other imaging modality, which is not related to the primary objectives of the

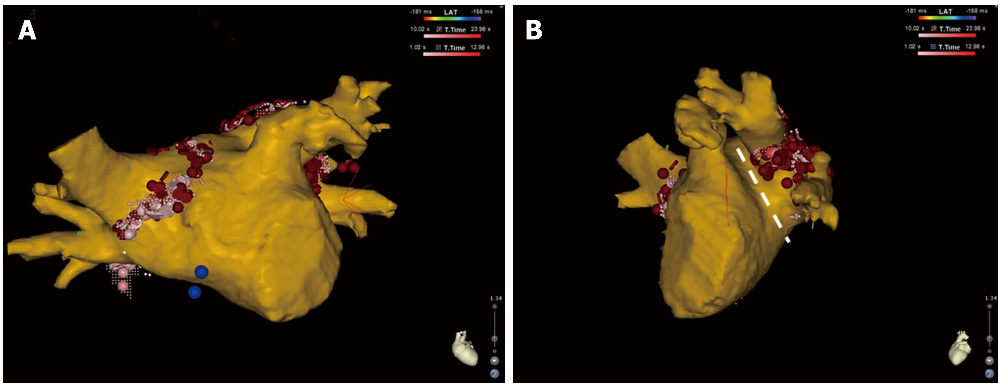

Figure 1 Antero-posterior (A) and left lateral (B) view of three-dimensional reconstruction of the left atrium and pulmonary veins after merging the cardiac computed tomography with the electroanatomical map created with the Carto 3 system (Biosense Webster, Inc., Diamond Bar, CA, United States). Note the ablation tags (red dots) placed around the pulmonary vein ostia on the computed tomography reconstruction. In the left lateral view, the narrow ridge between the left-sided pulmonary veins and the left atrial appendage can be appreciated (white dashed line).

examination; CFs are also called "incidental findings" or "incidentalomas"[20]. A collateral finding is considered "clinically significant" when its detection warrants further investigations or therapeutic measures, or causes a change in the patient management. Most encountered extra-cardiac CFs pertain to the lungs, particularly small (< 4 mm) pulmonary nodules. Other frequently met CFs are degenerative spine disease, aortic disease, swollen mediastinal or hilar lymph nodes, liver lesions.

On this basis, several working groups reported about the prevalence and clinical significance of such CFs during cardiac CT scans. The early reports mostly referred to CT studies performed in order to diagnose coronary artery disease, which is the main indication for cardiac CT scan[21-25]. The reported prevalence of CFs during 4 electron beam CT studies ranged between 7.8% to 53%, with 4.2% to 11% of scanned patients needing follow-up examinations; this wide range of prevalence can be explained by different technologies and definition of CFs used in those studies[26-29]. Along with the expanding indications for AF catheter ablation, there has been a parallel growth in the request of cardiac CT to depict LA and PV anatomy for image integration. As a consequence, some studies reporting CFs detected before AF ablation have been published (Table 1)[30-35].

Wissner *et al*[30] studied 95 patients undergoing PV isolation between 2003 and 2007 with a 16-slice and subsequently 64-slice multidetector scanner, covering an area from above the clavicle to diaphragm, and found that 53% of patients had either cardiac or extracardiac CFs. Most CFs were extracardiac (78 out of 83), and more than half (46 out of 83) were pulmonary. Fifteen patients (16%) needed additional tests, and 6 of them (6.8%) had therapeutic implications due to the detection of unexpected findings. One patient (1.1%) had an adenocarcinoma of the lung diagnosed, which was treated surgically[30].

Sohns *et al*[31] performed 64-slice multidetector CT of the chest and upper abdomen in 158 patients for identification of PV anatomy. They looked for extracardiac CFs only. A total of 198 extracardiac CFs were detected in 72% of patients, and 31% of patients had at least one clinically significant or potentially significant finding. Lung cancer was diagnosed in 2 patients (1.3%)[31].

The same group assessed the incidence of both cardiac and extracardiac CFs among an extended population of 224 AF patients. In 91% of patients an average of 3.2 cardiac findings per patient were discovered, while 619 extra-cardiac findings (2.8 per patient) were detected in 80% of patients. Thirty-two percent of the 619 extracardiac findings were classified as "clinically significant", including 2 cases of previously unknown cancers (esophageal and pulmonary, respectively; 0.9% of patients) and a newly diagnosed aortic dissection. The authors explained the relatively high incidence of extra-cardiac findings with the detailed image and the advanced age of their patients[32].

Schietinger *et al*[33] reached analogous conclusions, finding extra-cardiac CFs in 69% of patients, the majority being pulmonary, and clinically significant CFs in 24% of patients at ECG-gated multidetector CT for PV evaluation.

Martins *et al*[34] described a lower prevalence of CFs among 250 consecutive patients (23%). Half of the 76 CFs were pulmonary, including 2 lung cancers (0.8% of patients) and 2 pulmonary fibroses. Several findings led to specific disease management, but no focused follow-up was performed in order to get information about the impact of reviewing the entire FOV on patients' outcome[34].

Our group enrolled 173 patients referred for catheter ablation of AF. Fifty-six percent of the patients ha at least one CF, and 33% had clinically significant CFs warranting further follow-up or investigations. In 10% of them, the detection of a CF led to therapeutic decisions. Three cases of bronchogenic carcinoma were eventually diagnosed (1.7% of the study population)[35]. After publication of the study, two more cases of bronchogenic carcinoma were diagnosed during further follow-up chest CTs performed in patients with incidentally detected pulmonary nodules (unpublished data). All lung cancers detected among our patients were at a relatively early stage; therefore, curative treatment was possible in all the cases.

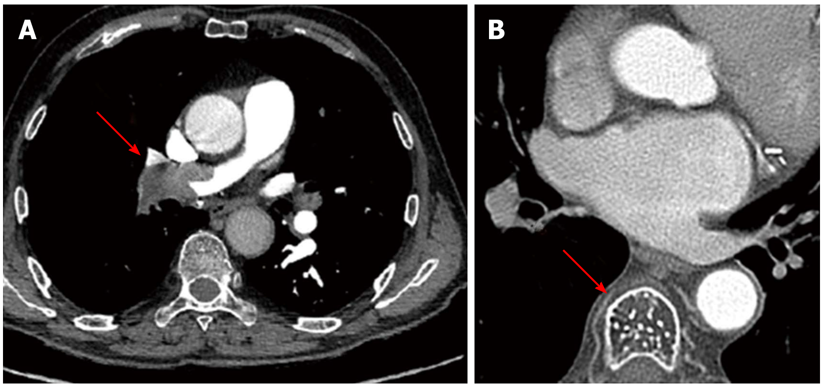

Figure 2 Examples of collateral findings detected with the preprocedural cardiac computed tomography. A: Pulmonary thromboembolism involving principal branch of right pulmonary artery (red arrow); B: Classic "polka dotted" appearance due to the thickened vertebral trabeculae, highly suspicious for vertebral hemangioma (red arrow).

