Contact force technology in catheter ablation of atrial fibrillation

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Abstract

Catheter ablation of atrial fibrillation (AF) has an indisputable value in the treatment of patients with symptomatic drug refractory AF. Nowadays, special interest is paid to improve the efficacy and the safety of the procedure and new approaches allowing better understanding of the lesions creation and its control have been developed. A lot of factors including power and duration of energy delivery, impedance, type and temperature of electrode and local blood flow contribute to quality of lesions. As the catheter – tissue contact is crucial for effective lesion formation, there is growing role of contact force (CF) technology. There are four different systems actually approved for the measurement of contact force between the catheter tip and the targeted myocardium in real time. Several in vitro and vivo studies confirmed procedural importance of contact force technology. Also data from clinical trials suggest that use of contact force technology results in reduction of recurrence rate of AF in patients after ablation.

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Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia that still remains one of the most difficult to treat. The risk of a lifetime occurrence of atrial fibrillation is 22% to 26%. AF significantly influences morbidity and mortality, increasing the risk of stroke and the risk of all cause mortality [1,2] and reduces the quality of life in affected patients [3]. According to the current guidelines in patients with symptomatic AF resistant to or intolerant of antiarrhythmic drugs a radiofrequency (RF) catheter ablation is recommended [4,5]. The catheter ablation is considered as a standard procedure after failure of at least one antiarrhytmic drug and in selected patients may be performed as a first line therapy. The major concern remains a high recurrence rate of AF after catheter ablation, with up to 40% patients requiring redo procedure [6]. In the last years we have seen an evolution in our understanding of the treatment of AF with catheter ablation. "The goal" in AF ablation is complete electrical pulmonary veins isolation (PVI) confirmed by exit and entrance block, because the recurrence of AF is very often related to recovery of conduction between pulmonary veins and left atrium. Complete PVI is dependent on quality, size and continuity of lesions obtained during RF energy applications [6-8]. Complete and durable PVI during first procedure allows to avoid repeated procedures, that may be related to the risk of serious complications involving stroke, esophageal fistula or even death. [9,10]. New ablation technologies have been developed to enhance the quality of lesions and that way to improve ablation safety, efficacy, speed and precision and in consequence patients outcomes. These technologies include using of irrigated and circular catheters, robotic systems, 3 – dimensional imaging and electrical mapping systems, magnetic resonance guided ablation strategies, tests with adenosine to reveal dormant conduction and several others. One of the most promising techniques seems to be contact force technology.

The role of contact force catheters in lesion formation

During RF energy delivery the electrical energy is converted to thermal energy. Currently used generators deliver unmodulated single – wave alternating current at a frequency of 300-750 kHz that is too high to induce rapid myocardial depolarization resulting in atrial or ventricular fibrillation. The passage of current between the tip of electrode and tissue results in resistive heating limited to narrow space at the electrode – tissue interface. Affecting of deeper cardiac tissue layers depends on passive heat conduction. Resistive heating is proportional to current density that is inversely proportional to the distance from the ablation electrode [11]. When the myocardium heats up, the impedance of the tissue decreases. As the greater current density of the tip of electrode results from RF power delivery, influencing lesions size and depth, thus levels and power of RF delivery are conventionally monitored during ablation. Another biophysical parameter that determines formation of lesion is duration of energy application. It was proved that the half-time of lesion formation is approximately 8 seconds, with maximum lesion volume obtained if RF energy is delivered for 30 to 40 seconds [12,13]. Lesions quality depends on the tissue temperature. Although higher tissue temperatures achieving during RF application are connected with larger lesion size, temperatures greater than 100C° result in coagulative necrosis due to boiling of tissue water and proteins denaturation. Another factors contribute to adequate lesions include electrode tip size and orientation, irrigation, electrode material, properties of tissue, intramyocardial and intrachamber blood flow and electrode – tissue contact. Better CF reduces energy dissipation to the circulating blood that results in improvement of energy delivery into the tissue. The ability to asses in the real time CF between catheter tip and cardiac tissue has remained subjective for the operator. This was done with using methods such as fluoroscopic imaging, tactile feedback from catheter manipulations or monitoring changes in electrocardiograms and impedance obtained intarcardially. These methods are only surrogates and their accuracy is poor, that was suggested in prior studies [14,15]. Inadequate contact determines non – continuous and non transmural lesions creation and no contact results in the lack of lesions. CF technology is a new approach, that allows to obtain real- time contact information between the catheter tip and the targeted cardiac tissue. In theory this technology improves the quality of obtained lesions as well as safety of procedure.

