

Are The Virtual Lines Created with the Ensite Electroanatomical Mapping System Really Continuous?

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Abstract

Background: EnSiteNavx electroanatomic mapping system is widely used in radiofrequency (RF) atrial fibrillation ablation, helping the creation of linear lesions. However, the correspondence of the virtual line created by EnSite with the pathological lesion has not yet been evaluated.

Objective: to assess the continuousness of Ensite-guided virtual lines in a swine model.

Methods: we performed RF ablation linear lesions (8mm and irrigated catheters tips) in both atria of 14 pigs (35Kg) guided by the EnSite. The animals were sacrificed 14 days post-ablation for macroscopic and histological analysis.

Results: a total of 23 lines in the right atrium and 21 lines in the left atrium were created in 14 animals. The medium power, impedance and temperature applications were 56 W, 54 °C and 231 Ω for the 8mm tip, and 39W, 37°C, 194 Ω for the irrigated tip catheter, respectively. All (100%) lines were identified on the epicardial and endocardial surfaces, denoting transmural. At macroscopic examination, lesions were extensive and pale, continuous, with 3.61 cm long and 0.71 cm deep. The transmural of the lesions was confirmed by microscopy. There was a correlation in the location of the lines at the virtual map and the anatomical lesions in 21 of 23 (91.3%) of the right atrium and 19/21 (90.4%) of the left atrium.

Conclusion: In this model, the lines created in the virtual map by EnSiteNavX system correspond to continuous transmural linear lesions in anatomical specimen, suggesting that this method is suitable for linear ablation of atrial fibrillation (Arq Bras Cardiol. 2013; [online].ahead print, PP.0-0).

Keywords: Swine; Catheter Ablation, Atrial Fibrillation; Heart Atria / anatomy & histology.

Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia in clinical practice and an important medical problem due to its impact in quality of life and high risk of vascular accidents, heart failure and mortality¹. Since Haissaguerre² described the role of pulmonary veins in AF, radiofrequency (RF) ablation rapidly evolved from experimental procedure to a common practice. In recent guidelines^{1,3,4}, isolating the veins is enough for short-lasting paroxysmal and persistent cases, however, in remodeled atria, it is required a more detailed approach⁵, which includes seeking for complex fractionated atrial electrograms (CFAEs) and creation of continuous lesion lines connecting structures that are electrically inactive. In this case, it is crucial for this procedure to be successful that the line is continuous, for

continuity solutions in its extension facilitate the development of reentrant atrial tachycardias, which are very symptomatic and difficult to be clinically controlled⁶.

The onset of the electroanatomic mapping was decisive to help creating the lines^{7,8}. This technique allows building three-dimensional maps of the atrial geometry, visualization of catheters inside the heart (virtual map) and marking of ablation points, all in real time, becoming a gold-standard in AF ablation. However, marking the lesion points in the map, during RF application, is operator-dependent. I.e. continuous virtual lines may not have a pathological correspondence. The main electroanatomic mapping systems are CARTO (BiosenseWebster, Inc, Diamond Bar, USA) and EnSiteNavX (StJude Medical, St Paul, MN, USA). Although the correspondence between virtual and anatomopathological lines have been assessed with CARTO⁷, this correlation has not been evaluated with EnSiteNavx. Therefore, we have performed linear atrial lesions guided by electroanatomic mapping in pigs, in order to evaluate the continuity of virtual lines in the anatomic specimen.

Methods

The study was approved by the Ethics Committee of the Federal University of São Paulo (Unifesp) and implemented according to the institutional guidelines.