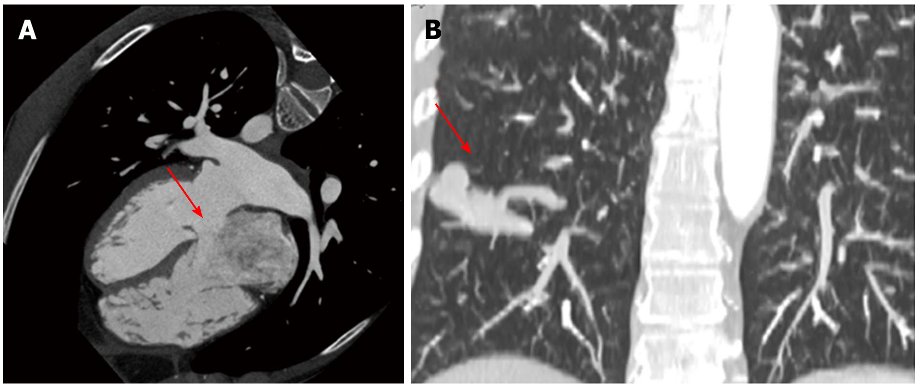

Figure 3 Examples of collateral findings detected with the preprocedural cardiac computed tomography. A: Ostium primum atrial septal defect (red arrow); B: Abnormal dilated vessels (red arrow) diagnostic for pulmonary arterovenous malformation located in the lower lobe of the right lung.

In summary, the proportion of patients with CFs is very high among the reported studies of cardiac CT performed for AF catheter ablation. Incidental findings requiring further investigations or follow-up are also quite frequent. Rather consistently, almost half of all collateral findings are represented by pulmonary nodules. Malignancy is diagnosed in a percentage ranging from 0% to 1.7% of patients.

REPORTING AND FOLLOWING UP COLLATERAL FINDINGS: AN OPEN DEBATE

Because of the large diffusion of AF catheter ablations, an increasing number of cardiac CT is being performed worldwide. The number of reported CFs is increasing, due to the growing number of cardiac CT performed and to the improved spatial resolution of the CT scanners. The main problem in reporting CFs is the subsequent flow of further investigations and procedures that are performed in order to rule out potentially deleterious pathologies. On the one hand, one should always keep in mind that in some cases, the detection of an early stage malignant disease might allow appropriate treatment and prolong or save a patient's life. However, to date robust data regarding the potential clinical benefits of reporting and following-up CFs is still lacking, and it has not been shown that reporting CFs may change the course of the disease or prolong survival, especially in the case of metastatic cancers or pathologies with an unpredictable natural history. The risk of undesirable effects carried by additional procedures, such as contrast medium-induced complications or the lifetime risk of ionizing radiation exposure-related cancer, must be kept in mind as well. This hinders the development of a widely accepted approach to such findings[36]. As a consequence, there is still disagreement about the appropriateness of reviewing and reporting extra-cardiac CFs during cardiac CT studies[37,38].

Once a CF is reported, there is also uncertainty about the decision to follow-up such findings over time. Some CFs are promptly deemed insignificant, that is, they do not require any additional examination. The dilemma about CFs follow-up arises when so-called "clinically significant collateral findings" are detected. While the anxiety for medico-legal implications from underreporting incidental findings would lead to describe and follow-up any lesion that is found in the FOV, some concern has been raised about increased financial burden in front of

Table 1 Studies about collateral findings detected at cardiac computed tomography performed for atrial fibrillation ablation

Ref.	*n* of pts	Mean age (yr)	Smoking history	Scanner	FOV	Collateral Findings, *n* (% of patients)	Cardiac (*n*)	Extracardiac (*n*)	Pulmonary (*n*)	Extra pulmonary (*n*)	Clinically significant	Malignancies
Wissner *et al*[30]	95	62 ± 10	45%	16- and 64-slice	Above clavicle to diaphragm	83 (53%)	5	78	46	37	16% of patients	1 (1.1%)
Sohns *et al*[31]	158	NR	NR	64-slice	Supraaortic region to the heart base and upper abdomen	198 (72%)	NR	198	47	151	31% of patients	2 (1.3%)
Sohns *et al*[32]	224	64 ± 10	38%	64-slice	Supraaortic region to the heart base and upper abdomen	1343	724	619	77	542	32% of extracardiac findings	2 (0.9%)
Schietinger *et al*[33]	149	55.9 ± 11	47%	16-slice	Aortic arch to diaphragm	110 (69%)	NR	102	70	32	24% of patients	0 (0%)
Martins *et al*[34]	250	55.2 ± 9.6	NR	64-slice	20-25 cm centered on the heart	58 (23%)	3	73	38	38	NR	2 (0.8%)
Casella *et al*[35]	173	59 ± 10	50%	64-slice	Carina to diaphragmatic domes	164 (56%)	14	150	74	90	33% of patients	3 (1.7%)

FOV: Field of view; NR: Not reported.

an unclear benefit while pursuing this strategy.

American guidelines on coronary artery imaging recommend a systematical review of extracardiac structures within the FOV during a CT scan, especially when risk factors for cancer exist[39]. Missing a malignant cancer, especially in a potentially curable stage, would have deleterious consequences for the patient, as well as potential medico-legal implications for the radiologist. The Fleischner Society and the American College of Radiology provided some recommendations about how to manage incidentally detected small pulmonary nodules[40] and abdominal incidentalomas[41].

The Early Lung Cancer Action Project evaluated 1000 asymptomatic smokers aged at least 60 years, finding pulmonary nodules in 23% of the patients; 12% of these patients with noncalcified pulmonary nodules had lung malignancies, which were mostly non detectable on chest radiography[42].