Available contact force technologies

Currently approved in Europe methods of CF sensing include four systems: Intelissense (Hansen Medical Inc.Mount View CA, USA), Ensite Contact VeriSense (St Jude Medical, St Paul, MN, USA,), Tacti Cath Quartz (St. Jude Medical, formerly Endosense) and ThermoCool Smart Touch (Biosense Webster USA). The earliest available technology was a robotic catheter navigation system Intellisense (Hansen Medical). The Intellisense Fine Force Technology interface provides visual and vibration feedback information to the operator. Intellisense Vibe is a tactile vibration feature. The ablation catheter pulses four times per second in and out within the system inherent steerable sheath (Artisan). With each pulse, coaxial force data based on a resistance assessment of moving catheter are aquired. Measurements are displayed visually on the workstation Intellisense Flex. This technology can be only used in conjunction of the SenseiX Robotic Catheter System (Hansen Medical). The TactiCath (formerly Endosense SA), another commercially available 3,5 mm open irrigation-tip ablation catheter, contains a force sensor that allows real – time and continuous measurement of CF. This force sensor consists of elastic polymer and three optical fibres and provides informations on the total force and direction of the applied force based on micro-deformation of elastic polymer. The optical fibres transmit a laser light with a changed wavelength being proportional to the CF applied. CF informations are provided to additional workstation with the sensitivity of 1 g and a sampling rate of 50 Hz. The ThermoCool Smart Touch technology uses a sensor located at the distal tip of 3.5 mm open irrigated ablation catheter. The catheter tip electrode is connected on a precision spring to the shaft that permits a small amount of electrode movement. There is a magnetic transmitter coupled to the electrode distally to the spring emitting a reference signal and three magnetic location sensors. The degree of deformation of this spring is measured and transmitted every 50 ms. The CF is averaged over 1 second with accuracy 1 g. The catheter is fully integrated and widely used with Carto 3 electroanatomical mapping system and there is no need for additional workstation. The fourth system (Ensite Contact VeriSense) calculates contact force on the basis of electrical coupling as the local measure of impedance. Approachable three dimensional circuit model isolates and measures at the tip – to – tissue interface. The obtained local coupling information is provided to Ensite NavX three dimensional mapping system as a measure called electrical coupling index (ECI) and available as a scrolling waveform, a contact meter and a color coded beacon on the catheter. The end result describes electrical contact but the technology requires scaling to the individual patients repeated every 30 min, definition of the patient specific contact threshold and determination of an upper safety indication.

