JAFIB

Original Research

Journal of Atrial Fibrillation

www. jafib.com

Observations Of Electrical Coupling Index Using The Contact™ System During Pulmonary Vein Electrical Isolation Procedures

Daniel T. Walker B. App Sci[1], Karen P. Phillips MBBS[2]

[1]St Jude Medical,17 Orion Rd, Lane Cove, NSW, Australia 2066, [2]Heart Care Partners, Greenslopes Private Hospital, Newdegate St, Greenslopes, QLD, Australia 4120.

Abstract

The Contact (St Jude Medical) System uses a novel impedance- based measure of Electrical Coupling Index (ECI) to assess the quality of catheter tip to endocardium contact. We sought to establish average ECI measurements and behaviour during pulmonary vein (PV) isolation procedures.

Forty-five patients undergoing PV isolation for atrial fibrillation (AF) were studied. 'Non-contact' and upper range 'in-contact' catheter positioning was performed for system calibration. ECI measurements were recorded pre-ablation at 14 standardized locations around the PV antra.

The mean ECI non-contact value was 77 ± 11 (range 63–107); the mean upper range in-contact value was 111 ± 16 (range 81–145). Mean ECI values pre-ablation around the PV antra ranged from 85 ± 18 to 107 ± 19. A trend towards higher mean ECI values was noted with increasing body mass index (BMI). Pre-ablation mean ECI values were 92 ± 10 (BMI 20-25), 95 ± 12 (BMI 26-30) and 104 ± 11 (BMI >30) ($p< 0.01$ for 20-25 vs. >30). A positive correlation was noted for mean pre-ablation ECI values and BMI ($r=0.50$).

An expected range of ECI values during PV isolation has been documented in this study. Observed ECI values correlate with patient BMI. The potential limitations of the current generation Contact System and scope for future clinical applications are discussed.

Introduction

Radiofrequency (RF) ablation is a common therapy utilised in the treatment of atrial fibrillation (AF). Ablation catheter technology has been evolving rapidly with a recent innovation being the introduction of catheter tip-tissue sensing capabilities. One of these technologies is the Contact™ system introduced by St Jude Medical (St Paul, MN) which uses a novel measure of the Electrical Coupling Index (ECI) to assess the quality of catheter tip to endocardium contact. The technology has previously been described in depth and is associated with improved efficacy of pulmonary vein electrical isolation.[1-4] Currently there is little data explaining expected ECI values and behaviour during a left atrial ablation procedure. As such this paper sought to provide average ECI measurements in a cohort of patients who underwent first-time pulmonary vein isolation (PVI) procedures using the first generation Contact™ technology.

Key Words:

Ablation, Atrial Fibrillation, Electrical Coupling Index, Contact Sensing, Pulmonary Vein Isolation.

Disclosures:
None.

Corresponding Author:
Daniel Walker
St Jude Medical,
17 Orion Rd, Lane Cove,
NSW, Australia 2066.

Methods

Forty-five consecutive patients undergoing a first time PVI procedure for atrial fibrillation with a single operator were studied. Patients having a redo procedure were excluded. Patients with both paroxysmal and persistent forms of arrhythmia were included.

Procedure

The Ensite NavX 3D mapping system (St Jude Medical, St Paul, MN) was utilised for catheter guidance, geometry creation and fusion to a pre-segmented left atrial CT image. A decapolar catheter was placed in the coronary sinus and a circular, 20mm pulmonary vein mapping catheter was used for geometry collecting and localisation of pulmonary vein signals. Intra-cardiac echo was utilised in all procedures to aid in guidance of the double trans-septal punctures, geometry creation and tissue contact during ablation delivery. Pulmonary vein isolation was performed at an antral level with left and right sided pulmonary veins isolated in pairs. The primary end-point was electrical isolation of all pulmonary veins confirmed by entry and exit conduction block.