Nevertheless, it is still unclear whether the strategy of examining the entire FOV and reporting all CFs would be beneficial for the patients' clinical outcome. In fact, reporting all CFs translates into additional follow-up with potential further radiation exposure, increased costs and patients' anxiety, and sometimes, invasive procedures are needed in order to complete the follow-up. Most of those CFs are eventually found to be benign and have little or no clinical influence on patients' health. A large study provided a cost analysis of following-up such findings after CT scan for the screening of coronary heart disease[37]. Among 966 patients, 41.5% had extracardiac CFs. Additional diagnostic examinations required extra costs of 83.035 United States dollars. The authors concluded that reporting CFs did not provide a clear mortality benefit because CFs were not an independent predictor of noncardiac death. However, the authors did not report whether patients with a diagnosis of malignancy received life-saving or life-prolonging interventions, therefore it is not advisable to draw conclusions about difference in mortality between patients with and without CFs. Moreover, they used a too short mean follow-up (18 mo) to evaluate the course of potentially slow-progressing diseases. Sohns *et al*[32] estimated additional costs as high as about 42.543 United States dollars (190 United States dollars per patient) for subsequent diagnostic examinations (excluding invasive procedures) of incidentally detected extra-cardiac findings at cardiac CT before AF ablation. A clear clinical benefit was achieved in 1.1% of patients, however the authors did not attempt to investigate the potential clinical implications of such strategy.

Larger studies are warranted to understand the real impact on patients' outcome of CFs follow-up. In particular, a study randomizing patients with CFs to either further investigations or no follow-up would answer this question, if ethically viable.

In our opinion, on the basis of the potential detection of early stage cancers, until large studies analyze the cost-benefit ratio of such approach in a real-world scenario, the full set of abnormalities that are visible in the entire FOV should be reported, for ethical reasons. Obviously, once CFs are reported, smoking history, previous cancer, presence of first-degree relatives with history of cancer, or other known risk factors should be taken into account in the decision-making process of further follow-up.

CONCLUSION

The large number of cardiac CT performed for AF catheter ablation and the improved spatial resolution of modern CT scanners generates a huge number of serendipitously detected collateral findings (mostly extracardiac). Collateral findings are very frequently detected during cardiac CT studies, and a consistent proportion of them may require further investigations or follow-up. The optimal strategy to manage CFs is still debated, since most CFs are eventually found to be benign at the end of a diagnostic process which implies an increased financial burden and, in some cases, even some clinical risks for the patient. Moreover, a real clinical benefit of incidentally detecting malignant diseases has not been demonstrated. However, the risk of missing an early stage malignant disease should be considered while deciding whether reporting and following-up CFs or not. Almost all the studies published so far reported some malignant cancers, which could be treated after being serendipitously diagnosed by cardiac CT. We therefore advise a thorough inspection of the entire irradiated FOV, as well as a strict cooperation between cardiologists and radiologists for a comprehensive examination of cardiac CTs, in order to avoid missing important diseases in the examined FOV.

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ORIGINAL ARTICLE

Retrospective Study

Impact of computed tomography image and contact force technology on catheter ablation for atrial fibrillation

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Abstract

AIM: To investigate the impact of using computed tomography (CT) and contact force (CF) technology on recurrence of atrial tachyarrhythmia after atrial fibrillation (AF) ablation.

METHODS: This non-randomized study included 2 groups of patients. All patients had symptomatic recurrent paroxysmal or persistent AF and were treated with at least 1 anti arrhythmic medication or intolerant to medication. The first group included 33 patients who underwent circumferential pulmonary veins isolation (PVI) for AF during 2012 and 2013 guided by CT image integration (Cartomerge, Biosense Webster, Diamond Bar, CA, United States) of left atrium and pulmonary veins into an electroanatomic mapping (EAM) system (CT group) using standard irrigated radiofrequency catheter (ThermoCool, Carto, Biosense Webster, Diamond Bar, CA, United States) or irrigated catheter with integrated CF sensor (Smart Touch, Carto, Biosense Webster, Diamond Bar, CA, United States). The second group included immediately preceding 32 patients who had circumferential PVI by standard irrigated catheter (ThermoCool) using only EAM (Carto) system (EAM group). Linear lesions were performed according to the discretion of operator.

RESULTS: Sex, age, and persistent AF were not different between groups. PVI was achieved in all patients in both groups. Linear ablations including cavo-tricuspid isthmus and or roof line ablation were not different between groups. Free of atrial tachyarrhythmia during follow-up of 24 mo was significantly higher among CT group compared to EAM group (81% *vs* 55%; respectively; P = 0.027). When 11 patients from CT group who had ablation using Smart Touch catheter were excluded, the difference between CT group and EAM became non significant (73% *vs* 55%; respectively; P = 0.16). Sub analysis of CT group showed that patients who had ablation using Smart Touch catheter tend to be more free of atrial tachyarrhythmia compared to patients who had ablation using standard irrigated catheter during follow-up (100% *vs* 73%; respectively; P = 0.07). Major complications (pericardial effusion, cerebrovascular accident/transient ischemic attack, vascular access injury requiring intervention) did not occurred in both groups.

CONCLUSION: These preliminary results suggest that CT image integration and CF technology may reduce the recurrence of atrial tachyarrhythmia after catheter ablation for AF.

Key words: Atrial fibrillation; Catheter ablation; Image integration; Contact force

Core tip: The aim of this nonrandomized study was to determine the impact of integrating computed tomography (CT) image of left atrium into electroanatomical mapping (EAM) system and using of contact force (CF) technology on recurrence of atrial tachyarrhythmia after atrial fibrillation (AF) ablation. We found that combination of CT image integration into EAM and CF technology might reduce the recurrence of atrial tachyarrhythmia after catheter ablation for AF during follow-up period of 24 mo.

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INTRODUCTION

In treatment of symptomatic and drug refractory atrial fibrillation (AF), catheter-based pulmonary veins isolation (PVI) has been established as a standard procedure by using a single-tip ablation catheter for creating linear lesion surround ipsilateral pulmonary veins (PVs)[1]. Nevertheless, repeat procedures are required in a significant number of cases and recurrent PV conduction is responsible for most ablation failures in paroxysmal AF[2].

The durability of PVI and clinical outcome after radiofrequency (RF) ablation is affected by the contact force (CF) between the catheter tip and the tissue. Insufficient CF may result in an ineffective lesion, where as excessive CF may result in complications[3]. Catheter ablation using real-time CF technology was reported to be safe for the treatment of supraventricular tachycardia and AF[3]. In addition, understanding the anatomy of left atrium (LA) and PVs is essential for the safety and effectiveness of Procedure. Pre-procedural cardiac computed tomography (CT) helps to evaluate the three dimension (3D) and complex anatomy of LA and PVs[4].

We assume that integrating CT Image of LA/PVs into electroanatomical mapping (EAM) system and using CF technology may reduce the clinical recurrence of atrial tachyarrhythmia after ablation of AF.

MATERIALS AND METHODS

We summarized all patients who underwent circumferential PVI for AF during 2012 and 2013 guided by CT image integration into an EAM (Cartomerge, Biosense Webster, Diamond Bar, CA, United States) system (CT group). This group was compared to immediately preceding patients who had PVI using only EAM (Carto, Biosense Webster, Diamond Bar, CA, United States) system (EAM group).

