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Higher density mapping efficiency and ease of maneuverability of a novel mapping catheter in complex arrhythmias

Sarkozy A.[1]; Vijgen JV.[2]; De Potter TD.[3]; Schilling RS.[4]; Markides VM.[5]

[1]University Hospital of Antwerp, Edegem, Belgium
[2]Virga Jesse Hospital, Hasselt, Belgium
[3]Olv Hospital Aalst, Aalst, Belgium
[4]St Bartholomew"s Hospital, London, United Kingdom of Great Britain & Northern Ireland
[5]Royal Brompton Hospital, London, United Kingdom of Great Britain & Northern Ireland

Background: An advanced mapping catheter has been developed to facilitate reliable identification of ablation targets in complex arrythmias. This catheter has 48 platinum-iridium mapping electrodes, with 6 of those electrodes distributed across each of the 8 spines (Figure).

Purpose: To assess the mapping efficiency of the catheter in a feasibility study and characterize the ease of use through physician feedback.

Methods: This prospective, single arm, non-randomized, multi-center study was conducted at 5 European sites. The primary endpoint was the completion of protocol required fast activation and electro anatomical pre-ablation mapping. Catheter performance regarding its deployment, ease of use, and mapping results was assessed via a post procedure physician feedback survey. Physician feedback rated as ≥4 on the 7-point Likert scale (1 = poor, 7= excellent) indicated that the catheter met expectations. Subjects were followed 7 days post procedure for serious adverse events (SAEs).

Results: Thirty-one patients (age: 67.8 ± 8.52 years, 87.1% men) were enrolled (11 ventricular tachycardia [VT], 10 scar-related AT/re-do paroxysmal AF [PAF], 10 persistent AF[PsAF]). 28 subjects had study catheter inserted for mapping purposes. The primary endpoint was achieved in 23/28 patients (82.1%). Five patients did not complete pre-ablation mapping requirements due to physicians' choice as voltage mapping was considered sufficient (N = 3), inability of catheter to reach the basal inferior septal left ventricle (N = 1), and physician's decision to perform pulmonary vein isolation prior to protocol-required mapping (N = 1). Pre-ablation median mapping times (Q1/Q3) were 121.0 (71.0, 146.0), 72.5 (51.0, 107.0), and 31.5 (13.5, 48.0) minutes for the VT, AT/PAF, and PsAF groups, respectively. Median total procedure times for VT, AT/PAF, and PsAF were 192, 193 and 146 minutes, respectively. Median points acquired per minute were 24.4, 43.6, and 69.8 for the VT, AT/PAF, and PsAF subgroups. All subjects (16/16, 100%) who had conduction channel(s), gaps(s), or critical isthmus identified had the areas appropriately mapped. The incidence of SAEs observed was low (1/30; 3.3%) with only 1 heart failure case reported. Operators rated the ability to deploy as met expectations or better (median score: 5.0, Q1/Q3 4.0,6.0). Ability to maneuver was rated very positively in the atria: the catheter met expectations or was at least comparable to other devices for 90.0% of LA and 100.0% of right atrium (RA) use. Users felt the catheter met expectations or better in its ability to reach the atria and ventricles; 85%, 100%, and 60% of users ranked the catheter with a score of ≥ 4 in the LA, RA, and left ventricle, respectively. Conclusion(s): Our results demonstrate the feasibility of the high-density mapping catheter to efficiently map complex arrythmias with a good safety profile. Post procedural operators' feedback indicates satisfaction with the ease of use and maneuverability.

Abstract Figure