The Contact ablation catheter was calibrated as per the recommended manufacturer instructions for use. An initial 'non-contact' ECI baseline measurement was performed with the catheter tip mid left atrial cavity and not contacting the endocardium as confirmed by the absence of local intracardiac signal and intracardiac echocardiography (ICE) visualization. Previous validation of the technology has shown that tissue contact correlates well with

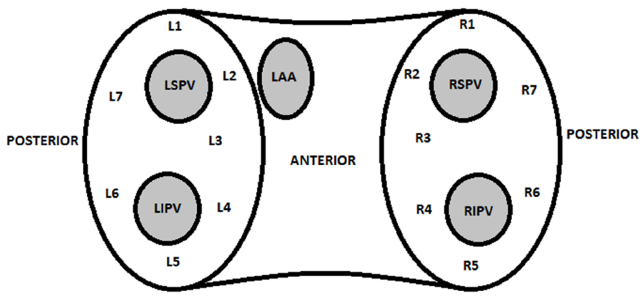

Figure 1: The 14 sites of data collection in the left atrium (seven each around the left and right pulmonary vein pairs). LAA = left atrial appendage; LIPV = left inferior pulmonary vein; LSPV = left superior pulmonary vein; RIPV = right inferior pulmonary vein; RSPV = right superior pulmonary vein.

a minimum 5 ECI points above non-contact measurement as demonstrated by progressive decrease in bipolar pacing thresholds and analysis of unipolar electrogram characteristics.[1] A second upper-level 'in-contact' ECI measurement was taken with the catheter positioned at the left atrial roof or posterior wall at a desired upper-limit of contact as determined by the physician to define the desired safety range. Endocardial contact was determined from intracardiac signals, intracardiac echo visualization and tactile feedback. A braided SL0 curve long sheath (St Jude Medical, St Paul, MN) was used for ablation catheter manipulation in the left atrium. Following calibration the Contact display dashboard indicates the actual ECI measurement in addition to a continuous graph display of ECI value plotted vs. time. A catheter 'beacon'on the real time NavX image displays the catheter tip yellow when ECI values are in a non-contact range, green for a contact range and flashing red when the 'upper-range' safety values are exceeded.

Fourteen pre-determined locations were selected for ECI measurements (Fig 1) along the antral line of ablation. Unblinded ECI measurement was taken pre-ablation as the highest reading in a 5 second period on non-ablated tissue.1 RF power settings ranged from 20 – 45 watts and heparinised saline irrigation was run at 12ml/min during RF power delivery. All procedures were performed under general anaesthesia with intermittent positive pressure ventilation.

Statistical Analysis

Results were analysed using SPSS software and expressed as mean ± standard deviation. Unpaired t tests and Pearson correlation coefficients were performed. A 2-tailed p value <0.05 was considered to be statistically significant. Graphs were constructed by using Prism (GraphPad Software, La Jolla, CA).

Results

Forty-five patients (seven female) underwent first time PVI procedures. Successful PVI (entry and exit block) was achieved in 100% of the patients. Fifteen patients had persistent forms of AF and 30 were paroxysmal; 26 patients were in sinus rhythm and 19 patients were in AF at the time of data collection. The mean age was 61.9 years (range 43-81 years) and mean body mass index (BMI) was 29.0 (range 20-42). Successful PV isolation was achieved in all patients with a mean procedural time of 171 ± 40 minutes (range 114 - 275). There were no complications associated with use of the technology. The mean ECI non-contact value for the cohort was 76 ± 10 (range 62 – 102); the mean upper range in-contact ECI value was 111 ± 15 (range 81 – 145). Mean pre-ablation ECI values at each of the measured PV sites are shown in Figure 2. Mean ECI values pre-ablation around the PV antra (L1-L7 and R1 – R7) ranged from 85 ± 18 to 107 ± 19, with an overall mean of 97 ± 12. The lowest mean pre-ablation values were recorded at the anterior ridge of the left upper and lower PVs (sites L2, L3, L4).