Experimental studies testing contact force

Since the 1990s several in vitro and in vivo experiments have been performed to assess the correlation of electrode contact with the tissue and the quality of lesions. In one of studies performed on canine right ventricular free wall preparations, authors observed a significant increase of lesions depth in relation to higher CF between 10 mN (~1g) and 400 mN (~40 g) with power delivery allowing to maintain a constant electrode – tissue interface temperature [13]. In another study in anesthetized dogs on the basis of investigation different levels of contact of electrode with tissue surface, it was proved that an increase in electrode – tissue contact results in a temperature rise and an increase of lesion size and depth [16]. In more recent study Shah and al. [17] attempted to prove an exact correlation between constant contact and lesions size. The study was performed in bovine tissue model of beating heart with the using an open tip irrigated catheter incorporating a dynamic force sensor (TactiCath). A time dependent measures of contact force expressed as force time integral (FTI) in correlation with lesion size were evaluated. The protocols included RF energy delivery by constant contact at 20 g with 20 and 40 W of power, variable contact with 20 g at peak and 10 g at nadir and intermittent contact with 20 g at peak and 0 g at nadir. Evaluated FTI was highest in the constant contact group, intermediate in the variable contact group and the lowest in the intermittent contact group. The authors observed that constant contact allowed to create the largest lesions. The linear correlation between FTI and lesion volume in the different contact groups was found. In conclusions authors suggest that achieving a variable contact patterns might result in effective and predictable lesion formation. Ex vivo porcine models were used to determine the role of CF technology during irrigated - tip RF ablation. Perna et al. [18] attempted to evaluate the force required to perforate cardiac chambers during an ablation to avoid this serious complication of procedure. CF was measured with the using of Thermo Cool Smart Touch open irrigated-tip catheter. The average force resulting in perforation of atrium was 175.8 ± 60.4 g and was reduced to 151.8 ± 49.9 after time of RF application achieving 30 seconds. In another animal models [19,20] were demonstrated that CF determines the tissue temperature and lesion size during power and duration controlled RF energy application with open- irrigated tip catheters and higher CF results in higher incidence of thrombus and steam pops. Okamura and al. [21] performed a canine study to examine the impact of catheter CF on lesion creation with using the remote robotic catheter system. Intracardiac echocardiography and fluoroscopy were used for validation of catheter – tissue contact and CF. Authors found that in protocols including contact force 10-20 and >20 g complete lesions were performed in contrast with <10 g contact force applications allowing for lesser thickness lesions formation. In conclusions authors underlined that catheter orientation may result in contact loss and impaired measurements of applicated force.

Impact of contact force technology on procedural parameters and clinical outcome

Several studies have been performed to demonstrate role of CF technology in obtaining adequate lesion quality and size [22-24] as well as patient outcome. The first clinical study evaluating TactiCath system safety for the force controlled ablation was the TOCCATA study [23]. Patients with paroxysmal AF underwent PVI by using a RF ablation catheter with a CF sensor integrated at its tip, and they were followed for 12 months. Acute isolation was obtained in all the veins. All patients treated with a low average CF of <10 g experienced recurrences, whereas 80% of the patients treated with an average CF of >20 g were free from AF recurrence at 12 months. The analysis of the average FTI showed that 75% of the patients treated with <500 gs have AF recurrence in comparison to only 31% of the patients treated with >1000 gs. The authors concluded that CF during catheter ablation