The LocaLisa system as the key to shortening the procedure duration and fluoroscopy time during ablation of atrial fibrillation

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Abstract

Background: Ablation of atrial fibrillation (AF) can be difficult and time-consuming. Systems facilitating catheter navigation may be helpful.

Aim: To compare the efficacy of the LocaLisa system with the conventional mapping/ablation approach to radiofrequency (RF) ablation of AF.

Methods: Group 1, consisting of 64 patients (48 male; aged 51.5±10.6 years), underwent segmental isolation of the pulmonary veins with the Lasso catheter and the LocaLisa system. Group 2, consisting of 64 patients (44 male, aged 51.4±11.0 years), had RF ablation guided by means of a conventional fluoroscopy-based approach. Clinical and procedural data were analysed.

Results: Nine patients from group 1 and three patients from group 2 had persistent AF. In group 1 the mean number of isolated veins was 3.98±0.96, while in group 2 – 4.0±0.95 (NS). In group 1 cavotricuspid isthmus lines were created in four patients and lines in the roof of the left atrium in two patients. One patient needed slow pathway ablation. In group 2 six patients had ablation of the cavotricuspid isthmus and a line was created at the roof of the left atrium in one patient. Two patients had ectopic activity ablated in the crista terminalis. Procedure times were 131.6±40.3 and 170.0±56.5 min ($p < 0.0001$) and fluoroscopy times were 16.93±9.7 and 35.66±12.7 min ($p < 0.0001$) for groups 1 and 2, respectively. Long-term efficacy of RF ablation was similar in both groups (for example, complete success was achieved in 59% of patients using LocaLisa and 50% without using this system, NS).

Conclusions: The LocaLisa navigation system makes it possible to shorten both the duration of the procedure and the total fluoroscopy time during ablation of AF.

Key words: atrial fibrillation, radiofrequency ablation, LocaLisa system, pulmonary vein isolation

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Introduction

Atrial fibrillation (AF) is the most common arrhythmia and is difficult to treat because of its complex aetiology and pathophysiology. The problem with AF is not only related to its high prevalence but also to persistent symptoms, frequent recurrences and major complications such as thromboembolism and heart failure, which result in increased mortality [1]. The frequency of AF, its life-threatening complications and lack of satisfaction with medication therapy have led to a significant improvement in non-pharmacological therapies. Radio-frequency (RF) ablation of AF as a method of treatment of AF was acknowledged in recent ACC/AHA/ESC guidelines and the HRS/EHRA/ECAS Expert Consensus [2, 3]. The aim of AF ablation is to achieve electrical isolation of the pulmonary veins by destroying muscular breakthroughs connecting the atrium and the veins. During this procedure the substrate is often modified and rotors are eliminated.

Radio-frequency isolation of pulmonary veins is a technically complicated and time-consuming procedure which often requires a long fluoroscopy time [4, 5]. Technological development enabled new electrophysiological systems to be systematically introduced, and made the ablation safer and the procedural and fluoroscopy times

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shorter. One of these systems is LocaLisa (Medtronic EP Systems, Minneapolis, MN, USA). The aim of the study was to compare the efficacy of the LocaLisa system with the conventional mapping/ablation approach to RF ablation of AF.

Methods

Patients

The study included 128 symptomatic patients with a history of drug-refractory AF (at least ≥1 failed medication), treated between December 2004 and February 2006. Group 1 consisted of 64 patients (48 males, 16 females; aged 51.5±10.6 years), who underwent ablation for AF using the Lasso 2515 (Johnson & Johnson) catheter and the LocaLisa system (Figure 1). Nine of these patients had permanent AF.

The control group consisted of 64 consecutive patients (44 males, 20 females; aged 51.4±11 years) assigned to undergo RF ablation guided by a conventional fluoroscopy--based approach with a Lasso 2515 catheter but without the LocaLisa system. Three patients in this group had permanent AF.

All patients gave their informed written consent to participate in the study. Transthoracic and transoesophageal echocardiography was performed to exclude thrombus and to assess cardiac and pulmonary vein anatomy before ablation. Patients were randomly assigned into groups with or without use of the LocaLisa system. To exclude the role of the learning curve, all ablation procedures were performed within a short period of time (December 2004 – February 2006).

Ablation

The procedures were performed using four catheters introduced through both femoral veins: the Lasso catheter, a Marinr with a 4 mm tip (Medtronic) as the ablation catheter, and four-pole diagnostic catheters placed in the coronary sinus and the inflow tract of the right ventricle. Left heart catheterisation was performed through a patent foramen ovale (19.5%) or by a trans-septal puncture. The Lasso catheter was subsequently located in each pulmonary vein under fluoroscopic guidance in both groups.

