Safety and Efficacy of Novel Multipolar Steerable Mapping Catheter in Atrial Arrhythmia: A Single Centre Experience

Thalia Hua[1], Damian P. Redfearn[2], Andres Enriquez[2], Benedict Glover[3], Danielle Hart[2], David Bakker[2], Hoshiar Abdollah[1], Adrian Baranchuk[1], Christopher Simpson[1], and Sanoj Chacko[2]

[1]Queen's University
[2]Kingston General Hospital
[3]Toronto General Hospital

May 26, 2020

Abstract

Background: There is limited data on the safety and efficacy of a novel high-definition mapping catheter with 16 equidistant electrodes (Advisor HD Grid). We describe procedural details for the treatment of complex atrial arrhythmias and associated outcomes using this novel catheter design. **Methods and Results:** The HD Grid was employed for patients with clinically relevant arrhythmia using the EnSite Precision electroanatomic mapping system. AVRT and typical flutter cases were excluded. Major procedural complications were defined as bleeding, stroke or TIA, sepsis, and death from any cause, whereas minor complications were defined as no changes to the length of hospital stay or to the expected management of the patient. Recurrence was defined as sustained tachycardia after 3 months post-procedure. Consecutive patients attending for the treatment of paroxysmal atrial fibrillation (66), persistent atrial fibrillation (38), atrial tachycardia (29), and atypical flutter (18) were included, resulting in a final inclusion of 142 patients and 151 procedures. Eighty-four patients (55.3%) received general anesthetic and intracardiac echocardiography was used in 23 (15.1%). Long term follow-up was available in 150/151 procedures, mean 185.2±134.3 days; 32 patients (21.3%) documented recurrence. Three (2.0%) patients experienced complications within 30-days of the procedure including acute tamponade (1), TIA (1) and stroke (1) and 1 (0.7%) died from complications of septic arthritis 183 days post-procedure. **Conclusion:** The novel HD Grid differs significantly in design and handling compared to the traditional multielectrode catheters. Our data report procedural outcomes in line with contemporary clinical expectations with low complication and recurrence rates.

Introduction

The mapping of atrial arrhythmia has evolved rapidly over the last two decades, most notably with the advances in computer assisted topographic electrogram feature representations via electroanatomic mapping systems (EAM). The collection of thousands of datapoints via multielectrode catheter platforms has increased our level of confidence in arrhythmia diagnosis and treatment. However, the multielectrode catheters used in the atrium have largely been based on the original spiral or circular catheters designed primarily for segmental pulmonary vein isolation. Approaches to catheter ablation of atrial arrhythmia is evolving and the introduction of a planar catheter consisting of an equally spaced grid of electrodes is radically different from the traditional spiral shape and heralds a new era in high definition and high resolution mapping of atrial substrate and complex atrial arrhythmias. There is little data on the efficacy and safety of this novel design in a longitudinal cohort whereas there is abundant data on the circular mapping catheter. Here we will be using the diagnostic Advisor HD Grid mapping catheter (Figure 1) (Abbott, Plymouth, MN) to describe our initial experience with mapping and treatment of atrial arrhythmia using this novel catheter design.

Methods

The Queen's University Health Sciences and affiliated teaching hospitals research ethics board reviewed the study protocol and granted clearance. Data were collected from consecutive patients attending for diagnostic electrophysiologic study at Kingston General Hospital from May 2018 to December 2019. Our inclusion criteria were any patients undergoing procedures with instrumentation using the diagnostic Advisor HD Grid mapping catheter (Abbott, Plymouth, MN) with the intent to map and treat clinically relevant arrhythmia using the Ensite Precision electroanatomic mapping system (Abbott, Plymouth, MN). We excluded any cases where the HD Grid was not used, AVRT due to an accessory pathway, and cases of typical cavotricuspid isthmus dependent flutter.

Therapy was guided by a combination of EAM data, activation mapping, pacing entrainment criteria and local electrogram features such as bipolar amplitude, onset, and offset (last deflection). Eligible patients were identified using a query of the electronic medical record from the electrophysiology lab database (Mac-Lab, GE Healthcare). Electrogram data was collected and stored in recorded segments or diagnostic landmark maps for future analysis. For the purposes of this study, all patient demographic and outcome data were collected from electronic medical records, telephone interviews, and paper documents from medical charts. Demographic patient data were collected at the time of the procedure; in addition, we recorded the type of arrhythmia, procedural details, acute and procedure related complications, and outcomes defined as documented or subjective sustained arrhythmia recurrence after 3 months post procedure.