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Sample

This study is a subanalysis of a paper recently published by our group⁹, which aimed at evaluating the impact of prophylactic corticosteroids in inflammation generated by extensive atrial ablation. 14 Pernalan, young adult pigs (3 months old), male (35 + 3 kg), subjected to quarantine under veterinary supervision to ensure the animals health status. After fasting (8-12h), the animals were premedicated with acepromazine (0.2 mg/kg IM) and midazolam (0.4 mg / kg IM) and, anesthetized 15 minutes later with propofol (1-2 mg / kg IV followed by continuous infusion 1-4 mg/kg/hour), intubated and maintained on artificial ventilation with oxygen necessary to maintain adequate saturation (>90%), with electrocardiographic monitoring and pulse oximetry. Body temperature was maintained at approximately 37°C with a heating blanket. After shaving and antisepsis, patches of the EnSite NavX8.01 (St.Jude Medical, St. Paul, MN, USA) System were applied, in addition to an indifferent plate electrode. Under sterile surgical conditions, the left (11F) and right (11F) femoral veins and the right jugular vein (7F) were dissected and cannulated, through which were introduced, under fluoroscopic guidance, respectively, the intracardiac echocardiogram catheters (AcunavAcusson 10F, Siemens AG, Germany); sheath (SL1-St.Jude Medical) and needle (BRK – St. Jude Medical) for transseptal puncture and diagnostic quadripolar catheter 6F (St.JudeMedical) allocated in coronary sinus. Local electrograms and ECG were filtrated (30 - 500 Hz) by Polygraph TEB SP32 (Brazilian Electronic Technology, São Paulo Brazil). After transseptal puncture guided by intracardiac echocardiogram (Figure 1), 5.000 units of unfractionated heparin (Liquemine® IV) were administered intravenously.

Electroanatomic mapping

The atrial geometry was performed by the EnSiteNavX electroanatomic mapping system, and the quadripolar catheter was positioned in the coronary sinus as the anatomical reference electrode. Impedance calibration and compensation of respiratory movements were always performed. Three-dimensional geometry of cavities was obtained in sinus rhythm using the pair of distal electrodes of the deflectable ablation catheter 7F⁹.

Ablation procedure

Under fluoroscopy and with the aid of the virtual map, a linear lesion was initially created inside the right pulmonary vein from the distal portion (± 2 cm) to the ostium. 1–2 linear lesions were created in each atrium: from the appendage to the right pulmonary vein and from the roof to the right pulmonary vein; in the left atrium, from the superior vena cava to the inferior vena cava through the lateral surface of the atrium and from the appendage to the superior vena cava. Each unipolar RF application (Stockert generator, Biosense Webster Inc., Diamond Bar, CA, USA) lasted 90 seconds, with the catheter being dragged along the line every 15-20 seconds simultaneously to the acquisition of the marks on the virtual map. However, no electrophysiological maneuvers were performed to confirm the line of block. Ablation was performed with 7Fr catheters either with an 8mm tip (Biosense Webster, Diamond Bar, USA) at a maximum power of 70W and under controlled temperature at 60°C, or with a 3.5mm irrigated tip (Irvine, St.Jude Medical, St. Paul, USA) at a maximum power of 50W, a temperature of 50°C and with continuous irrigation of 17 mL/min during the application. The power (Watts), impedance (Ω), and temperature ($^{\circ}\text{C}$) of the catheter tip were monitored during