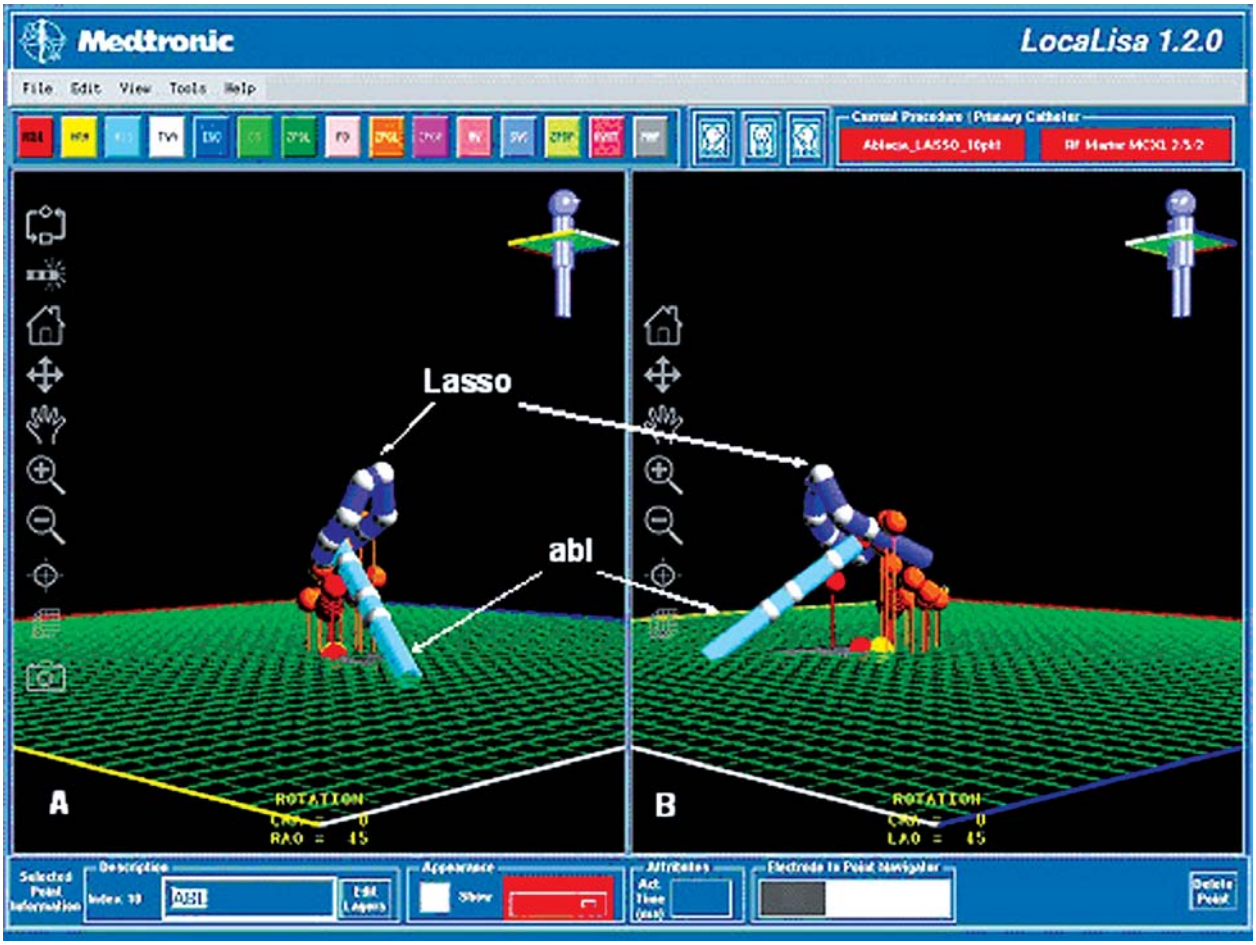

Figure 1. The LocaLisa system during ablation of pulmonary veins. **A** – RAO 45° view, **B** – LAO 45° view. Both views are simultaneously displayed on the screen in real time. The arrows indicate catheters: the Lasso and the ablation catheter (abl), placed in the ostium of the left superior pulmonary vein

Abbveriations: RAO – right anterior oblique, LAO – left anterior oblique

In the first group the Lasso catheter was placed in the ostium of the vein and then the procedure was continued with the help of the LocaLisa system and fluoroscopy only when needed. After the Lasso had been positioned, segmental isolation of all accessible pulmonary vein ostia was performed. The temperature and power were set at 50°C and 30 W respectively. The end point of the ablation of a single vein was achieved when it was demonstrated that pulmonary vein potentials had disappeared from the Lasso catheter or there was an exit/entrance block. The ablation procedure was completed when all pulmonary veins were electrically isolated. In the event of concomitant arrhythmias such as typical atrial flutter (AFL), atrioventricular nodal re-entry tachycardia (AVNRT) or atrial tachycardia (AT), the ablation procedure was extended to the cavotricuspid isthmus (CTI), slow pathway or arrhythmogenic ectopy in the atrium, respectively.