Procedural complications related to atrial instrumentation were pre-defined as bleeding, stroke or TIA, sepsis and death from any cause. Specifically, these complications are considered major as defined by prolonged length of hospital stay, patient readmission for reasons other than arrhythmia recurrence, and/or a change in treatment was ensued because of the complication. Complications that did not meet these criteria were considered minor and not included for further analysis.

Statistics

Patient characteristics, procedure details, and follow-up outcomes were reported using descriptive statistics. Categorical data are presented as percentages and continuous data as mean ± standard deviation. Significance of mean values were determined by independent samples t-tests and one way ANOVA, post-Hoc Tukey test. All statistical analyses were completed using SPSS software (version 26, SPSS Inc., Chicago, Illinois).

Results

Patient Characteristics: A total of 166 atrial arrhythmia cases were guided by the HD Grid from May 2018 to December 2019, with 151 patient procedures meeting our inclusion criteria accounting for 142 patients. Fifteen patients were excluded due to AVRT (7) and typical cavotricuspid isthmus dependent flutter (8). Atrial fibrillation (AF) accounted for the majority of cases (68.9%), with 66 paroxysmal cases and 38 persistent cases; the remainder of the cases were classified as atrial tachycardia (including a focal or re-entrant, incisional pathology), 29 (19.2%) cases and atypical atrial flutter (macro-reentrant), 18 (11.9%) cases. The majority of patients were male (67.8%) with a mean age of 61.1 ± 11.2 years. A detailed summary of patient demographics are described in Table 1.

Procedural Details: General anaesthesia was administered for 84 cases with a mean procedure time of 237.8 ± 75.6 minutes and mean cumulative fluoroscopy dose of 137.9 ± 134.8 mGy. Intracardiac echocardiography was employed for 23 procedures. Radiofrequency (RF) lesions applied for each respective atrial arrhythmia case are described in Table 2. Acute procedural success was observed in all patients, defined as pulmonary vein isolation, the identification and termination of clinical arrhythmia, and demonstration of bidirectional block when applicable.

Post-operative Complications: Three patients experienced major complications within 30 days post-procedure including pericardial tamponade, TIA, and stroke. Both embolic events occurred 3 days post-procedure; the TIA occurred in a patient non-compliant with anticoagulation upon returning home and the stroke patient had significant co-morbidities. Both patients made a complete neurological recovery. Minor

complications were reported for three patients including one reported case of urinary retention and two cases of pericarditis that responded to conservative management without any prolonged hospital stay.

Follow-up and Arrhythmia Recurrence: Patients were followed-up for a mean 185.2 ± 134.3 days post-procedure and one patient was lost to follow-up. One patient died from complications of septic arthritis 183 days post procedure. Long-term outcome data is presented for the remaining 150 patients described in Table 3; 32 (21.2%) reported an arrhythmia recurrence with 12 (8.1%) of these cases reporting recurrence of atrial fibrillation and 20 (13.4%) for any atrial arrhythmia. Five patients had immediate arrhythmia recurrence with two patients receiving cardioversion within one week and one month post-procedure, one recorded event of atrial fibrillation lasting 1-hour, two undocumented episodes of atrial fibrillation reported by the patient without later recurrence, and atrial tachycardia 24 hours post-procedure in the context of urinary retention with no further recurrence. There was no significant differences for any demographic, procedural, or complication data between recurrent and no recurrent arrhythmia cases.

Discussion

This is the first and largest study to report the safety and efficacy of the mapping of atrial arrhythmias using the planar 'grid' design. The novel organization of electrodes allows for multidirectional determination of signal conduction that has not been previously available from other HD mapping catheters through the simultaneous recording of electrograms in multiple bipolar orientations.[1] The use of fixed 3mm equidistant electrodes in a two-dimensional square organization allows bi-directional and omnipolar interpretations of signal conduction both along and across the splines. This unique feature contrasts from other non-spiral multi-spline mapping catheters that adopt flexible spline arrangements. Notably, the continuous fluctuations of electrode distances between splines in these catheters may compromise the integrity of voltage maps collected due to minute discrepancies in wavefront interpretations. In addition, the grid design does not allow for deformation and crowding of electrodes that results in some mathematical benefit to putative rotor mapping during atrial fibrillation, allowing an increase in atrial area covered for possible rotor identification.[2] However, to the best of our knowledge, the new design catheter has been largely absent in large case series and real-world efficacy and risk associated with the Grid design are not reported.

