Deep Foci RF ablation using 3830 Medtronic pacemaker lead: proof of concept

Luciano Martin AYALA-VALANI[1], Sebastien MELANCON[2], Matilde EVANS[1], Mannix AUGER-MESSIER[1], and Felix Ayala Paredes[1]

[1]Centre integre universitaire de sante et de services sociaux de l'Estrie Centre hospitalier universitaire de Sherbrooke du Quebec
[2]Biosense Webster Canada 200 Whitehall drive Markham Ontario L3R 0T5 Canada

May 12, 2022

Abstract

Introduction Radiofrequency (RF) is the preferred thermal energy used in electrophysiology. RF catheter must deliver the energy close to arrhythmia foci. A new method to deliver RF to deeper locations using a pacemaker lead is explored. Methods A Medtronic 3830 lead screwed in chicken breasts delivered 50 watts RF energy in three methods: A) direct fashion (RF catheter touching the proximal end of the 3830 lead, acting as an extension of RF catheter), or B) 3830 lead as a return patch (RF delivered in the bath without contact), or C) 3830 lead as a return patch (RF delivered touching the breast surface close to the 3830 lead screwed deep in the flesh). Different power settings were also tested. Lesion surface area is reported in cm2. Results 76 measurements were available. Bigger lesions were obtained at 10W method A (0.78cm2), 50W method C (0.72cm2) and 5W method B (0.44cm2). High impedances were noted at 10W and 50W with tissue remaining attached to the lead when removed. Conclusion RF can be delivered to deeper foci through a 3830-pacemaker lead with maximum size lesion formation using proximal unipolar direct delivery and proximal close bipolar as the return patch. In humans, it opens a path to attain deep septal foci (LV summit) or epicardial structures (vein of Marshall, transmural ablation from RF endocardial to LV coronary sinus lead as return patch): using standard, 4F pacemaker leads, and 2F small EP catheters or even isolated guidewires.

Introduction

Radiofrequency (RF) is the preferred thermal energy used in electrophysiology. RF catheter must deliver the energy close to arrhythmia foci. A new method to deliver RF to deeper locations using a pacemaker lead is explored.

Methods

A Medtronic 3830 lead screwed in chicken breasts delivered 50 watts RF energy in three methods: A) direct fashion (RF catheter touching the proximal end of the 3830 lead, acting as an extension of RF catheter), or B) 3830 lead as a return patch (RF delivered in the bath without contact), or C) 3830 lead as a return patch (RF delivered touching the breast surface close to the 3830 lead screwed deep in the flesh). Different power settings were also tested. Lesion surface area is reported in cm2.

Results

76 measurements were available. Bigger lesions were obtained at 10W method A (0.78cm2), 50W method C (0.72cm2) and 5W method B (0.44cm2). High impedances were noted at 10W and 50W with tissue remaining attached to the lead when removed.

Conclusion

RF can be delivered to deeper foci through a 3830-pacemaker lead with maximum size lesion formation using proximal unipolar direct delivery and proximal close bipolar as the return patch. In humans, it opens a path to attain deep septal foci (LV summit) or epicardial structures (vein of Marshall, transmural ablation from RF endocardial to LV coronary sinus lead as return patch): using standard, 4F pacemaker leads, and 2F small EP catheters or even isolated guidewires.

Keywords: Ablation, Deep foci, Ventricular Arrhythmia, Radiofrequency, Pacemaker lead

Introduction

Radiofrequency (RF) ablation is the standard source of thermal energy used in electrophysiology. To eliminate the arrhythmia foci, the ablation catheter must deliver the energy as close as possible to those foci (less than 5mm). Several strategies have been used to increase the depth of a lesion: bigger catheters, irrigated catheters, and retractable needle-tip catheter. For even deeper foci, simultaneous unipolar ablation and bipolar catheter ablation have also been used.[1]

This study explores a new method to deliver RF to deeper locations using an already available pacemaker lead. The Medtronic 3038 4F bipolar pacemaker lead is available since early 2000s, but in 2017 its use to deep septal ventricular pacing was first described, to reach the left bundle branch coming from the right side, thus crossing all the septal depth.[2] It is hypothesized that RF can be delivered through the 3830 lead and an ex-vivo animal model was used to test this hypothesis.