All procedures were performed by the same experienced electrophysiologist (EK), who had performed more than 200 AF ablations before the study. Moreover, the same radiology apparatus, namely Ziehm Vision 9153 (Ziehm Imaging GMBH Germany), was used in all procedures at the same settings (12.5 exposures per minute). The radiation dose was assessed as fluoroscopy time and the dose-area products (expressed in cGy × cm^2) derived from the radiology equipment.

Table I. Clinical characteristics of the study patients

Parameter	Group 1 (LocaLisa)	Group 2	p
Number of patients	64	64	NS
Male	48	44	NS
Age [years]	51.5±10.6	51.4±11	NS
Patients with permanent atrial fibrillation	9	3	NS

Table II. Comparison between the two groups with respect to ablation details

Parameter	Group 1 (LocaLisa)	Group 2	p
Number of isolated veins	3.98±0.96	4.0±0.95	NS
Additional ablation lines	6	7	NS
Total procedure time [min]	131.6±40.3	170±56.5	<0.0001
Fluoroscopy time [min]	16.93±9.7	35.66±12.7	<0.0001
Dose-area product [cGy × cm^2]	3960±2392.9	8243±4014	<0.0001
Major complications	0	2	NS

Follow-up

The assessment of efficacy of RF ablation was performed on the basis of ECG monitoring and the severity of symptoms. Duration of follow-up was one year. During this time patients were asked to record standard ECG or transtelephonic recordings whenever symptoms occurred. Additionally, regardless of symptoms, patients were scheduled for seven 24-hour Holter ECG recordings per year. AF recurrence was diagnosed when arrhythmia lasted at least 30 seconds. Success was defined as freedom from AF during the whole follow-up period. A partially successful procedure was defined as a situation in which AF recurred during ECG follow-up but the patient reported significant improvement of symptoms. The 'therapy stabilisation' (blanking) period was 6 weeks, during which AF recorded on ECG was not regarded as failure of the procedure.

Statistical analysis

The results are presented as mean ± standard deviation. The analysed parameters were compared using Student's T test and the chi square test. A p value <0.05 was considered statistically significant.

Results

Clinical and demographic data are presented in Table I. There were no significant differences between the two analysed groups regarding demographic data and percentage of patients with permanent AF. Procedural data are compared in Table II. In the first group additional ablations included CTI ablation in 4 patients and creating a line in the roof of the left atrium in 2 patients. One patient needed a slow pathway ablation. In 6 patients from the second group CTI ablation was performed and in 1 patient a line was created in the roof of the left atrium. Two patients had additional ectopic activity ablated in the crista terminalis. Two patients from the first group had a bi-atrial pacing system implanted and one subject had a PLAATO occluder inserted in the left atrial appendage. In the second group one patient had an AAI pacemaker implanted and another underwent atrial and ventricular defect repair. A persistent left superior vena cava with atrophy of the superior right caval vein was detected in one patient. Altogether, the number of isolated veins and the number of additional lines created was similar in both groups.

Complications occurred only in group 2. One patient had cardiac tamponade, which was treated with cardiac surgery. Another patient had a transient ischaemic attack (TIA). In group 1 the procedures were completed without any major complications (Table II).

Ablation procedures with the use of LocaLisa system were significantly shorter (by 23%) than those performed without LocaLisa. The use of the LocaLisa system enabled fluoroscopy time to be significantly reduced, by 53%. The dose-area product was also significantly reduced when the LocaLisa system was used (Table II).

Efficacy of AF ablation in both groups is compared in Figure 2. The proportion of patients with complete elimination of symptoms, those with partial success and those with failed ablation was similar in both groups.