Effect of Body Mass Index

A trend towards higher mean ECI values was noted with increasing BMI. Non-contact values were 73 ± 9 (BMI 20-25), 75 ± 11 (BMI 26-30) and 81 ± 9 (BMI >30) ($p<0.04$ for 20-25 vs >30). Upper range in-contact mean ECI values were 104 ± 12 (BMI 20-25), 111 ± 15 (BMI 26-30) and 116 ± 15 (BMI >30)($p< 0.05$ for 20-25 vs. >30). Pre-ablation mean ECI values were 92 ± 10 (BMI 20-25), 95 ± 12 (BMI 26-30) and 104 ± 11 (BMI >30)($p= 0.01$ for 20-25 vs. >30). A modest positive correlation was noted for mean pre-ablation ECI values and BMI ($r=0.50$, $p=0.0005$) as shown in Figure 3.

Effect of Rhythm

Atrial fibrillation rhythm at the time of the procedure did not appear to impact ECI values in males, after controlling for BMI. Females were excluded from this analysis to avoid confounders as all were in sinus rhythm with a mean BMI of 25 ± 4. The mean non-

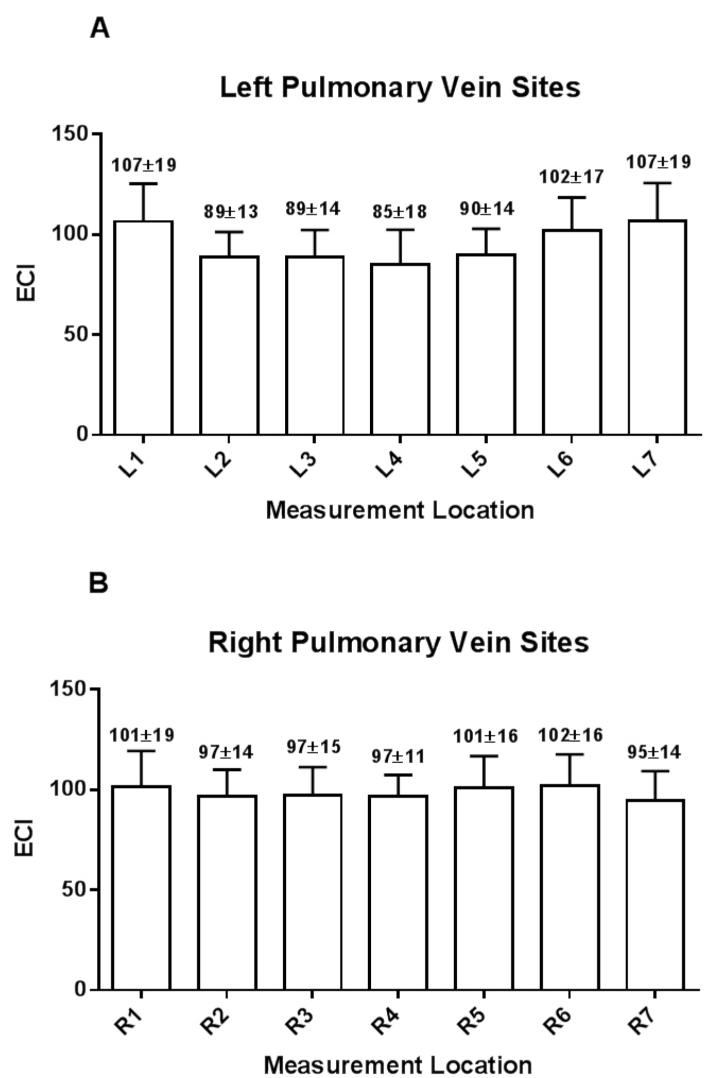

Figure 2: Average pre-ablation ECI values for total patient group at A) collection sites L1-L7, and B) collection sites R1-R7. Average ECI and upper boundary of standard deviation are displayed