All patients had symptomatic recurrent paroxysmal AF or persistent AF (less than 3 mo duration) who were treated with at least 1 anti arrhythmic drug (AAD) or intolerant to medication. All patients with paroxysmal AF were treated with IC AADs, and all patients with persistent AF were treated with amiodarone.

Ablation procedure

The procedure was performed during deep sedation with fentanyl and midazolam. Double trans-septal punctures were done with guidance of intra-cardiac echo (ICE): One for circular mapping catheter (Lasso, Biosense Webster, Diamond Bar, CA, United States) and one for ablation catheter.

The ablation catheter used was 3.5-mm standard externally - irrigated (ThermoCool, Carto, Biosense Webster, Diamond Bar, CA, United States) for all patients in EAM group and part of patients of CT group. Externally-irrigated Smart Touch catheter (ST, Carto, Biosense Webster, Diamond Bar, CA, United States) was used in the remaining patients of CT group (Figure 1). The Smart Touch catheter is capable of directly assessing CF and showing its absolute value and orientation by means of a 3D vector in real time during the procedure[5].

In the EAM group, wide circumferential ablation of ipsilateral veins pair at the antrum about 1 cm of veno-atrial junction was performed (Figure 1). The ostium and veno-atrial junction of each PV was identified by intra cardiac electrogram, dragging the ablation or Lasso catheter back under fluoroscopic guidance, and ICE. Isolation of each vein was confirmed by lasso catheter. In the CT group, the EAM was merged with 3D-anatomical chamber reconstructions of LA and PVs derived from pre procedure (up to 24 h) cardiac CT. Image integration

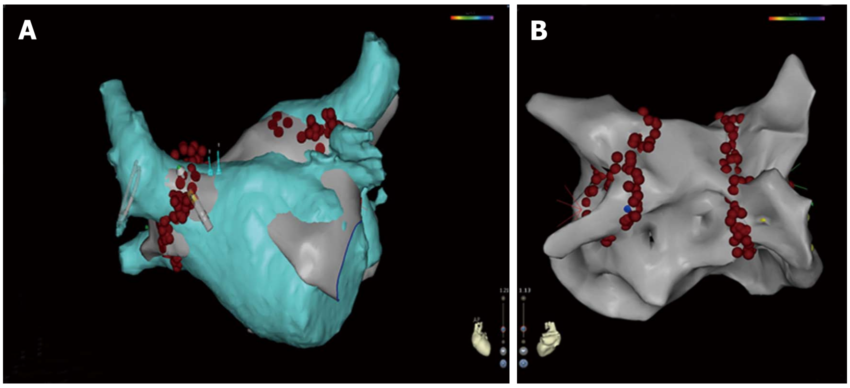

Figure 1 Carto screenshot during pulmonary veins isolation. A: Anterior-posterior view showing CT image of left atrium integrated into the electroanatomic map (CT group). The ablation in this case was performed using the Smart Touch catheter. The tip of the Smart Touch catheter is shown with 3D vector; B: Posterior-anterior view showing electroanatomic mapping (EAM group) of left atrium with ablation points around pulmonary veins. EAM: Electroanatomic mapping; CT: Computed tomography; 3D: Three dimension.

Table 1 Baseline characteristics

	EAM group (n = 32)	CT group (n = 33)	P
Sex (male)	19	24	0.3
Age (yr)	55 ± 8.8	56.7 ± 11.6	0.6
Persistent AF	5	4	0.7
CTI Ablation	7	7	0.76
Roof line ablation	8	8	0.77
Major complications	0	0	

EAM: Elecroantomic mapping; AF: Atrial fibrillation; CTI: Cavotricuspid isthmus; CT: Computed tomography.

is based on registration involving landmark points and surface alignment using the Cartomerge software as described previously[6] (Figure 1). The ablation was performed in similar way as in the EAM group by standard irrigated catheter or Smart Touch catheter. When Smart Touch catheter was used, ablation was done only when the force was at least 10 g (optimal range for ablation was considered as 10-40 g). We tried to deliver RF energy when the CF is > 10 g and is stable for at least 20 s.

RF energy was delivered at a maximum power of 25 W at a flow rate of 17 mL/min along the posterior wall, and at a maximum power of 35 W at a flow rate of 30 mL/min along the anterior wall and elsewhere in the atria. The maximum temperature was set at 43 ℃. RF ablation was continued at each site until local electrograms were abolished or for 30 s. Linear lesions including roof line and or cavo-tricuspid isthmus line were performed in some patients according to discretion of the operator. All the procedures in both groups were performed by 2 experienced operators.

All patients were followed in the outpatient clinic every 3 mo for 24 mo. Recurrence was defined as any clinical or documented atrial tachyarrhythmia lasts more 30 s after a blanking period of 3 mo. All patients were treated with anticoagulation for at least 3 mo. Anticoagulation was continued after 3 mo in high risk patients. AADs were stopped after 3 mo.

Statistical analysis

Variables are expressed as mean ± SD. Comparisons between groups were performed with Student's t test. Categorical variables expressed as numbers and percentages were compared with a χ^2 test. Kaplan - Meier survival curve was used for estimation of recurrence of atrial tachyarrhythmia during 24 mo follow-up. A P value < 0.05 was considered statistically significant. The statistical methods of the study were reviewed by biomedical statistician.

RESULTS

The EAM group included 32 patients, and the CT group included 33 patients. Baseline characteristics are similar (Table 1). The AF duration before ablation in both groups was 1-3 years.

Circumferential PVI with confirmation of isolation was performed in all patients in both groups. Cavotricuspid isthmus ablation was performed in the index procedure in 7 patients in the EAM group and in 7 patients in the CT group (P = 0.76). Roof line was performed in the index procedure in 8 patients in the EAM and in 8 patients in the CT group (P = 0.77) (Table 1).

All patients completed the 24 mo follow-up. Free of atrial tachyarrhythmia during 24 mo was significantly higher among CT group compared to EAM group (81% *vs* 55%; respectively; P = 0.027) (Figures 2-4). When 11 patients from CT group who had ablation using Smart Touch catheter were excluded, the difference became non significant (73% *vs* 55%; respectively; P = 0.16) (Figures 2 and 3).

Sub analysis of CT group showed that patients who had ablation using Smart Touch catheter tended to be more free of atrial tachyarrhythmia compared to patients who had ablation using standard irrigated catheter (100% *vs* 73%; respectively; P = 0.07) (Figure 3). Of note, all patients who had recurrence of atrial tachyarrhythmia had AF except 1 patient from CT group and 2 patients from EAM group who had atypical atrial flutter.

