Efficacy and safety of pulmonary vein isolation with irrigated radiofrequency balloon with a zero-fluoroscopy protocol

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Introduction: From the beginning, the use of X-ray (XR) has been a critical component in both the guidance and development of arrhythmia ablation procedures. Despite the development of non-fluoroscopic navigators, the single-shot techniques for atrial fibrillation ablation procedures still rely almost exclusively on the use of XR. Recently, the Heliostar® irrigated radiofrequency balloon has been developed, which can be completely visualized on the Carto 3® navigation system. This special feature makes it possible to minimise the use of XR in this type of procedure or even suppress it. We present our first experience after the implementation of a "zero-XR" protocol for this procedure.

Objectives: The aim of this study was to demonstrate that "zero-XR" ablation of atrial fibrillation with Heliostar® radiofrequency balloon is possible and safe.

Methods: This is a single-centre study. Consecutively 22 patients with paroxysmal (63.6%) or persistent (36.4%) atrial fibrillation underwent pulmonary vein isolation by irrigated radiofrequency balloon (Heliostar®). Eight of the cases were performed without fluoroscopy, supported by the navigation system and intracardiac ultrasound, and the remaining 14 were performed without limitation of the use of XR. Clinical, echocardiographic and technical data were collected from all 22 patients. All cases were performed under general anaesthesia, with the Carto 3® navigation system. Mapping was performed in sinus rhythm whenever possible.

Results: 100% isolation of the veins was achieved, with 62.1% first pass isolation in the non-XR group versus 56.4% in the XR group (non-significant difference). The vein with the highest percentage of first pass isolations was the left inferior vein in both groups. There were no complications in either group. Procedure times were similar (left atrial dwell time of 32 minutes in the non-XR group and 40 minutes in the XR group, non-significant difference), although the mapping time was slightly shorter in the non-XR group (9,9±5 non-XR vs 16±6.9, p=0.04). There was also no difference in the mean time to isolation from the start of radiofrequency application in each vein (10.6 seconds in the non-XR group and 11 seconds in the XR group, p=0.75). The non-XR group had a higher number of patients with left main trunk, but the XR group had a higher percentage of patients with persistent forms of atrial fibrillation. Left atrial size was normal in most patients, and ventricular function was preserved, with no differences between the two groups.

Conclusion: Pulmonary vein isolation with the Heliostar® radiofrequency balloon without XR is possible and safe, with similar efficacy and first pass isolation rate, similar procedure time and no relevant complications in our series.

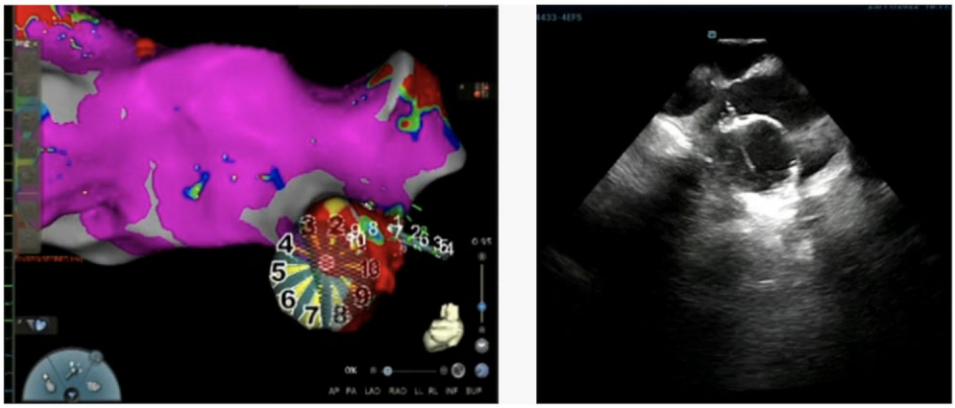

Figure. *Left: Heliostar*® radiofrequency balloon displayed on *Carto 3*® navigation system, showing its 10 electrodes. *Right:* intracardiac ultrasound image showing the sheath crossing the interatrial septum and the Heliostar balloon lodged in a pulmonary vein.