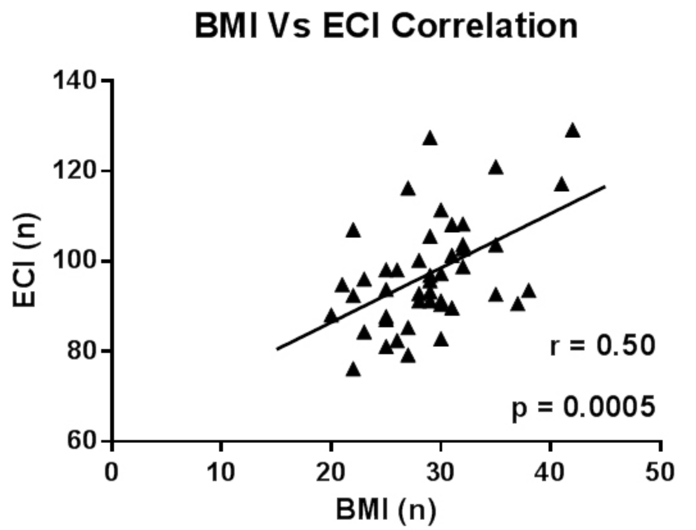

Figure 3: Graph of correlation between the Body Mass Index (BMI) on x axis and mean pre-ablation Electrical Coupling Index (ECI) on y axis for the total patient group

contact for males in AF was 81 ± 10 vs. 75 ± 8 in sinus (p=0.06); mean upper range contact values were 116 ± 16 for AF vs. 109 ± 13 in sinus (p= 0.22); mean pre-ablation values were 100 ± 13 for AF vs. 98 ± 9 in sinus (p=0.47).

Effect of Gender

Females in the cohort had lower mean ECI values than males, however there was a confounding trend towards lower mean BMI in females (25.7 ± 4 vs. 29.1 ± 5, p=0.07) and all female patients were in sinus rhythm (7/7) as compared with males (19/38). Mean non-contact ECI values were 67 ± 9 for females vs. 78 ± 9 for males (p =0.01); mean pre-ablation values were 86 ± 9 for females vs. 99 ± 11 vs. males (p<0.01).

Observed Intraprocedural Variations in ECI

During many procedures cyclical variation in continuous ECI measurement pre-ablation was noted on the graphical representation (ECI measurement vs. time) despite apparent stable catheter position. Oscillation which appeared to correlate with cardiac motion (Fig 4a) and respiratory motion (Fig 4b) was noted, often visible with direct ICE visualization of the catheter contact with atrial tissue. A rapid decrease in ECI value, followed by plateau was routinely observed with the onset of RF energy application (Fig 4c), as previously described.[2]

Discussion

While the Contact™ technology has been commercially available its clinical use in the EP laboratory has remained limited. It is perhaps, for many physicians, a less intuitive concept than simple force- sensing for catheter- tissue contact. The potential benefits of ECI over simple force- sensing have been previously described and include the ability to use the technology with any choice of ablation catheter, and improved information about the electrical interaction of the catheter interface with different cardiac tissue types both before and during ablation delivery.1 The clinical utility of the technology however depends on the ability to take the concept from the benchtop to the EP laboratory aided by a developed understanding of how the supplied information varies according to different clinical parameters and scenarios. The current study contributes to the knowledge base of how ECI measurement and monitoring might best be used as a clinical tool during catheter ablation.