Methods

Fresh (5 days non frozen) chicken breasts (Voltigeurs Farm, Drummondville, Qc, Canada) were placed and fixed to a rubber mat, in a water tank (wet lab) filled with an isotonic saline solution maintained at 37ºC. Medtronic SelectSecure 3830-69 cm pacemaker leads were screwed (by clockwise turning the lead until it reaches the desired location -left bundle branch lead implanters know how easily the 3830 lead advances just by screwing it into the septum-) with the proximal ring at least 5mm deep in the flesh. A Stockert EP Shuttle generator and a Thermocool SF NAV Bi-Directional Catheter (BNI35FJCT) from Biosense Webster were used to deliver RF energy for one minute at each iteration. Each 50 watts (W) power setting RF delivery was repeated at least once in another breast.

Three variations of a test were done. In the first variation (method A), the Biosense RF catheter touched the proximal ends of the pacemaker lead (sequentially distal tip and proximal ring) which was used to deliver the RF energy (direct fashion), the current passes from the RF catheter to the 3830 lead by having their ends touch together, and temperature rises on the interface where both catheters touch, and on the distal end of the 3830 lead which touches the flesh. The power was set at 50W, temperature was set but not limited at 70ºC, and a long metal string at the bottom of the water tank acted as the return patch. Power variations of this method were done at 10W, 5W, 2W and 1W.

In the second variation (method B), the Biosense RF catheter delivered the energy immersed freely in the solution of the tank (not in contact with the chicken breast) and the pacemaker lead was used as the return patch (sequentially attaching the metal string to the proximal and distal ends). The power was set at 50W, power variations of this method were done with 5W for the proximal end and 1W at the distal end.

In the third variation (method C), the Biosense RF catheter delivered the energy by touching the breast surface at one centimeter of the 3830 lead, screwed perpendicular to the RF catheter (see picture 2), and this 3830 lead was used as the return patch. The power was set at 50W.

Chicken breasts were used to test this concept since RF lesions turned promptly white, easily differentiable from raw chicken (non reported tests showed that after around 10-20 seconds of RF delivery the flesh turned white).

One chicken breast was prepared with RF applications at 50W, 10W, 5W, using A, B and C methods with a new 3830 lead for histologic examination.

To report the results, each lesion was cut in its middle, following the pacemaker lead long axis. A high-quality picture was obtained and digitized (24.1Mpx with a NIKON D5200 camera and a AF-S DX VR Nikkor 18-55mm f/3.5-5.6G II lens). Lesion surface area was then measured using the SketchAndCalc software (*https://www.sketchandcalc.com*). Each lesion surface area was averaged for the same kind of iteration and expressed as cm^2.

Results

There were 76 measures done from the 18 lesions created (see picture 1). See detailed results in the accompanying table 1. High impedances were detected at 10W and 50W which resulted in tissue remaining attached to the lead when it was removed (impedance limit had to be turned off). Power settings of 1 to 5 W were associated with normal impedance range (under 300 ohms). The bigger lesions were obtained at 10W method A ($0.78cm^2$), 50W method C (0.72 cm^2see picture 2) and 5W method B (0.44 cm^2).

Discussion

The results show that using the 3830 lead it is possible to create potential clinically relevant lesion sizes (they vary between similar or bigger to standard RF lesions area -$42mm^2$- when the proximal and bigger surface end of the 3830 lead is used, and also bigger than cryoablation lesions area -$20mm^2$- when the distal and smaller tip is used)[3]. Depending on the required lesion location and size, it is possible to deliver RF energy choosing the proximal or distal ends of the 3830 lead (signal acquisition for mapping and visualization in a 3-D mapping system is possible using standard crocodile connectors in humans), either in a direct fashion (3830 lead as an extension of the ablation catheter) or using it as the equivalent of a return patch; a bigger lesion area can be created when the RF is applied close to the 3830 lead which acts as a return patch. Small powers (W) are needed since the 3830 lead is embedded in the flesh (no irrigation increases sharply the impedances and precludes current flow with higher powers) and 1W to 10W are enough to create a lesion while keeping the impedances in a physiological range which prevents tissue boiling and tissue adherence to the 3830 lead. If most of the research direction points to irrigation to achieve deeper lesions, the opposite is possible with this 3830 (or other small catheters) as we can bring the 'tip' of our catheter or the 'return patch' closer to the arrhythmia foci, even deeper in flesh.