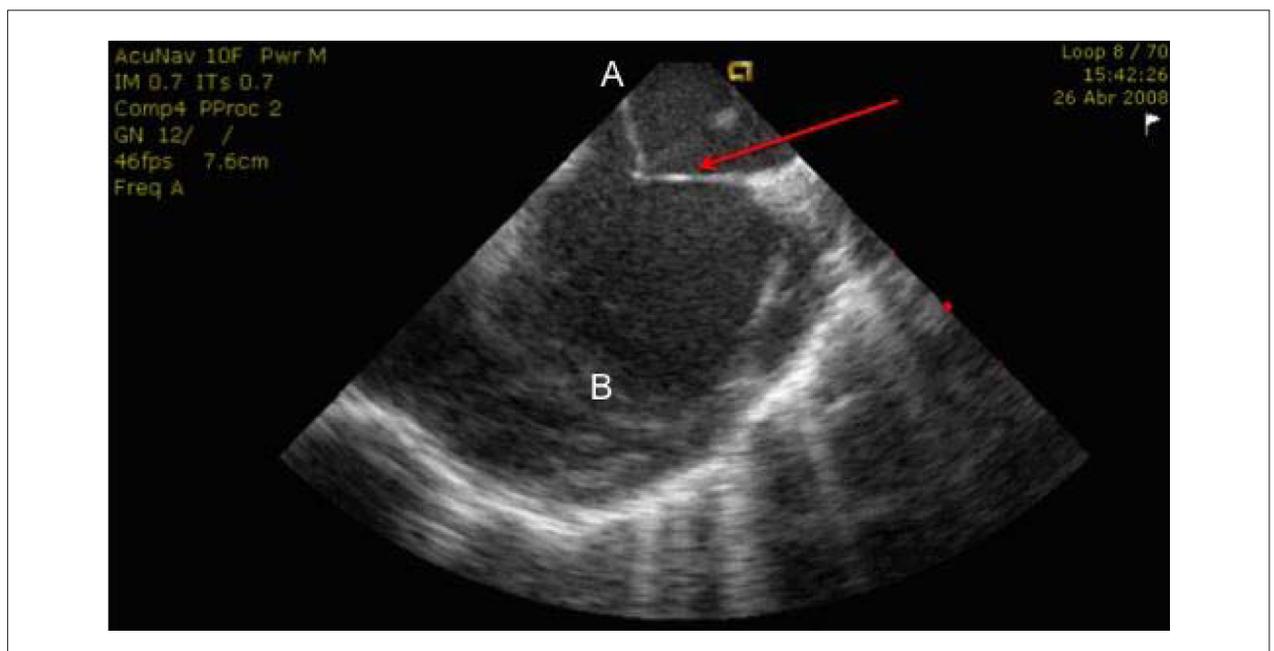


Figure 1 – Image of the intracardiac echocardiogram during transseptal puncture. The red arrow indicates the tent formed in the interatrial septum immediately after the puncture. A: right atrium. B: left atrium.

each application and the mean value was recorded for analysis. The application was interrupted if a pop occurred and the catheter was checked for the presence of clots. The animals that presented arrhythmias during the procedure, with ventricular fibrillation being the most common (pigs are highly susceptible to this arrhythmia), were subjected to transthoracic defibrillation with the plates positioned transversely. By the end of the procedure, catheters were removed, blood vessels were connected and wounds were sutured. Procedures were performed by the same operator and in sterile conditions, without the need of prophylactic antibiotics. Neither anticoagulants or antiplatelet aggregant agents were administered. Animals subjected to ablation were divided in 02 groups: control (n=7), which did not receive any drugs; and corticosteroids (n=7), which received 500mg metilprednisolone IV in bolus at anesthetic induction. In both groups, 5 animals were ablated with 8mm catheter and 2 with an irrigated catheter. All pigs were monitored for 14 days under veterinary care.

Since there were no differences between the groups regarding ablation parameters, inflammation markers and the histology of RF lesions⁹ in this study, all 14 animals (treated with corticosteroids and controls) were aggregated in one single group.

Macroscopic analysis

The animals were returned to the laboratory 14 days after the procedure, weighed, and sacrificed with a lethal KCl injection under general anesthesia. The heart was carefully removed and the ablation lines were macroscopically identified, correlated with the applications to the cardiac cavities, measured (width, length, and depth) with a millimeter ruler on the epicardial and endocardial surfaces, and then documented with digital photography.

Histological analysis

The linear lesions were sliced on various sequential transverse histological sections so that they would be fully covered, i.e. the line was approached from the beginning to the end to ensure the continuity analysis. The slides were stained with Haematoxylin–Eosin (HE) and Masson Trichrome and qualitatively analyzed by a pathologist who was blind to the study groups. Special attention was paid to the healing characteristics of the lesions such as transmuralità, continuity, density of fibrosis, and inflammation.

Statistical Analysis

SPSS 8.0 system was used. A descriptive analysis of the continuous variables was performed based on the mean and standard deviation.

Results

RF ablation

Using a virtual map, a total of 23 linear lesions in the right atrium and 21 linear lesions in the left atrium were created in 14 animals. The mean power, temperature, and impedance

of application were 56W, 54 °C and 231Ω for the 8mm tip, and 39W, 37°C, 194Ω for the irrigated tip catheter. The description of the animals, application parameters and measures of lesion lines are shown in Tables 1 and 2. All 14 animals completed the 14-day follow up without interurrences.

Macroscopic analysis

All of the 23 linear lesions created in the right atrium and the 21 lesions created in the left atrium of the 14 animals (100%) were identified on both the epicardial and the endocardial surfaces, indicating transmuralità of the lesions. Macroscopic inspection revealed extensive and pale lesions, measuring 3.61±0.67cm in length and 0.71±0.18cm in width, and continuous. The lesions created with the irrigated catheter were more difficult to visualize macroscopically since they were paler and had less defined margins, although they did not differ in dimensions or transmuralità. When analyzing the virtual maps provided by EnSiteNavX 8.01 System, there was a correspondence in the location of virtual map lines with anatomic specimen lines (Figure 2) in 21 of 23 (92.3%) of right atrium lines and 19/21 (90.4%) of left atrium.