In the previous work by Piorkowski et al1, non-contact ECI values of 115 ± 12 and mean contact values of 140 ± 16 (159 ± 14 for 'firm contact') were found in a study population of n=16, all studied in sinus rhythm. These values are markedly different from those observed in the current series (77 ± 11 and 97 ± 12 [110 ± 16 for upper range contact]). The study did not find any significant variation in ECI values with BMI, however their cohort was small with a mean BMI of 26 ± 2 which did not allow for comparison with patients in the obese or very obese range. The current study documented a mean increase in ECI value of 26% pre-ablation over the non-contact reading as compared with 22% (Piorkowski)1,

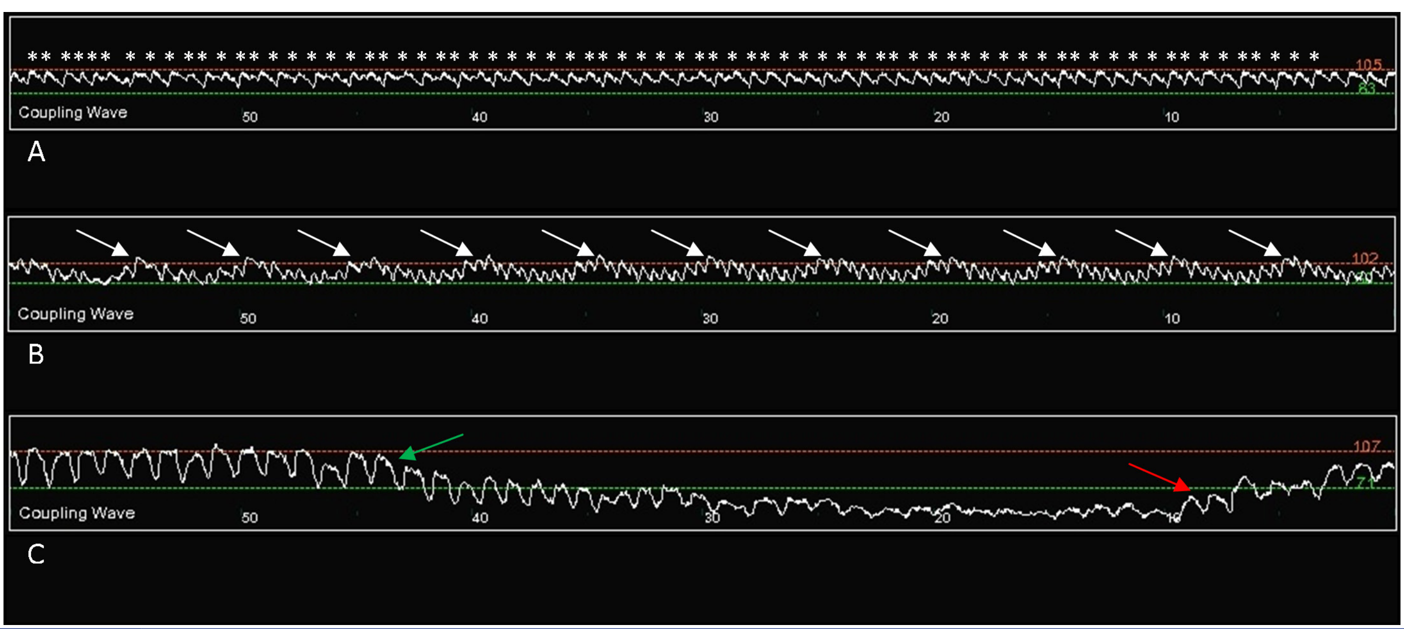

Figure 4: Examples of oscillations in the Electrical Coupling Index waveform A) due to cardiac motion (asterisks), B) due to respiration (arrows) and C) changes in the waveform at initiation and cessation of radiofrequency energy delivery (green and red arrows respectively)

and a mean increase of 43% for upper range contact as compared with 38% for 'firm contact' (Piorkowski).[1] The results of the current study, however, are comparable to pre-ablation ECI values from a contemporary published abstract by Dello Russo et al.[5] who found mean pre-ablation ECI values ranging from 96.7 ± 11.1 to 102.4 ± 11.8 around the pulmonary veins.