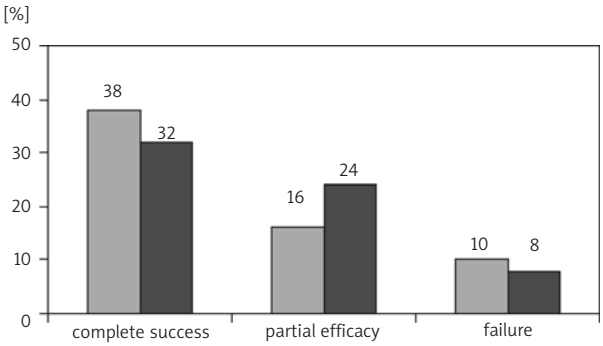

Figure 2. Efficacy of AF ablation in patients using the LocaLisa system (gray bars) and in those in whom the system was not used (black bars) (all differences NS)

Discussion

LocaLisa is one of the navigation systems currently available in electrophysiology. The system has the ability to visualise catheters in real time and in 3D geometry, and to localise with a high degree of accuracy almost all the available catheters used in the electrophysiology laboratory [6]. These would appear to be sufficient reasons to recommend the use of the system in ablations of well-defined substrates such as AFL or AVNRT, as well as in children [7–9]. Although the system does not enable voltage, activation and propagation maps to be created, LocaLisa was tested in the ablation of more complex arrhythmias such as atrioventricular re-entry using accessory pathways, supraventricular tachycardia, postcardiotomy AT, ventricular tachycardia and even AF [10-15].

Schneider et al. conducted prospective randomised research that compared the ablations of typical AFL performed both with and without the LocaLisa system [7]. The results showed a reduction of 53% in radiation exposure when LocaLisa was used. Kirhof et al. demonstrated that LocaLisa enabled fluoroscopy time to be reduced by 35% during ablations of supraventricular tachycardia in comparison to a conventional approach [11]. However, that study included a relatively small group of patients (n=29). Moreover, the majority of the patients (n=15) had AVNRT. There were only 4 patients with AF in this group, which made a comparison of fluoroscopy time between their and our study practically impossible. Kowalski et al. confirmed in their work the reduction of total fluoroscopy time in a group of 26 patients with AVNRT [9].

Of note, neither Kirchhof et al. [11] nor Kowalski et al. [9] were able to demonstrate a shortening of total procedure time when the LocaLisa system was used. In our study fluoroscopy duration and total procedural time were considerably shorter. This can be explained by the fact that isolation of the pulmonary veins is a more complex ablation, demanding more RF applications and a wider ablation area. It is possible that the small number of RF applications (1 to 4), as frequently encountered during an AVNRT ablation, may be the reason why LocaLisa did not reduce the total procedure time.

As all the above examples show, LocaLisa has been widely used with success in the treatment of various arrhythmias. Our study was not the first one in which this system for ablation of AF was used [5, 14, 15]. However, we managed to show in a large group of patients that the use of LocaLisa enables fluoroscopy and procedure times to be shortened during segmental ablation of pulmonary vein ostia without affecting efficacy. It has been suggested that the total procedure time reduction due to use of the LocaLisa system can be better demonstrated during more complex procedures. Our data are in agreement with the findings of Macle et al., who reported a significant reduction in fluoroscopy time and procedure duration when the LocaLisa system was used in a randomised study which included a smaller group of patients (n=52) than our study [5].

In contemporary electrophysiology, there are, apart from the above-mentioned LocaLisa system, many other electroanatomical and navigation systems, such as CARTO (Biosense Webster, Diamond Bar, CA, USA) and EnSite/NavX (Endocardial Solutions Inc, St. Paul, MN, USA). After a comparison in randomised trials between ablations of typical AFL in which CARTO was used and the conventional (fluoroscopy) technique it became clear that the electroanatomical system shortens radiation time [16, 17]. The duration of the procedure in one of these studies was significantly longer in a group where a conventional ablation technique was used than in a group in which CARTO was used (75.5±27.1 vs. 57.1±24.2 min, $p < 0.05$). In another study there were no differences between the two groups in the length of the procedure (172.5±47.4 vs. 169.3±47.3 min, NS). Other investigators, such as Khongphatthanayothin et al., compared the effectiveness, the fluoroscopy duration and the total time of both a conventional ablation and one with the CARTO system, concentrating on the following arrhythmias: AVNRT, AVRT, AT, typical AFL and ventricular tachycardia [18]. The authors showed that in all types of arrhythmias there was a significantly shorter fluoroscopy time when the CARTO system was used. The total time of the procedures did not differ between the groups studied, except for patients with AVRT, where CARTO reduced this time (from 5.5±2.5 h to 4.0±1.3 h, $p < 0.05$). The effectiveness of the procedures was similar in the two groups.

Liu Xu et al. compared results achieved with the CARTO and the Ensite/NavX systems, performing ablations for persistent (n=12) and paroxysmal (n=63) AF [19], with patients randomly assigned to the CARTO or Ensite/NavX group. The authors failed to show any difference in the

time needed to create the 3D geometry of the heart. However, they reported a significant prolongation of both total procedure and fluoroscopy times in the Ensite/NavX group in comparison with the CARTO group (from 150±23 to 170±34 min and from 18±17 to 25±16 min respectively).