Histological analysis

The lesion lines were cut transversely into consecutive sections and their transmuralità finding was confirmed (Figure 3). There was reproduction of the findings in every consecutive plates, indicating the lesion continuity. The qualitative analysis was very consistent: there was coagulative necrosis with necrotic muscle being replaced with newly formed fibrosis. Granulation tissue, calcification and lymphocytic infiltration were present in some lesions (Figure 3B), and in others there was recent thrombus (Figure 3C). The borders of the lesions were characterized by necrotic tissue with an inflammatory cellular infiltration rich in macrophages and lymphoplasmacytic cells (Figure 3D) and also various degrees of fibrosis and neovascularization.

Discussion

In this model of extensive atrial ablation in pigs we demonstrated that creating continuous lines in the virtual map of EnSite system was correlated with the presence of transmural anatomic lines identified by macroscopy and microscopy. Although the CARTO⁷ system has already demonstrated, this study is the first one to evaluate the relation of virtual map lines, acquired with EnSiteNavX 8.01 system, with the respective localization in the anatomic specimen. It is worth noting that the methodology used to access the left atrium, as well as the creation of lines by RF application was similar to that used clinically and findings were consistent for over 90% of the animals. Moreover, the swine model is used in studies to assess atrial lesions generated by radiofrequency^{10,11}.

AF ablation in remodeled atria, mainly in the persistent long-lasting form, remains challenging. In these cases, creating lesion lines on the left atrium, imitating the surgical procedures for AF treatment, such as, for example,

Table 1 – Characteristics of the animals (n = 10), radiofrequency application parameters and size of lesion lines when an 8mm-tip catheter is used

Pig	Weigh kg	RF ablation parameters				Lesion size (cm)		
No.	Basal / Final	Chamber	T (°C)	P (Watts)	Time (s)	No. of lines	Length	Depth
1	32/31	RA	52 ± 6.0	62 ± 15.9	603	1	4.0	0.8
		LA	56 ± 8.2	59 ± 16.0	528	1	4.0	0.9
2	36/48.6	RA	55 ± 5.6	50 ± 23.6	505	2	3.5/4.0	0.8/0.9
		LA	54 ± 5.9	63 ± 15.8	488	1	5.0	0.9
3	32/41	RA	49 ± 8.4	68 ± 5.2	420	2	3.0/3.0	0.5/0.6
		LA	55 ± 6.6	45 ± 23.3	519	2	4.0/3.0	0.8/0.7
4	40/42	RA	52 ± 5.0	65 ± 11.7	468	2	4.0/3.0	0.8/0.6
		LA	57 ± 4.2	45 ± 21.3	510	2	3.5/3.4	0.6/0.7
5	38/44	RA	58 ± 4.3	52 ± 22.0	503	2	4.0/3.5	0.8/0.5
		LA	57 ± 4.8	40 ± 22.8	510	2	3.0/3.0	0.5/0.6
8	42/42	RA	54 ± 7.9	45 ± 25.3	487	1	5.5	1.2
		LA	56 ± 6.8	41 ± 28.4	520	2	3.5/3.0	0.5/0.6
9	35/31	RA	51 ± 8.3	55 ± 23.8	526	2	3.5/3.0	0.8/0.7
		LA	58 ± 3.4	57 ± 14.1	496	2	3.0/3.0	0.5/0.5
11	35/40	RA	49 ± 8.8	65 ± 9.3	530	1	3.6	0.5
		LA	45 ± 18.5	56 ± 19.4	540	1	3.6	0.5
12	39.6/33	RA	57 ± 5.2	49 ± 15.8	505	1	5.0	0.9
		LA	53 ± 6.3	58 ± 20.6	497	1	4.0	0.8
13	36/34	RA	55 ± 4.7	57 ± 19.3	627	2	3.5/3.0	0.8/0.6
		LA	58 ± 17.8	55 ± 5.6	543	1	5.5	1.1
Total	36.5 ± 3.3/ 38.7 ± 6.0	RA	50.2 ± 9.14	54.4 ± 20.8	517.4 ± 60.5	16	3.09 ± 0.73	0.69 ± 0.24
		LA	54.6 ± 8.02	53.7 ± 21.3	515.1 ± 18.5	15	3.63 ± 0.77	0.68 ± 0.19

RA: right atrium; LA: left atrium; P: power; RF: radiofrequency; T: temperature.