Major complications (pericardial effusion/tamponade,

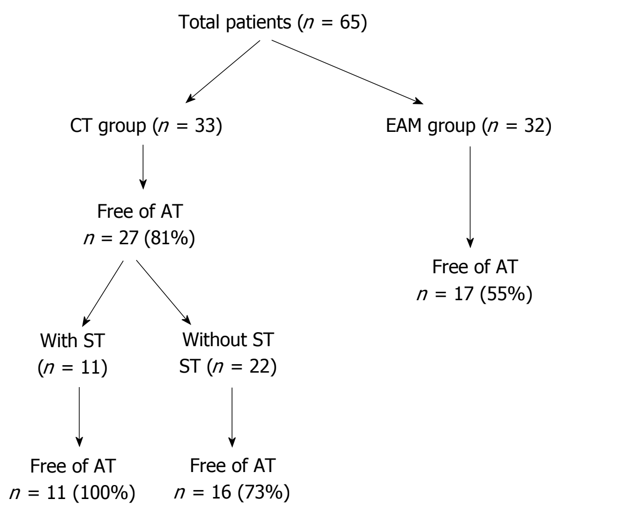

Figure 2 Flowchart reporting the different patient groups and the results. ST: Smart touch; AT: Atrial tachyarrhythmia; EAM: Electroanatomic mapping; CT: Computed tomography.

cerebrovascular accident/transient ischemic attack, and or vascular access injury requiring intervention) did not occur in both groups.

DISCUSSION

The main finding of this study was that ablation of AF guided by of CT image integration of LA/PVs into an EAM and the use of CF technology was associated with reduced recurrence of atrial tachyarrhythmia. CT image integration without CF technology was associated with non-significant reduced recurrence of atrial tachyarrhythmia. CF technology tended to reduce recurrence of atrial tachyarrhythmia among patients who underwent ablation of AF guided by of CT image integration.

Kistler *et al*[7] reported in a nonrandomized study that catheter ablation for AF guided by CT image integration (Cartomerge) was associated with reduced fluoroscopy times, arrhythmia recurrence, and increased restoration of sinus rhythm compared to a similar ablation strategy guided by a 3D mapping. Successful PV electrical isolation did not differ between the two groups. However, Kistler *et al*[8] reported in another study which was randomized study that CT image integration (Cartomerge) to guide catheter ablation for AF did not significantly improve the procedural and clinical outcome compared to EAM.

As we showed in our non-randomized study, CT image integration without CF technology was associated with non-significant reduced recurrence of atrial tachyarrhythmia compared to EAM. This result is in agreement with the randomized study of Kistler *et al*[8]. In addition, CF technology tended to reduce recurrence of atrial tachyarrhythmia among patients who underwent ablation of AF guided by CT image integration. Thus, it seems that the contribution of CF technology is significant.

In the TOCCATA study[9], patients with paroxysmal AF underwent PVI by using a RF ablation catheter with a different integrated CF sensor (TactiCath; Endosense, Geneva, Switzerland). The CF during catheter ablation for AF correlated with clinical outcome after 12 mo. Arrhythmia control is best achieved when ablation lesions were placed with an average CF of > 20 g, and clinical failure is universally noted with an average CF of < 10 g.

In the EFFICAS I multicenter study[10], a RF ablation catheter with integrated CF sensor (TactiCath; Endosense, Geneva, Switzerland) was used to perform PVI in patients with paroxysmal AF. At follow-up, an interventional diagnostic procedure was performed to assess gap location as correlated to index procedure ablation parameters. Minimum CF and minimum Force-Time Integral (FTI) values were strong predictors of gap formation. According to this study, optimal CF parameter recommendations are a target CF of 20 g and a minimum FTI of 400 g for each new lesion. In our study, we tried to keep the force at least 10 g at each site for at least 20 s until electrogram abolition or at least for 30 s.

Recently, Sciarra *et al*[5] studied 3 types of irrigated-tip ablation catheters. Sixty-three patients with paroxysmal AF underwent ablation by standard ThermoCool catheter, Smart Touch catheter, or Surround Flow catheter (Biosense Webster, Diamond Bar, CA, United States). The percentage of isolated PVs was comparable between groups. Both the Smart Touch catheter and the Surround Flow catheter significantly reduced radiofrequency and fluoroscopy times, as well as PVs reconnection rate at 30 min. Moreover, the Smart Touch catheter reduced overall duration of the procedure. However, the long term clinical significance of these results is not known.

We do not know the exact mechanism why combination of technologies is more useful. Image integration could improve clinical outcome because it helps to understand the 3D complex anatomy of LA/PV and appreciate the variant anatomy of PVs including common trunks or more than 4 veins. In addition, it could help to make the lesion set more precise. CF technology could lead to durable lesions. We think that the results of our study emphasized the fact that AF is a complex arrhythmia. The AF ablation is also a complex procedure with relatively high rate of recurrence due to PV reconnection. Many technologies were introduced to overcome this issue like steerable sheath[11]. Recently, a novel irrigated multi electrode mapping and ablation catheter (nMARQ catheter, Biosense Webster, Diamond Bar, CA, United States) was introduced for PVI with promising results[12]. However, there is no specific technology that is significantly more useful than others. We think, that combination of technologies rather than single one can lead to the best results as in this study. In addition centers and operators should choose the technologies according to their experience and according to the 3D anatomy of LA/PVs as detected by pre-procedure echocardiography, CT and or other modalities.

Limitations

This is a small non-randomized study comparing AF ablation using integrated CT/EAM with AF ablation using EAM only. We used two types of ablation catheters in the CT group, the standard irrigated catheter as in