Baseline characteristics			
	Without fluoroscopy (n=8)	With fluoroscopy (n=14)	*p*
Age (years)	58.7 ± 12.1	56 ± 9.2	0.56
Left ventricular ejection fraction (%), m ± sd	55.5 ± 22.8	56.3 ± 9.9	0.9
Indexed left atrial volume (mL/cm2), m ± sd	38.2 ± 15.7	39.9 ± 9.9	0.75
Left atrial dilation, n(%)	-No: 5 (65.5%) -Mild: 2 (25%) -Moderate: 0 -Severe: 1(12.5%)	-No: 6 (42.9%) -Mild: 5 (35.7%) -Moderate: 1 (7.1%) -Severe: 2 (14.3%)	0.77
High blood pressure (%)	4 (50%)	6 (42.9%)	0.75
Diabetes Mellitus (%)	1 (12.5%)	3 (21.4%)	0.6
Male sex (%)	5 (62.5%)	11 (78.6%)	0.42
CHA2DS2VASc (md, IQR)	1.5 (1-2)	1 (1-2)	0.64
Obstructive sleep apnea syndrome (%)	0	2 (14.3%)	0.26
Chronic obstructive pulmonary disease (%)	0	2 (14.3%)	0.26
Previous antiarrhythmic treatment (%)	6 (75%)	6 (42.9%)	0.15
Success (%)	8 (100%)	14 (100%)	1
Complications (%)	1 (12.5%)	7 (50%)	0.08
1st pulmonary vein isolation procedure (%)	100	100	1
Structural heart disease, n(%)	1 (12.5%)	7 (50%)	0.08
Type of atrial fibrillation, n(%)	-Paroxistic: 8 (100%)	-Paroxistic: 6 (42.9%) -Persistent: 8 (57.1%)	0.007
Technical aspects and results			
	Without fluoroscopy (n=8)	With fluoroscopy (n=14)	*p*
Fluoroscopy time (min), m ± sd	0	22.4 ± 12.3	0.0001
Irrigation (mL), m ± sd	1138 ± 251	985 ± 281.2	0.22
Time to isolation (sec), m ± sd	10.6 ± 2.8	11 ± 3.2	0.75
Number of applications per case, m ± sd	6 (4-6.5)	6 (5-7)	0.49
Common left trunk, n(%)	3 (37.5%)	1 (7.1%)	0.08
Complete pre and post mapping, n(%)	6 (75%)	11 (78.6%)	0.85
Rhythm during mapping, n(%)	SR: 6 (100%)	SR: 7 (63.6%) AF: 4 (36.4%)	0.09
Mapping catheter, n(%)	-Pentarray®: 2 (33.3%) -Lassostar-Nav®: 4 (66.7%)	-Pentarray®: 9 (81.8%) -Lassostar-Nav®: 2 (18.2%)	0.046
First pass isolation (%)	Global: 62.1% -LSPV: 40% -LIPV: 100% -RSPV: 62.5% -RIPV: 75%	Global: 56.4% -LSPV: 53.9% -LIPV: 69.2% -RSPV: 64.3% -RIPV: 42.9%	0.61
Veins isolated with ≤ 2 applications	93.1%	81.8%	0.16
Total procedure time (min), m ± sd	166.1 ± 29.8	179 ± 40.3	0.44
Left atrial dwell time (min), m ± sd	32 ± 12.9	40.9 ± 17.1	0.21
Mapping time (min), m ± sd	9.9 ± 5	16 ± 6.9	0.04
Success (%)	100	100	1
Complications (%)	0	0	1

Table. Baseline characteristics, technical aspects and analysis of electro-anatomical maps. SR: sinus rhythm; AF: atrial fibrillation. LSPV: left superior pulmonary vein; LIPV: left inferior pulmonary vein; RSPV: right superior pulmonary vein; RIPV: right inferior pulmonary vein. m ± sd: mean ± standard deviation. md ± IQR: median ± interquartile range.