Table 2 – Characteristics of the animals (n = 4), radiofrequency application parameters and size of lesion lines when an irrigated-tip catheter is used

Pig	Weigh kg	RF ablation parameters				Lesion size (cm)		
No.	Basal / Final	Chamber	T (°C)	P (Watts)	Time (s)	No. of lines	Length	Depth
6	32/39.5	RA	36 ± 1.5	40 ± 0.8	548	2	3.5/3.0	0.7/0.7
		LA	37 ± 2.9	40 ± 0.5	468	1	4.0	0.7
7	36/39.8	RA	38 ± 3.6	40 ± 1.6	512	2	3.5/3.0	0.7/0.5
		LA	38 ± 4.2	39 ± 1.9	347	2	4.0/3.3	0.8/0.6
10	35/43.5	RA	37 ± 2.7	40 ± 0.9	525	2	3.0/3.0	0.5/0.5
		LA	36 ± 4.2	40 ± 2.4	506	2	3.5/3.0	0.9/1.1
14	36/38	RA	38 ± 3.2	40 ± 1.2	488	1	5.5	1.0
		LA	38 ± 4.3	38 ± 3.7	509	1	3.5	0.6
Total	34.8 ± 1.9/ 40.2 ± 2.3	RA	37.2 ± 2.98	39.7 ± 1.19	518.2 ± 25.0	7	3.50 ± 0.91	0.65 ± 0.18
		LA	37.3 ± 4.01	39.3 ± 2.55	457.5 ± 76.0	6	3.55 ± 0.49	0.78 ± 0.19

RA: right atrium; LA: left atrium; P: power; RF: radiofrequency; T: temperature.