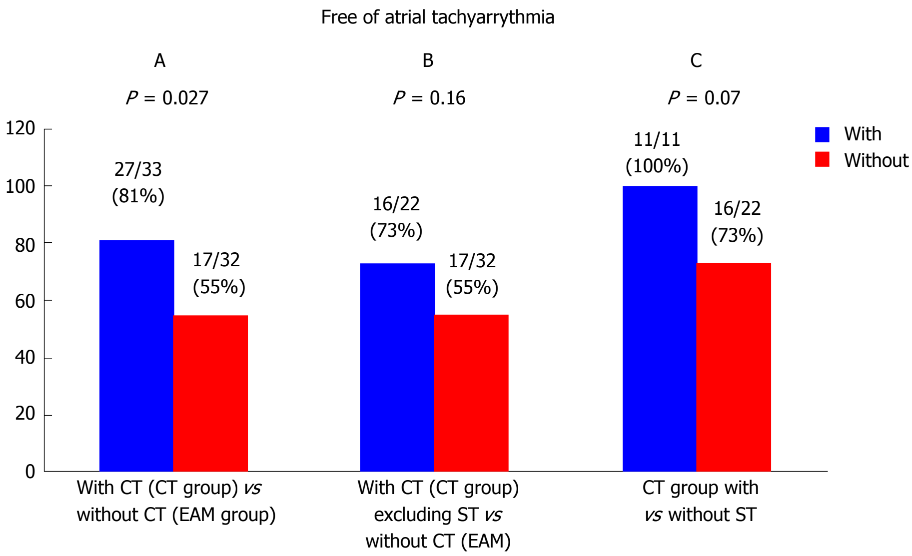

Figure 3 Free of atrial tachyarrhythmia during 24 mo. A: Among CT group *vs* among electroanatomic group; B: Free of atrial tachyarrhythmia among CT group (excluding Smart Touch) *vs* among electroanatomic group; C: Free of atrial tachyarrhythmia among CT group with or without ST. ST: Smart touch; EAM: Electroanatomic mapping; CT: Computed tomography.

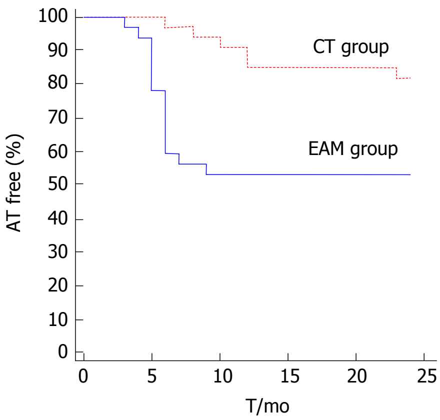

Figure 4 Kaplan-Meier estimate of recurrence atrial tachyarrhythmia during 3-24 mo after ablation for atrial fibrillation. Free of atrial tachyarrhythmia was significantly higher among CT group compared to electroanatomic mapping group. AT: Atrial tachyarrhythmia; EAM: Electroanatomic mapping; CT: Computed tomography.

EAM group and CF catheter. Only the combination of CT and CF technology was associated with significant reduction of atrial tachyarrhythmia. Thus, we could not determine the relative contribution of these technologies. Future randomized studies are needed to determine the optimal combination of technologies that gives the best procedural and clinical results of AF ablation.

In summary, these preliminary results suggest that CT image integration into EAM in combination with CF technology may reduce the recurrence of atrial tachyarrhythmia after catheter ablation for AF.

COMMENTS

Background

Recurrence of atrial arrhythmia after pulmonary vein isolation (PVI) is mainly due to recurrent pulmonary veins conduction. The durability of PVI and clinical outcome after radiofrequency ablation is affected by the contact force (CF) between the catheter tip and the tissue. In addition, understanding the anatomy of left atrium (LA) and PVs is essential for the safety and effectiveness of procedure. Pre-procedural cardiac computed tomography (CT) helps to evaluate the three dimension (3D) and complex anatomy of LA and PVs. In this study, the authors evaluated the impact of integrating CT image of LA/PVs into electroanatomical mapping system and using CF technology on clinical recurrence of atrial tachyarrhythmia after ablation for atrial fibrillation (AF).

Research frontiers

CT image integration of cardiac chamber into electroanatomic mapping (EAM) is widely used to guide catheter ablation for AF and related arrhythmias. Some studies showed that it improved the procedural and clinical outcome compared to EAM but others did not. In addition CF technology was found recently to associated with better clinical outcomes. Research is focused now in defining the parameters of CF that are universally associated with better clinical outcomes.

Innovations and breakthroughs

The authors found that combination of CT image integration into EAM and CF technology may reduce the recurrence of atrial tachyarrhythmia after catheter ablation for AF during follow-up period of 24 mo.

Applications

The authors think, that combination of technologies rather than single one can lead to the best results as in this study. Centers and operators should choose the technologies according to their experience and according to the 3D anatomy of LA/PVs as detected by pre-procedure echocardiography, CT and or other modalities.

Terminology

EAM: Electroanatomic mapping enables reconstruction of 3D anatomy of LA and PVs. Image integration: A technique to integrate a CT image of LA/PVs into EAM. CF technology: Enables assessing contact between tip of catheter and tissue and showing its absolute value and orientation by means of a 3D vector in real time during the procedure.

Peer-review

This is an interesting article analysing the influence of novel technologies (image integration and CF evaluation) on the outcome of catheter ablation of AF.

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CASE REPORT

Single lead catheter of implantable cardioverter-defibrillator with floating atrial sensing dipole implanted *via* persistent left superior vena cava

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Author contributions: All authors have contributed significantly to the submitted work and approved submission of the manuscript.

Institutional review board statement: The paper entitled "Single lead catheter of implantable cardioverter-defibrillator with floating atrial sensing dipole implanted *via* persistent left superior vena cava" has been reviewed and approved at an internal meeting of the Department of Cardiology, S. Anna Hospital, University of Ferrara, Italy for submission to the World Journal of Cardiology.

Informed consent statement: All the involved persons gave the informed consent prior to the writing of this study. Any detail that might disclose the identity of the patient has been omitted or anonymized.

Conflict-of-interest statement: The authors have no conflicting interest, including but not limited to commercial, personal, political, intellectual or religious interest, related to this study.

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Abstract

Persistent left superior vena cava (LSVC) is a congenital anomaly with 0.3%-1% prevalence in the general population. It is usually asymptomatic but in case of transvenous lead positioning, *i.e.*, for pacemaker or implantable cardioverter defibrillator (ICD), may be a cause for significant complications or unsuccessful implantation. Single lead ICD with atrial sensing dipole (ICD DX) is a safe and functional technology in patients without congenital abnormalities. We provide a review of the literature and a case report of successful implantation of an ICD DX in a patient with LSVC and its efficacy in treating ventricular arrhythmias.

Key words: Implantable cardioverter defibrillator; Left superior vena cava; Floating atrial sensing dipole

Core tip: The implantation of devices in patients with left superior vena cava is often unsuccessful. In case of single lead implantable cardioverter defibrillator with atrial sensing dipole implantation, little is known about the efficacy of the device during follow-up. This case report represents not only a successful implantation, but also the first case of effectiveness of anti-tachycardia therapy during follow-up.