The search for deeper lesions when using RF ablation has successfully passed animal trials (early 2000s)[4,5] and has begun on small group of patients using a needle catheter.[6,7]

The main advantage of 3830 leads for future use is that they are flexible and small enough to be directed (subclavian or jugular access) from the right side of the heart to any place in the ventricular septum or the left ventricular summit using a deflectable introducer. Longer distances (more than 1cm from the right ventricular surface) can be reached choosing 3830 lead both proximal and distal ends to target the delivery of RF energy in a direct way (3830 lead as an extension of the RF catheter keeping stability -it is screwed-in potential dangerous areas as the left ventricular summit. Finally, the ability to use the 3038 lead as a return patch showed bigger lesion formation, but il also opens the door to a modified -and closer- bipolar RF delivery, as, instead of using another ablation catheter to close the RF circuit, any small catheter with easier deployment properties car be used as return patch either to create small lesion (RF delivered just in the blood) or bigger lesions (RF touching the tissue close to the pacing lead)

Limitations

The histologic examination could not be done. Paraffin chicken fixation (60^oC) cooked (turned white) the flesh, resulting in non-differentiation between the lesion sections and raw sections; no volume could be measured. Therefore, it was decided to cut each lesion in the middle and to measure just each lesion surface area. This is an ex-vivo experience, and done in a chicken breast, not myocardium, there is no way to ascertain how the lesions will be formed (and RF delivered) in a beating heart.

Conclusion

A 3830 pacemaker lead can be used to deliver RF and to create deep ablation lesions, with clinical relevant

size. The 3830 lead is widely available, and its employment is increasing, making its use for deep ablation purposes appealing. This opens a path to attain deep septal foci (LV summit) or epicardial (vein of Marshall) structures, using standard 4F pacemaker leads, 2F small EP catheters or isolated guidewires.

Data availability statement

Data available on request

Conflict of Interest

Sebastien Melancon is a clinical sales representative for Biosense Webster Canada. He brought free of charge the water tank which served as wet lab. The Thermocool SF NAV Bi-Directional Catheters (BNI35FJCT) from Biosense Webster were expired and thus free of charge.

Funding

None

References

1. Guandalini GS, Liang JJ, Marchlinski FE. Ventricular Tachycardia Ablation: Past, Present, and Future Perspectives. JACC Clin Electrophysiol. 2019;5(12):1363-1383. doi:10.1016/j.jacep.2019.09.015
2. Huang W, Su L, Wu S, et al. A Novel Pacing Strategy With Low and Stable Output: Pacing the Left Bundle Branch Immediately Beyond the Conduction Block. Can J Cardiol. 2017;33(12):1736.e1-1736.e3. doi:10.1016/j.cjca.2017.09.013
3. Lower incidence of thrombus formation with cryoenergy versus radiofreqncy catheter ablation. Khairy P, Chauvet P, Lehmann J, et al. Circulation; 2003;107(15):2045-50.
4. Sapp JL, Cooper JM, Soejima K, et al. Deep myocardial ablation lesions can be created with a retractable needle-tipped catheter. Pacing Clin Electrophysiol. 2004;27(5):594-599. doi:10.1111/j.1540-8159.2004.00492.x
5. Sapp JL, Cooper JM, Zei P, Stevenson WG. Large radiofrequency ablation lesions can be created with a retractable infusion-needle catheter. J Cardiovasc Electrophysiol. 2006;17(6):657-661. doi:10.1111/j.1540-8167.2006.00439.x
6. Sapp JL, Beeckler C, Pike R, et al. Initial human feasibility of infusion needle catheter ablation for refractory ventricular tachycardia. Circulation. 2013;128(21):2289-2295. doi:10.1161/CIRCULATIONAHA.113.003423
7. Stevenson WG, Tedrow UB, Reddy V, et al. Infusion Needle Radiofrequency Ablation for Treatment of Refractory Ventricular Arrhythmias. J Am Coll Cardiol. 2019;73(12):1413-1425. doi:10.1016/j.jacc.2018.12.070