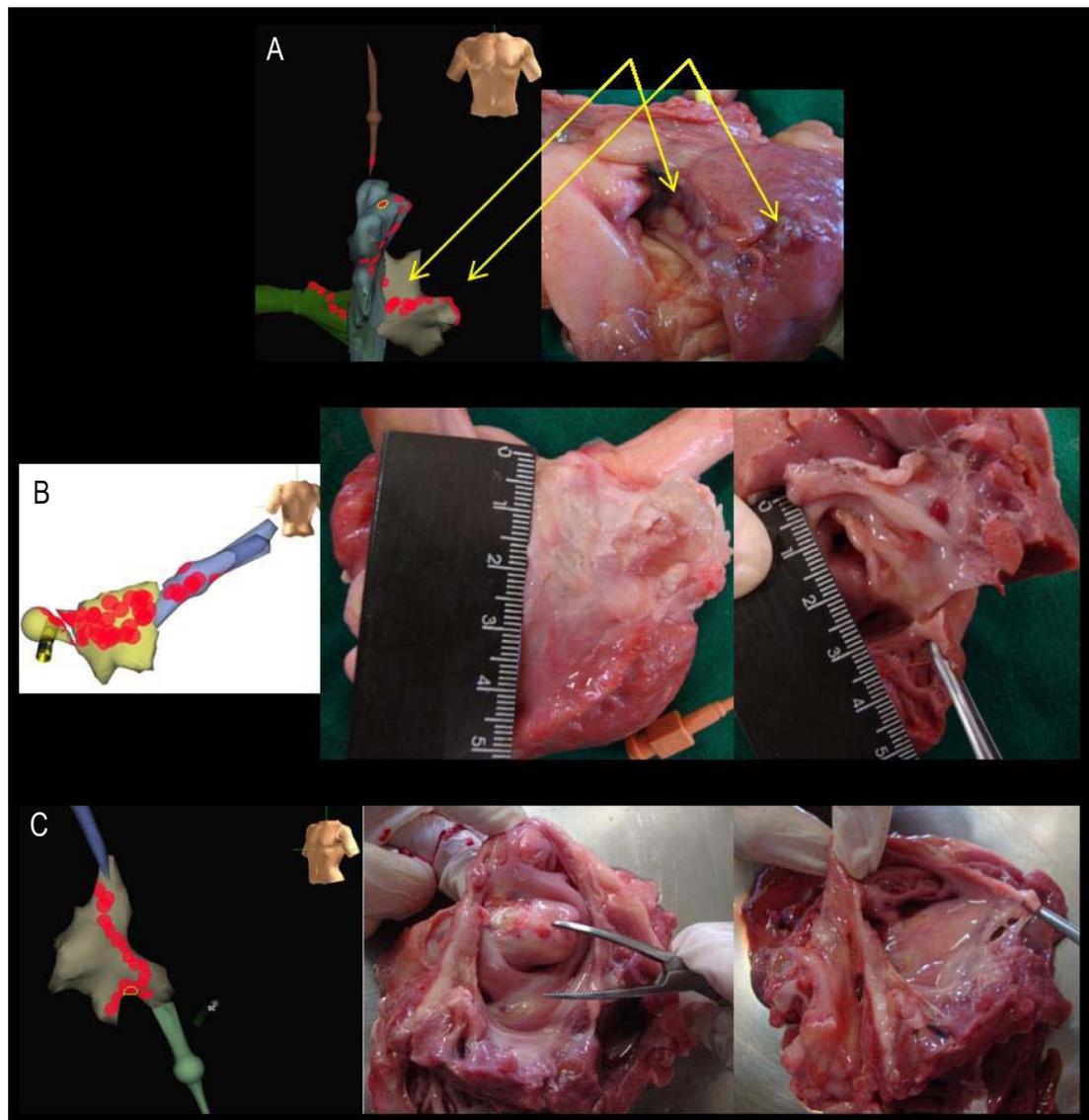


Figure 2 – Correlation of lesion lines obtained in virtual map and anatomic specimen. A: line on left atrium, epicardial correlation. B: line on left atrium, epicardial and endocardial correlation. C: line on right atrium between the inferior and superior vena cava shown on the endocardial surface.

the Cox/Maze operation is used^{12,13}. However, the presence of gaps in the lesion line provides the genesis of reentrant atrial tachycardias, which are very symptomatic and difficult to control^{5,14,15}. The electroanatomic mapping enabled the visualization of the catheter movement in real time (without fluoroscopy) and also the marking of each lesion point during the application. Thus, the operator can return to the same position and create a line "perfect to the naked eye". However, there is no guarantee that the virtual map line corresponds to a real lesion line. Although the assessment of the continuity of lines can be performed using electrophysiological maneuvers³, this process is laborious and time consuming, often causing the operator to be based exclusively on the virtual line. Our findings suggest this is an appropriate strategy.

It should be noted, however, that the acquisition of the points was thorough and each point was obtained after 20 seconds of RF application.

It should be noted that several technologies are developed in order to increase the accuracy of the lesion creation using RF, namely. i) magnetic navigation systems to guide the catheter, either a platinum¹⁰ or golden tip¹⁶, which increase its stability; ii) pressure sensors on the tip of the catheter¹⁷, allowing to measure its contact with the atrial surface, hypothetically improving the creation of transmural lesions; iii) integrating an ultrasound to the catheter tip to visualize in real time the lesion formation is capable to distinguish necrosis from hemorrhage in real time¹¹; iv) endoscopic ablation system with balloon that