Malagù M, Toselli T, Bertini M. Single lead catheter of implantable cardioverter-defibrillator with floating atrial sensing dipole implanted *via* persistent left superior vena cava. *World J Cardiol* 2016; 8(4): 323-326 Available from: URL: http://www.wjgnet.com/1949-8462/full/v8/i4/323.htm DOI: http://dx.doi.org/10.4330/wjc.v8.i4.323

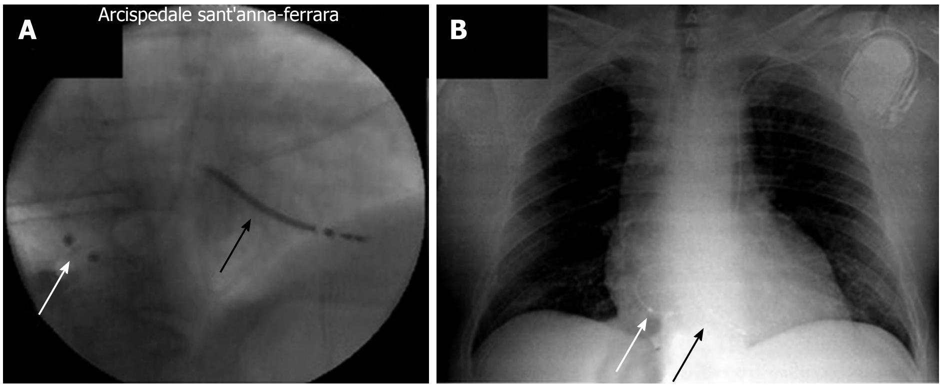

Figure 1 Final position of implantable cardioverter defibrillator sensing dipole. A: Fluoroscopic posteroanterior view during implantation; B: Chest X-ray after implantation. Note the position of atrial sensing dipole (white arrow) and defibrillation coil (black arrow).

INTRODUCTION

About 0.3%-1% of the general population has a persistent left superior vena cava (LSVC)[1,2], which drains blood from the left upper part of the body into the coronary sinus[3]. Persistence of LSVC is generally asymptomatic and may be an incidental finding, however it may also be associated with an increased risk of cardiac arrhythmias[4]. Device implantation in patients with LSVC is a challenge for two main reasons: The congenital anomaly is often an incidental finding during the procedure, leading to possible complications or implant failure. In addition, little is known on the effectiveness of shock therapy in the treatment of malignant arrhythmias.

Single lead implantable cardioverter defibrillator (ICD) with floating atrial sensing dipole (ICD DX, Biotronik SE and Co, Berlin, Germany) is a safe and functional technology in patients without congenital abnormalities[5]. Previous experiences with VDD leads with a similar floating atrial dipole, however, were burdened by instability of the atrial sensing amplitude[6]. Thus, in patient with LSVC, the presence of a floating atrial sensing dipole on the ventricular lead may result in uncorrect positioning and unsatisfactory atrial sensing. To our knowledge, only one case of successful ICD DX implantation in presence of LSVC has been previously reported, without any information at follow-up[3]. There are no data in literature about follow-up stability and effectiveness of therapy in these patients.

CASE REPORT

A 58-year-old man was referred to our cardiological institution from our heart failure center with indication to ICD implantation in primary prevention of sudden cardiac death. He suffered 14 years ago of myocardial infarction treated with medical therapy. A previous coronary angiogram showed chronic total occlusion of proximal left anterior descending artery. The electrocardiogram showed sinus rhythm with right bundle branch block and left anterior fascicular block. The echocardiogram documented a severe left ventricular dilation with reduced ejection fraction (< 35%). His NYHA functional class was between Ⅱ and Ⅲ.

During the implant procedure, the catheter inserted *via* the left cephalic vein took an anomalous route to coronary sinus. A venous angiography *via* the cubitalis vein revealed a previously unknown persistence of LSVC draining into the coronary sinus. The right superior vena cava was present, normally draining into the right atrium. We then performed ICD DX implantation with insertion of a single-coil single lead with atrial sensing dipole (Biotronik Linox Smart S DX) *via* the left cephalic vein through LSVC and coronary sinus. The catheter was positioned in the right ventricular posterior wall towards the apex, with the atrial sensing dipole into the right atrium at a postero-inferior level and with the defibrillation coil near the interatrial septum inserted beyond the tricuspid valve (Figure 1). Electrical measurements showed acceptable values of atrial and ventricular sensing (4.3 mV and 5.7 mV, respectively), as well as ventricular pacing (0.6 V pacing threshold), impedance (377 Ohm) and shock impedance (65 Ohm). Total X-ray exposure time was 26 min and 24 s. Defibrillation test was not performed. The patient was then discharged and followed-up with remote monitoring (Biotronik Home Monitoring).

During 10 mo of follow-up, several events were reported. In particular, the patient experienced 4 episodes of sustained ventricular tachycardia/ventricular fibrillation. Of these, 3 were interrupted with antitachycardia pacing (ATP) and the fourth with a single 40 Joule DC-shock (vector between right ventricular coil and anterior can), which restored sinus rhythm (Figure 2). No atrial arrhythmias were detected. Diagnostics also revealed sensing/pacing time with 90% AS-VS, which indicate spontaneous rhythm, and only few times of pacing. Remote monitoring showed acceptable values of atrial and ventricular sensing, stable over time, indicating stable position of the lead (Figure 3).

DISCUSSION

In our patient, given the posterior position of RV catheter, we expect normal or even better efficacy of ICD since