for AF correlates with clinical outcome. The aim of EFFICAS I study [24] was to demonstrate the correlation between CF parameters during initial procedure and the incidence of isolation gaps at 3-month follow-up. A RF ablation catheter with integrated CF sensor (TactiCath, Endosense) 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. Ablations with minimum FTI <400 gs showed increased likelihood for reconnection. Reconnection correlated strongly with minimum CF and minimum FTI at the site of gap. According to researchers minimum CF and minimum FTI values are strong predictors of gap formation and optimal CF parameter recommendations are a target CF of 20 g and a minimum FTI of 400 gs for each new lesion. In the study performed by Haldar et al. [22] symptomatic AF patients undergoing first time PVI, were divided into two groups, "unblinded" and "blinded". An irrigated radiofrequency CF sensing catheter was used in both groups. In the "unblinded" group, the operator could view the CF value during mapping and ablation in real time. In the "blinded group", the operator was "blinded" to this information, although the data were recorded. All PVs were successfully isolated during the procedure. There was a significant association between blinding and the higher rate of PV reconnection. Blinding the operator resulted in lower mean CF overall. Sites where applied CF was significantly lower than others were usually the sites where reconnection occurred. According to authors availability of real time CF information during PVI was associated with a significantly lower acute pulmonary vein reconnection rate. Marijon E et al. [25] in prospective trial investigated patients with symptomatic paroxysmal AF, comparing circular antral catheter ablation (guided by Carto 3 System, Biosense Webster) using an open-irrigated CF catheter (SmartTouch Thermocool, Biosense Webster) or a non-CF open-irrigated catheter (EZ Steer Thermocool, Biosense Webster). After procedure patients were observed with a standardized 12-month follow-up, free of antiarrhythmic therapy. Complete PVI was achieved in all cases in both groups, but success using an exclusive anatomic approach was significantly higher in CF group than in control group. CF use was associated with significant reductions in fluoroscopy exposure and radiofrequency time. The incidence rates of AF recurrence were lower in the CF group than in the control group. In opinion of authors these findings suggest a potential benefit of real-time CF sensing technology, in reducing AF recurrence during the first year after PVI. Park et al. [26] evaluated symptomatic AF patients undergoing circumferential PV isolation (PVI) with SmartTouch™ CF catheter. The exact locations of acute PVI and spontaneous or adenosine-provoked reconnections were annotated on CARTO. CF was significantly lower at PVR versus PVI sites for RF lesions; majority of PVR occurred with a mean CF < 10 g (FTI<400 gs); and the remaining number occurred at ablation sites with a long interlesion distance despite mean CF≥10 g. Authors did not find any significant differences in regard to arrhythmia freedom between the patients without (69%) versus with PVR (67%) and they concluded that acutely durable PVI can be achieved when RF lesions are delivered with a mean CF≥10 g and an interlesion distance <5 mm. Recently a metaanalysis of 11 studies (2 randomized controlled trials and 9 cohorts) [27] assessing the safety and efficacy of CF guided AF was performed. Authors of this metaanalysis demonstrate a lower recurrence rate of AF defined as any symptomatic or asymptomatic atrial arrhythmia after ablation in patients treated with CF methods. Times of procedure, ablation and fluoroscopy are also significantly shorter. Not only reduction in procedural time and ablation time in comparison to point – by – point RF ablation were confirmed but also similar to using "single shot" devices as cryoballoon technique. Major (including: embolic events, cardiac tamponade, phrenic nerve palsy, atrio – esophageal fistula, pulmonary vein stenosis or death) and minor complications (including hematoma, arteriovenous fistula or aneurysm) were similar in compared groups.