Personal communication with St Jude Medical engineers has informed the authors that calibration of the Contact 'dashboard' settings was based the previously documented minimum cutoff of 5 ECI points above 'non-contact' baseline and demonstrated to be highly reproducible. However, Contact hardware that is currently commercially available in Ensite Systems may not be calibrated to the same standard, such that inter-laboratory variation in absolute ECI values may occur. Because each patient serves as their own reference for the Contact measurement (non-contact through upper range contact ECI scale) this does not appear to impact clinical accuracy but does currently prevent inter-laboratory comparisons. Standardised calibration of Contact hardware will reportedly be a feature of the second generation Contact system. The observations in the current study of ECI measurements approximately 20 – 30% for 'contact' and 40 – 45% for 'upper range contact' above the non-contact baseline were confirmed by St Jude Medical engineers to be consistent with laboratory bench data.

Expected variation in catheter contact behaviour during respiratory and cardiac motion was also observed with ECI measurement as has been noted in other catheter force-sensing studies.[5] The finding of lowest mean 'in-contact' measurement at the anterior ridge of the left pulmonary veins has also been documented by other force-sensing technology.[6-8] Overall the current study appears to validate the consistent and expected behaviour of Contact technology during left atrial ablation.

The current study points to a significant effect of body mass index on observed absolute ECI values. The '3- terminal model' theory of ECI measurement claims to yield only the catheter tip to tissue impedance by cancelling out other sources of thoracic resistance.1 Cardiac adiposity could potentially directly impact tissue impedance to increase ECI values. The possibility of 'incomplete cancelling' by the technology of increased thoracic resistance in the setting of obesity also needs to be considered and has been acknowledged by St Jude Medical engineers to be the likely explanation. A significant decrease in non-contact and contact ECI values from beginning to end of left atrial ablation procedure (mean procedure time 135 minutes) has previously been noted and suggested to arise from changes in total body fluid.[1] This would provide another consistent example of 'incomplete cancelling' of reductions in thoracic resistance. Further evaluation of the impact of BMI on ECI measurements is required as recommended system calibration or scale may be impacted. Equally, the potential for 'drift' of measurements during a procedure (thereby affecting system accuracy) needs to be further explored and accounted for with an offsetting algorithm or with recommendations for intermittent recalibration.

Table 1: Patient Characteristics

	N=45
Age (yrs)	61.9 ± 8.2
Sex: Males, n (%)	38 (84)
Type of AF, n (%)	
Paroxysmal	30 (67)
Persistent	15 (33)
Hypertension, n (%)	24 (53)
Diabetes, n (%)	8 (18)
EF (%)	61.3 ± 8.1
BMI (n)	29.0 ± 5

AF: Atrial Fibrillation, EF: Ejection Fraction, BMI: Body Mass Index

Study Limitations

The possibility of variation in ECI values according to gender has also been raised by the current dataset but the confounding effect of BMI and the small number of females studied prevents accurate conclusions being drawn. The current study also did not remeasure non-contact ECI values during or at the end of procedures to document measurement stability.

Future Clinical Research and Technology Improvements

The lack of integration of Contact measurements with Ensite NavX mapping software currently limits the clinical utility in the operator's experience. The capacity to record mean pre-ablation ECI measurements at each ablation location on the Ensite NavX geometry may have benefits for 'gap' mapping to suggest possible sites of acute PV reconnection.4,6 Additionally, the potential benefit of ECI monitoring over other catheter force-sensing technology is the ability to document real-time ablation lesion efficacy by a critical reduction in ECI value during ablation.[2] Benchtop animal studies have previously documented that a ≥ 12% reduction in ECI value during ablation delivery was associated with transmural lesions.[2] The ability to record 'delta ECI' at each ablation location would improve clinical usefulness of the technology.