Our study showed a significant shortening of both procedural and fluoroscopy times using LocaLisa. The duration of procedure and fluoroscopy also depends on the experience of the operator [20, 21]. In addition, the amount of radiation depends on the X-ray apparatus and its settings (for example, whether pulse or continuous fluoroscopy is used). All our procedures were carried out within a relatively short period of time by one operator using the same X-ray equipment and its settings. This enabled us to rule out potential bias caused by these factors.

Our study has some limitations. One of these is the lack of formal randomisation; patients were arbitrarily assigned to one of the groups. However, use of the LocaLisa system was random, depending on the availability of the system and not on preselected criteria. There were, moreover, some patients with additional ablations lines and arrhythmias. This makes the study groups not purely homogeneous. However, there were no clinically important or significant differences between the groups analysed, and these small discrepancies should not affect the results. It should be emphasised that the use of navigation/mapping tools, even the simplest systems, enables fluoroscopy to be minimised and reduces the risk of delayed side-effects of radiation, such as skin injury, malignancy and genetic abnormality.

Conclusions

The LocaLisa navigation system enables total procedure and fluoroscopy time to be shortened during ablation of AF.

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System LocaLisa jako klucz do skrócenia czasu zabiegu i skopii RTG podczas ablacji podłoża migotania przedsionków

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Streszczenie

Wstęp: Ablacja podłoża migotania przedsionków jest uznaną metodą leczenia migotania przedsionków (AF). Do ablacji AF wykorzystuje się różne systemy elektrofizjologiczne i nawigacyjne.

Cel: Porównanie zabiegów ablacji podłoża AF wykonanych z wykorzystaniem systemu nawigacyjnego LocaLisa (Medtronic) i bez niego.

Metodyka: Grupę 1. stanowiło 64 chorych (48 mężczyzn, 16 kobiet; wiek 51,5±10,6 roku), u których wykonano izolację przepustów mięśniowych z wykorzystaniem elektrody Lasso 2515 (Johnsn & Johnson) i systemu LocaLisa. Do grupy 2. włączono ostatnich 64 chorych (44 mężczyzn, 20 kobiet; wiek 51,4±11,0 lat) poddanych ablacji z użyciem elektrody Lasso bez systemu LocaLisa. Analizowano dane kliniczne i związane z zabiegiem.

Wyniki: Przewlekłe AF stwierdzono u 9 chorych z grupy 1. i u 3 z grupy 2. Izolacji poddano odpowiednio 3,98±0,96 *vs* 4,0±0,95 żył. W grupie 1. dodatkowo wykonano linię w cieśni dolnej prawego przedsionka u 4 chorych i w dachu lewego przedsionka u 2 chorych. U jednego chorego wykonano jednocześnie ablację drogi wolnej z powodu nawrotnego częstoskurczu węzłowego. W grupie 2. dodatkową linię w cieśni dolnej wykonano u 6 chorych, linię w dachu lewego przedsionka u jednego chorego, ablację dodatkowego ogniska w grzebieniu granicznym u 2 chorych. W grupie 1. dwóch chorych miało wszczepiony dwuprzedsionkowy układ stymulujący, jeden miał wszczepiony okluder do uszka lewego przedsionka (PLAATO). W grupie 2. jeden chory miał implantowany układ stymulujący typu AAI, inny był po zaszyciu przegrody międzyprzedsionkowej (ASD) i komorowej (VSD). U jednego chorego występowała przetrwała żyła główna lewa z atrezją żyły głównej górnej. Porównanie grup 1. i 2. pod względem czasu zabiegu i skopii RTG: 131,6±40,3 *vs* 170,0±56,5 min (p <0,0001); 16,93±9,7 *vs* 35,66±12,7 min (p <0,0001). U jednego chorego w grupie 2. wystąpiła tamponada serca wymagająca leczenia chirurgicznego, u innego przejściowe niedokrwienie ośrodkowego układu nerwowego (TIA). W grupie 1. zabiegi wykonano bez powikłań. Skuteczność ablacji była podobna w obu grupach.

Wniosek: System nawigacyjny LocaLisa pozwala na skrócenie czasu zarówno zabiegu, jak i skopii RTG podczas ablacji przepustów mięśniowych w ujściach żył płucnych.

Słowa kluczowe: ablacja RF, migotanie przedsionków, system LocaLisa, izolacja żył płucnych

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