After initial use in more complex cases, our operators quickly became familiar with the handling and performance of the new design and its use became first-line in the majority of patients. Given that the planar design does not conform to the circular fit of most catheters used for mapping pulmonary veins, one might question the role in pulmonary vein mapping and isolation. We found the use of the catheter did not compromise acute procedural success and during long-term follow-up we observed low recurrence rates. Complications reported in our case series are low and in keeping with contemporary data on complications and risks. The pericardial tamponade occurred after the catheter ablation and remote from mapping. Both incidents of cerebral ischemic insult occurred in long standing (2.9 and 3.3 years) persistent atrial fibrillation patients with cardiomyopathy and severe left atrial (LA) enlargement (46.4 and 48.1 ml/m^2). Previous studies have demonstrated an independent association of mortality with increased LA volume index after 5-year follow-up, with a 2.4 relative risk of stroke for every 10-mm increase in LA size.[3,4] We did not attribute these complications to the novel catheter design particularly, as one patient omitted oral anticoagulation for several days post discharge.

A possibility of recurrence due to inadequate mapping in significant LA enlargement rather than ablation failure was not observed in our patient cohort, as there were no significant differences in LA volume and size observed in the reported recurrent arrhythmia cases. Acute procedural success was reported in all patients, supporting the use of the HD Grid as a mapping tool. Our rate of arrhythmia recurrence (21.3%) is similar to rates previously described by multiple circular mapping catheter studies (21% and 26%).[5,6]

The low rates of complications reported in the current study (2.0%) demonstrate comparable levels of mapping safety to established circumferential pulmonary vein ablations using traditional circular mapping catheters (3.5%) with similar reports of complications causes including stroke and cardiac tamponade.[7] Cardiac tamponade arising due to the use of contact force-sensing catheters remains low in our study (0.67%)

and is consistent with the low incidence of tamponade in non-contact force catheters (0.44%).[8]

The highest recurrence rate reported from atrial tachycardia was somewhat surprising given the potential advantages of the mapping technology and catheter. However, these patients were a mixed bag of incisional atrial tachycardia and focal sources. Recurrence in 6 of the 7 cases were classified with the same type of arrhythmia, suggesting a failure of ablation strategy rather than diagnosis and mapping. The group collectively had shorter procedure and ablation times, with one case reported to have observed only 10 seconds of RF lesions to achieve termination of tachycardia, therefore no further lesions were delivered. Recurrence was mapped to the same location and longer ablation was delivered to achieve durable success.

Limitations

This is a relatively small single centre experience; patients were not randomized and no age-matched control group using the circular mapping catheter design was compared to the current patient group. Details on mapping time or time to isolation were not recorded separately but are currently being studied. Nonetheless, accurate follow-up data is available on the majority of patients supporting the safety and efficacy of the HD Grid.

Conclusion

This is the largest database reporting follow-up outcomes for patients where the novel HD Grid catheter was used for the mapping of atrial arrhythmias. Our patient follow-up and low complications and recurrence support safety and reliability of this high-density mapping catheter in collecting accurate data comparable to traditional circular mapping catheters.

References

1. Tan VH, Lyu MZ, Tan PC, Wong LC, Yeo C, Wong KCK. Utility of directional high-density mapping catheter (AdvisorTM HD Grid) in complex scar-related atrial tachycardia. *J Arrhythmia* . 2020;36(1):180-183. doi:10.1002/joa3.12256

2. Guillem MS, Climent AM, Rodrigo M, Fernández-Avilés F, Atienza F, Berenfeld O. Presence and stability of rotors in atrial fibrillation: evidence and therapeutic implications. *Cardiovasc Res* . 2016;109(4):480-492. doi:10.1093/cvr/cvw011

3. Benjamin EJ, D'Agostino RB, Belanger AJ, Wolf PA, Levy D. Left Atrial Size and the Risk of Stroke and Death. *Circulation* . 1995;92(4):835-841. doi:10.1161/01.CIR.92.4.835

4. Fatema K, Bailey KR, Petty GW, et al. Increased Left Atrial Volume Index: Potent Biomarker for First-Ever Ischemic Stroke. *Mayo Clin Proc* . 2008;83(10):1107-1114. doi:10.4065/83.10.1107

5. Ha ACT, Wijeysundera HC, Birnie DH, Verma A. Real-world outcomes, complications, and cost of catheter-based ablation for atrial fibrillation: an update. *Curr Opin Cardiol* . 2017;32(1). https://journals.lww.com/co-cardiology/Fulltext/2017/01000/Real_world_outcomes,_complications,_and_cost_of.8.aspx.