Conclusions

An importance and usefulness of contact force technology is supported by multiple experiences and the benefit from contact force sensing in terms of acute and durable PV isolation was consistently shown. The impact on improvement of clinical outcome after ablation is less clear and should to be demonstrated in randomized trials.

References

1. Kirchoff P, Aurichio A, Bax J, et al. Outcome parameters for trials in atrial fibrillation; Executive summary. Recommendations from a consensus conference organized by the German Atrial Fibrillation Competence NETwork (AFNET) and the European Heart Rhythm Association (EHRA). Eur Heart J 2007; 28: 2803-2817
2. Stewart S, Heart CL, Hole DJ, McMurray JJ. A population – based study of the longterm risks associated with atrial fibrillation: 20-year follow up of the Renfrew/Paisley study. Am J Med 2002; 113: 359-364

3. Thrall G, Lang D, Carroll D, Lip GY. Quality of life in patients with atrial fibrillation; a systematic review. Am J Med 2006; 119: 448
4. Vahanian A, Auricchio A, Bax J, et al. Guidelines for the management of atrial fibrillation; the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC) Europace 2010:12:1360-1420.
5. Camm AJ, Lipp GY, De Caterina R, et al. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation. Eur Heart J 2012; 33: 2719-2747
6. Cappato R, Negroni S, Pecora D, Bentivegna S, et al. Prospective assessment of late conduction recurrence across radiofrequency lesions producing electrical disconnection at the pulmonary vein ostium in patients with atrial fibrillation. Circulation 2003; 108: 1599-1604
7. Mesas CE, Augello G, Lang CC, et al. Electroanatomic remodeling of the left atrium in patients undergoing repeat pulmonary vein ablation: mechanistic insights and implications for ablation. J Cardiovasc Electrophisiol 2006; 17: 1279-1285
8. Nanthakumar K, Plumb VJ, Epstein AE, et al. Resumption of electrical conduction in previously isolated pulmonary veins: rationale for a different strategy? Circulation 2004:1226-1229
9. Cappato R, Negroni S, Pecora D, et al. Prevalence and causes of fatal outcome in catheter ablation of atrial fibrillation. J Am Coll Cardiol.2009; 53:1798-1803
10. Danon A, Shurrab M, Nair KM, et al. Atrial fibrillation ablation using remote magnetic navigation and the risk of atrial – oesophageal fistula: international multicenter experience. J Interv Card Electrophysiol. 2015; 43: 169-174
11. Mehdi N, Dipen CS. Real- time contact force measurement for catheter ablation of cardiac arrhythmias. Cardiovasc Med 2015: 18(5): 155-162
12. Wittkampf FH, Hauer RN, Robles de Medina EO. Control of – radiofrequency lesion size by power regulation. Circulation 1989: 80: 962-968.
13. Haines DE. Determinants of lesion size during radiofrequency catheter ablation: The role of electrode – tissue contact pressure and duration of energy delivery. J Cardiovasc Electrophysiol. 1991;2:509-515
14. Holmes D, Fish JM, Byrd IA, et al. Contact sensing provides a highly accurate means to titrate radiofrequency ablation lesion depth. J Cardiovasc Electrophysiol. 2011; 22:684 - 690
15. Yokoyama K, Nakagawa H, Shah DC, et al. Novel contact force sensor incorporated in irrigated radiofrequency ablation catheter predicts lesion size and incidence of steam pop and thrombus. Circ Arrhthm Electrophysiol 2008; 1: 354-362
16. Avitall B, Mughal K, Hare J, et al. The effects of electrode – tissue contact on radiofrequency lesion generation. Pacing Clin Electrophysiol 1997; 20: 2899-2910
17. Shah DC, Lambert H, Nakagawa H, et al. Area under the real-time contact force curve (force – time intergal) predicts radiofrequency lesion size in an in vitro contractile model. J Cardiovasc Electrophysiol. 2010; 21: 1038-1043
18. Perna F, Heist EK, Danik SB, et al. Assessment of catheter tip contact force resulting in cardiac perforation in swine atria using force sensing technology. Circ Arrhthm Electrophysiol 2011; 4: 218-224
19. Thiagalingam A, D'Avila A, Foley L, et al. Importance of catheter contact force during irrigated radiofrequency ablation: evaluation in a porcine ex vivo model using a force – sensing catheter. J Cardiovasc Electropysiol 2010; 21: 806-11
20. Ikeda A, Nakagawa H, Lambert H, et al. Relationship between catheter contact force and radiofrequency lesion size and incidence of steam pop in the beating canine heart: electrogram amplitude, impedance, and electrode temperature are poorpredictor of electrode-tissue contact force and lesion size. Circ Arrhythm Electrophysiol 2014: 7: 1174-80
21. Okamura Y, Johnson SB, Bunch TJ, et al. A systematic analysis of in vivo contact forces on virtual catheter tip/tissue surface contact during cardiac mapping and intervention. J Cardiovasc Electrophysiol. 2008; 19: 632-640
22. Haldar KH, Jarman JW, Panikker S, et al. Contac force sensing technology identifies sites of inadequate contact and reduces acute pulmonary vein reconnection; a prospective case control study. Int j Cardiol 2013;168:1160-1166
23. Kuck KH, Reddy VY, Schmidt B, et al. A novel radiofrequency ablation catheter using contact force sensing. Toccata study. Heart Rhythm. 2012; 9: 18-23
24. Neuzil P, Reddy VY, Kautzner J, et al. Electrical reconnection after pulmonary vein isolation is contingent on contact force during initial treatment:

results from the EFFICAS I study. Circ Arrhyth Electrophysiol. 2013;6:327-333

25. Marijon E, Fazaa S, Narayanan K, et al. Real – time contact force sensing for pulmonary veiun isolation in the setting of paroxysmal atrial fibrillation: procedural and 1-year results. J Cardiovasc Electrophysiol. 2014;25: 130- 137
26. Park CI, Lehrmann H, Keyl C, et al. Mechanisms of pulmonary vein reconnection after radiofrequency ablation of atrial fibrillation: the deterministic role of contact force and interlesion distance. J Cardiovasc Electrophysiol 2014;25:701-8
27. Shurrab M, Di Biase L, Briceno DF, et al. Impact of Contact force technology on atrial fibrillation ablation: a meta – analysis. J Am Heart Assoc 2015; 4: 1-10