Figures and table

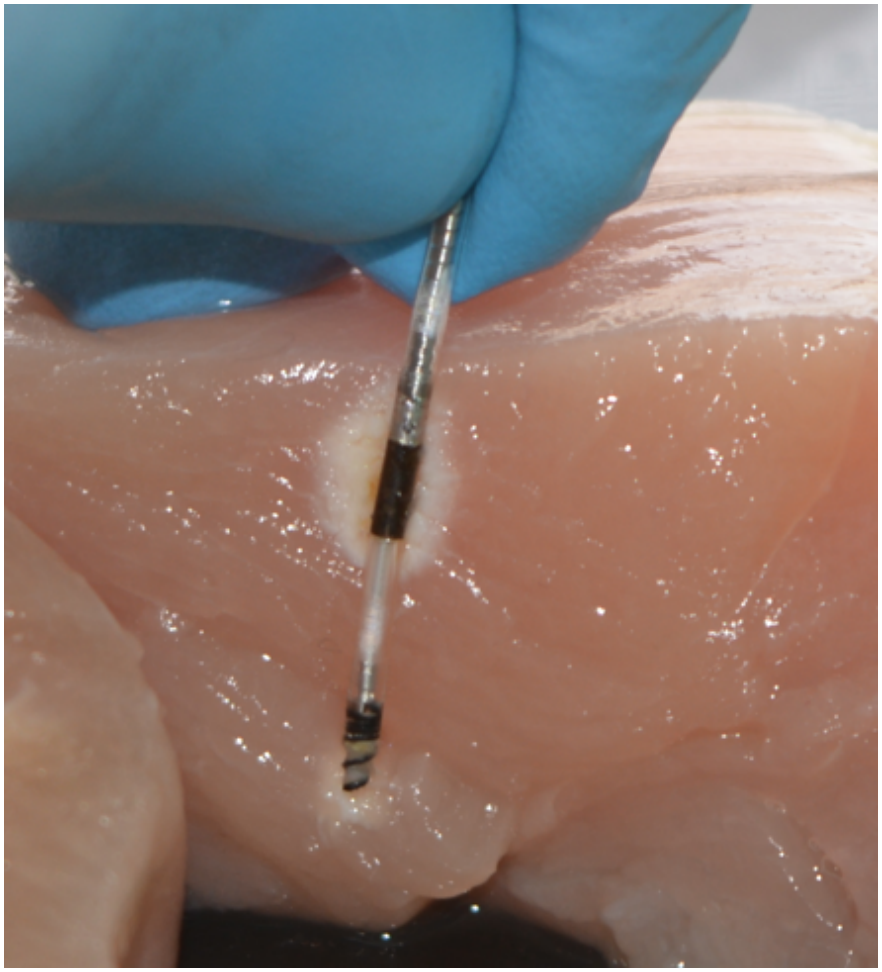

Figure 1: Position of 3830 pacemaker lead and lesion visualisation for proximal and distal ends

Figure 2: Bipolar indirect RF lesion, ablation catheter delivered RF in the surface of the chicken breast (upper part of picture) while the 3830 lead proximal pole (lower part of the lesion) acted as the return patch for RF

Table 1: Lesion size area (cm^2)

Watts	50	50	10	10	5	5	2	2	1	1
Method	Proximal	Distal	Proximal	Distal	Proximal	Distal	Proximal	Distal	Proximal	Distal
A	0.32	0.09	0.78	0.09	0.35	0.12	NA	0.11	NA	0.05
B	0.38	0.11	NA	NA	0.44	NA	NA	NA	NA	0.24
C	0.72	0.04	NA	NA	NA	NA	NA	NA	NA	NA

Each box is an average of the different iterations done for every method and their respective variations. Missing values -NA- are either non-lesion formation (low powers) or RF not delivered (high impedances)

Hosted file

`Deep Foci RF ablation using 3830 pacemaker lead_figures.docx` available at https://authorea.com/users/482063/articles/568808-deep-foci-rf-ablation-using-3830-medtronic-pacemaker-lead-proof-of-concept

Hosted file

`Deep Foci RF ablation using 3830 pacemaker lead_table.docx` available at https://authorea.com/

users/482063/articles/568808-deep-foci-rf-ablation-using-3830-medtronic-pacemaker-lead-proof-of-concept