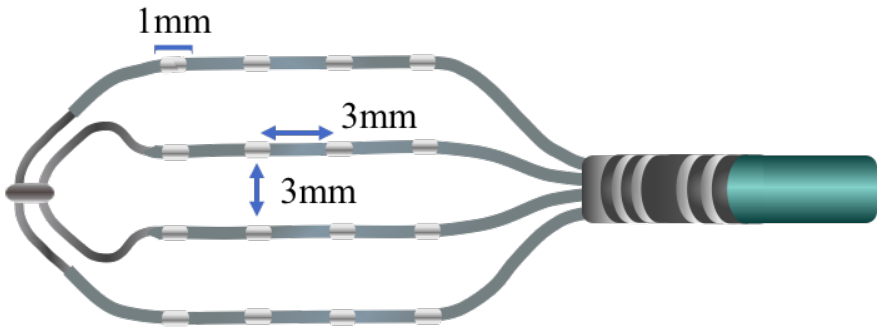
6. Pallisgaard JL, Gislason GH, Hansen J, et al. Temporal trends in atrial fibrillation recurrence rates after ablation between 2005 and 2014: a nationwide Danish cohort study. *Eur Heart J* . 2017;39(6):442-449. doi:10.1093/eurheartj/ehx466

7. Marrouche NF, Dresing T, Cole C, et al. Circular mapping and ablation of thepulmonary vein for treatment of atrial fibrillation: Impact of different catheter technologies. *J Am Coll Cardiol* . 2002;40(3):464-474. doi:https://doi.org/10.1016/S0735-1097(02)01972-1

8. Liu N, Zhao Q, Li L, et al. Association between the use of contact force-sensing catheters and cardiac tamponade in atrial fibrillation ablation. *J Interv Card Electrophysiol* . 2019;55(2):137-143. doi:10.1007/s10840-019-00516-z

Figures

Figure 1. The Advisor? HD Grid Mapping Catheter, Sensor Enabled? contains a total of 16x1 mm electrodes distributed across four splines with 4 electrodes per spline with an interelectrode space of 3mm.



Tables

Table 1. Summary of patient demographics stratified according to type of arrhythmia; atrial fibrillation is divided into paroxysmal vs. persistent. Table values are counts or mean values (standard deviation).

	All (N=151)	Paroxysmal AF (n=66)	Persistent AF (n=38)	Atrial Tach (n=29)	Atypical Flutter (n=18)
Age	61.1 (11.2)	60.2 (10.6)	61.9 (9.3)	59.1 (15.8)	65.8 (5.7)
Sex (M)	103 (67.8%)	50 (75.6%)	30 (79.0%)	10 (33.3%)	13 (72.2%)
BMI	31.2 (5.7)	29.93 (5.3)	33.3 (5.6)	29.6 (5.9)	33.9 (4.9)
CHADS 2	0.86 (0.97)	0.73 (0.87)	0.97 (0.97)	0.77 (0.97)	1.28 (1.23)
LVEF (%)	56.6 (13.1)	59.5 (10.0)	51.6 (16.2)	59.3 (10.3)	52.8 (15.8)
LA volume index (mL/m^2)	40.3 (15.2)	37.2 (13.9)	47.7 (16.1)	33.4 (14.4)	45.3 (10.8)
LA dimension (cm)	4.4 (2.8)	3.9 (0.66)	4.7 (0.65)	5.1 (6.5)	4.4 (0.47)

Table 2 . Summary of procedural details for atrial arrhythmia cases completed with HD Grid. Table values are mean values (standard deviation).

	All (N=151)	Paroxysmal AF (n=66)	Persistent AF (n=38)	Atrial Tach (n=29)	Atypical Flutter (n=18)
Procedure duration (min)	237.8 (75.6)	241.7 (67.8)	286.3 (70.3)	167.8 (56.0)	238.0 (55.7)
Fluoroscopy mGy	137.9 (134.8)	108.3 (70.7)	234.0 (195.1)	56.5 (54.5)	173.2 (126.7)
RF lesion time (seconds)	2069.5 (1346.2)	2333.67 (1007.1)	3244.8 (1035.9)	458.1 (466.3)	1305.1 (976.3)
RF lesions delivered	47.0 (38.4)	55.6 (34.5)	72.6 (39.3)	9.6 (6.6)	23.9 (17.1)

Table 3. Summary of arrhythmia recurrence as subjectively reported or documented by patient follow-up.

Table values are counts or mean values (standard deviation).

	All (N=151)	Paroxysmal AF (n=66)	Persistent AF (n=38)	Atrial Tach (n=29)	Atypical Flutter (n=18)
Days to Follow-up	185.2 (134.3)	181.8 (133.0)	203.0 (134.3)	160.2 (106.2)	201.1 (177.7)
Recurrent AF	12 [8.1%]	7 [10.6%]	5 [13.2%]	0	0
Recurrent atrial arrhythmia	20 [13.4%]	7 [10.6%]	5 [13.2%]	7 [24.2%]	1 [5.6%]