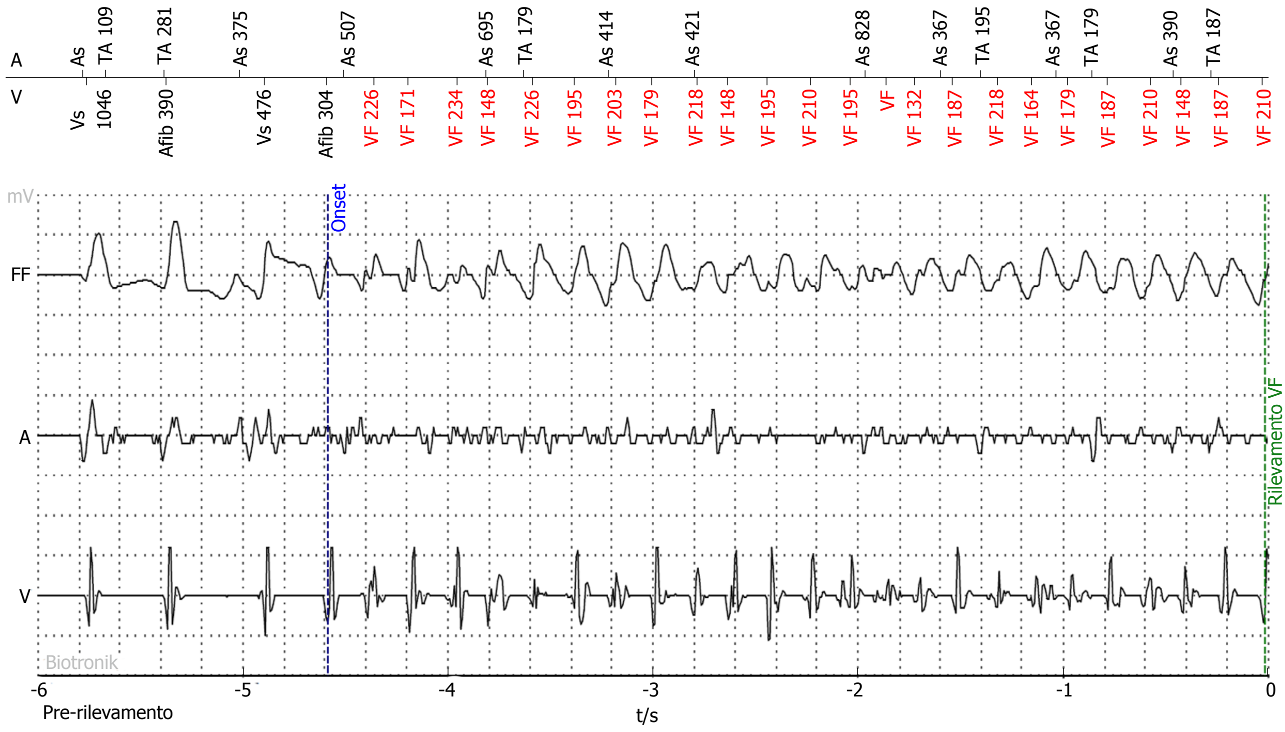

Figure 2 Ventricular fibrillation event.

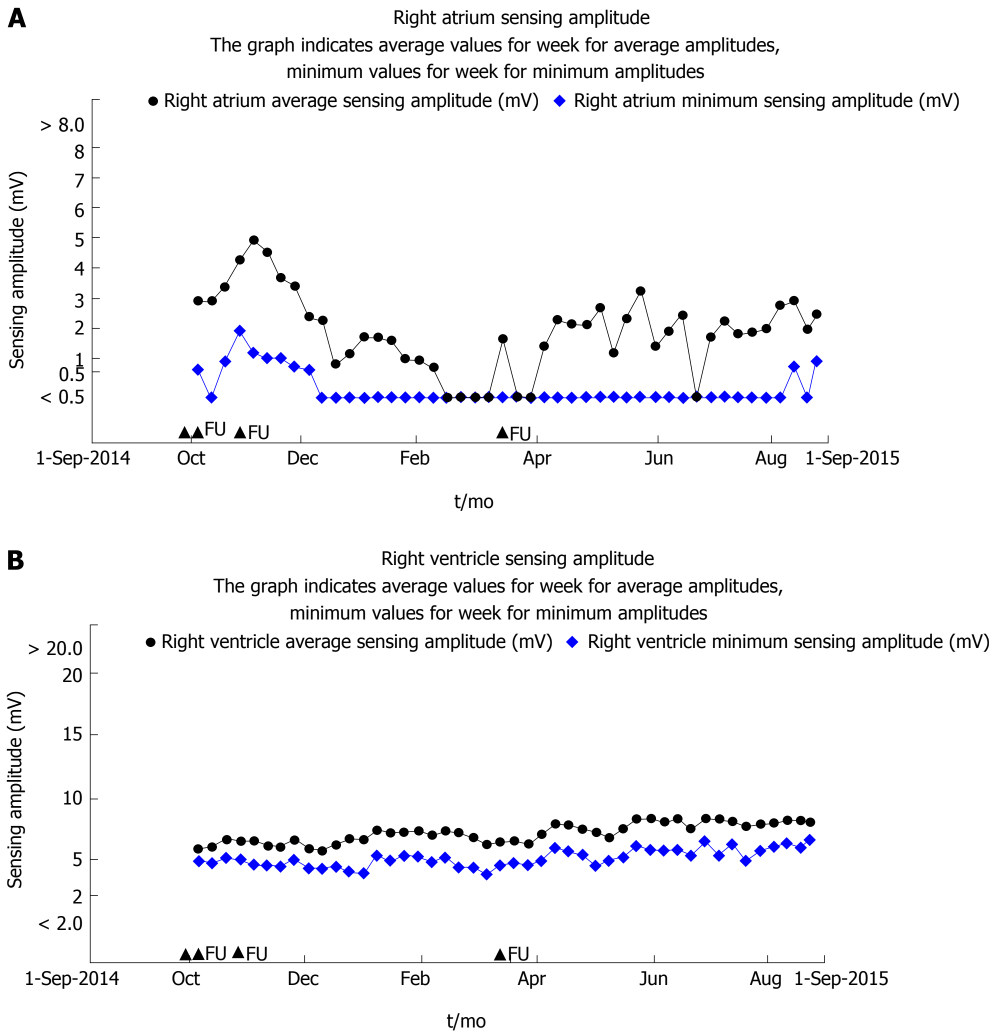

Figure 3 Trends of atrial and ventricular sensing during 10 mo of follow-up. FU: Follow-up.

defibrillation vector, directed from posterior (right ventricle) to anterior (can) could include huge critical ventricular mass. This consideration should discourage the implantation in the right side. Furthermore, in one third of cases of LSVC there is absence of right superior vena cava[1]. Therefore, in patients with LSVC it is in any case more appropriate to implant the device on the left side.

In conclusion, this case report gives a contribution to the knowledge on this subject by confirming the possibility of successful implantation and effectiveness of the therapy. During 10 mo of follow-up, our patient presented a few episodes of ventricular arrhythmias, which were effectively recognized and treated either with ATP and with DC-shock.

COMMENTS

Case characteristics

Ischemic cardiomyopathy with reduced ejection fraction, scheduled for implantation of single lead implantable cardioverter defibrillator (ICD) with atrial sensing dipole.

Clinical diagnosis

Persistent left superior vena cava (LSVC).

Imaging diagnosis

Fluoroscopy and angiography during ICD implantation.

Treatment

Single lead ICD with atrial sensing dipole implantation *via* persistent LSVC.

Related reports

Stability of lead and effective ICD therapy both with antitachycardia pacing and DC-shock during follow-up.

Experiences and lessons

Single lead ICD with atrial sensing dipole is a safe and effective technology even in patients with persistent LSVC.

Peer-review

The paper reports the implantation and follow-up data of a patient with persistent LSVC who underwent ICD implantation with a single lead capable of atrial sensing.

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