There is currently scope to examine the behaviour of ECI measurements across different clinical and ablation scenarios that may better inform physicians about optimal catheter placement and ablation delivery. Previous validation studies have shown that ECI measurements intrinsically vary according to vascular (pulmonary venous) tissue, trabeculated or atrial smooth muscle tissue.[1] Further clinical research is required into how energy delivery may need to be varied to achieve optimal ablation efficacy at vascular, trabeculated or smooth muscle tissue as informed by ECI values. Additional information about ECI measurement variation with scar tissue may also assist in applications for scar and scar-border mapping. Whether ECI measurement can further inform substrate or physiological mapping should also be explored. ECI might vary according to tissue fibrosis, ganglionic presence and innervation or signal specialized cardiac conduction tissue eg. Sinus or AV nodal tissue. Other potential questions include the expected variation in ECI readings from pre-ablation, immediately post-ablation, delayed post-ablation (to account for tissue oedema) and mature scar. Further observations are also required for applications of 'gap mapping' as to the variation in ECI values and spatial resolution when measuring areas of adjacent ablated and incompletely or non-ablated (but potentially oedematous) tissue.

Conclusions:

The current study documents consistent and expected behaviour of the tissue sensing capabilities of Contact technology during pulmonary vein isolation procedures, with the novel finding of a correlation of BMI with absolute ECI measurements. Currently a reference range and recommended ECI values for left atrial ablation cannot be established without further multicenter studies comparing different Ensite Contact systems and after controlling for uniform technology calibration. The potential limitations of the current generation Contact System have been discussed with recommendations for future research and improving the clinical utility of this emerging technology.

References:

1. Piorkowski, C., Haris, S., Sommer, P., Miller, S., Gaspar, T., Teplitsky, Hindricks, G: First in Human Validation of Impedance-Based Catheter Tip-to-Tissue Contact Assessment in the Left Atrium. J Cardiovasc Electrophysiol 2009; 20: 1366-1373.
2. Holmes, D., Fish, J., Byrd, I., Dando J., Fowler, S., Cau, H., Jensen, J., Puryear, H., Chinitz, L: Contact Sensing Provides a Highly Accurate Means to Titrate Radiofrequency Ablation Lesion Depth. J Cardiovasc Electrophysiol 2011;22: 684-690.
3. Gaspar T, Sih H, Hindricks G, Eitel C,Sommer P, Kircher S, Rolf S, Arya A, Teplitzky L, Piorkowski C. Use of electrical coupling Information in AF catheter ablation: A prospective randomized pilot study. Heart Rhythm 2013;10:176-181
4. Gaspar T, Sih H, Hindricks G, Eitel C, Sommer P, Kircher S, Rolf S, Arya A, Teplitsky L, Piorkowski C. Use of electrical coupling information in AF catheter ablation: A prospective randomized pilot study. Heart Rhythm 2013:10:176-181
5. Dello Russo A, Fassin G, Bologna F, Casella M, Riva S, Moltrasio M, Tundo F, Zucchetti M, Majocchi B, Marino V, Colombo D, Innocenti E, Izzo G, Al Nono O, Russo E, Carbucicchio C, Santangelli P, Di Biase L, Natale A, Tondo C. Robotic Contact Force Sensing and Electrical Coupling Index: A Validation Study of a Combined Approach for Successful Pulmonary Vein Isolation. Heart Rhythm 2013;10:S262
6. Kumar S, Morton JB, Halloran K, Spence SJ, Lee G, Wong MC, Kistler PM, Kalman JM. Effect of respiration on catheter-tissue contact force during ablation of atrial arrhythmias. Heart Rhythm 2012;9:1041 - 1047
7. Reddy VY, Shah D, Kautzner J, Schmidt B, Saoudi N, Herrera C, Jaïs P, Hindricks G, Peichl P, Yulzari A, Lambert H, Neuzil P, Natale A, Kuck KH.The relationship between contact force and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study. Heart Rhythm 2012;11:1789-1797
8. Kumar S, Morton JB, Lee J, Halloran K, Spence SJ, Gorelik A,Hepworth G, Kistler PM, Kalman JM. Prospective characterization of catheter-tissue contact force at different anatomic sites during antral pulmonary vein isolation. Circ Arrhythmia Electrophysiol: 2012;6:1124-1129