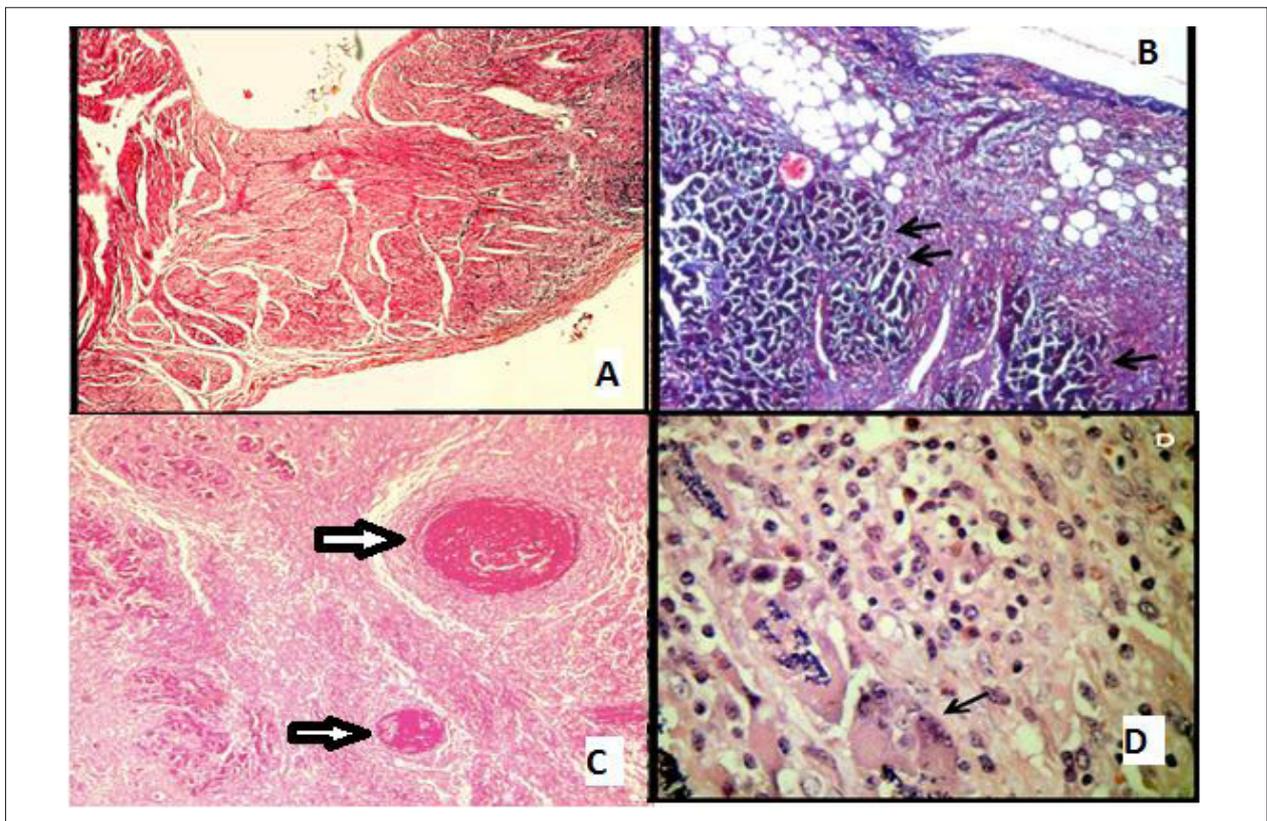


Figure 3 – Histological aspect of the lesions. A: Lesion transmural clearly demonstrated in smaller zoom (4X, H&E). B: Epicardial surface with fibrosis and discrete lymphocytic infiltrates (arrows) (10X, Masson). C: Presence of necrosis and thrombi clearly demonstrated (arrows) (5X, H&E). D: local inflammatory response characterized by infiltrate rich in lymphocyte-plasma cells and macrophages (giant cell, arrow) (40X, H&E).

visualizes directly the vein to be isolated and performs laser ablation. However, until the validation and daily use of these technologies, creating lines with electroanatomic mapping guidance remains as gold-standard for linear ablation for AF treatment.

Limitations

The lesion line continuity was measured by macroscopic and microscopic analysis. Electrophysiological assessment to confirm the line block was not performed during the ablation procedure, because the pigs are too susceptible to ventricular fibrillation induction with electric stimulation. The length of lesion lines on the virtual map was not determined, therefore, we could not perform the correlation with the length on anatomic specimens. The animals were sacrificed after 14 days of wound healing. Therefore, although very unlikely, we cannot exclude that discontinuities on the line may develop in longer segments, as suggested by electrophysiological observations provided from clinical studies. Ablation was performed with high peak powers (70W, 8mm and 50W, irrigated). There is no way to evaluate if the results would be maintained with the use of lower powers. Procedures were performed in atria of normal pigs, therefore, the results cannot be directly extrapolated to humans and sick atria, with AF.

Conclusion

In this model of atrial ablation, the lines created in the virtual map by EnSite NavX system correspond to continuous transmural linear lesions in anatomical specimen, suggesting that this method is suitable for linear ablation of atrial fibrillation.

Author contributions

Conception and design of the research and Writing of the manuscript: Nascimento T, Fenelon G; Acquisition of data: Nascimento T, Mota F, Santos LFN, Okada M, Fenelon G; Analysis and interpretation of the data: Nascimento T, Araújo S, Franco M, Paola AAV, Fenelon G; Statistical analysis: Nascimento T; Obtaining funding: Fenelon G.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

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