Reconstruction of the Left Atrium for Atrial Fibrillation Ablation using the Machine Learning CARTO 3 m-FAM Software

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Abstract

IIntroduction: Atrial fibrillation (AF) ablation requires a precise reconstruction of the left atrium (LA) and pulmonary veins (PV). Model-based FAM (m-FAM) is a novel module recently developed for the CARTO system which applies machine-learning techniques to LA reconstruction. We aimed to evaluate the feasibility and safety of a m-FAM guided AF ablation as well as the accuracy of LA reconstruction using the cardiac computed tomography angiography (CTA) of the same patient LA as gold standard, in 32 patients referred for AF ablation. Methods: Consecutive patients undergoing AF ablation. The m-FAM reconstruction was performed with the ablation catheter (Group 1) or a Pentaray catheter (Group 2). The reconstruction accuracy was confirmed prior to the ablation by verification of pre-specified landmarks of the LA and PVs by intracardiac echocardiogram (ICE) visualization and fluoroscopy. A cardiac CTA performed before the ablation was used as gold standard of LA anatomy. For each patient, the m-FAM reconstruction was compared to his/her cardiac CTA. Results: The m-FAM reconstruction was accurate in all patients regardless the catheter used for mapping. In 12% re acquisition of the LA landmarks was necessary to improve the accuracy. m-FAM time was shorter in group 2 while the M-Fam fluoroscopy time was similar. Pulmonary vein isolation was achieved in 100% of patients without major complications. The m-FAM reconstructions accurately resemble the cardiac CTA of the same patients. Conclusions: The m-FAM module allows for rapid and precise reconstruction of the LA and PV anatomy, which can be safely used to guide AF ablation.

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Methods: Consecutive patients undergoing AF ablation. The m-FAM reconstruction was performed with the ablation catheter (Group 1) or a Pentaray catheter (Group 2). The reconstruction accuracy was confirmed prior to the ablation by verification of pre-specified landmarks of the LA and PVs by intracardiac echocardiogram (ICE) visualization and fluoroscopy. A cardiac CTA performed before the ablation was used as gold standard of LA anatomy. For each patient, the m-FAM reconstruction was compared to his/her cardiac CTA.

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Conclusions: The m-FAM module allows for rapid and precise reconstruction of the LA and PV anatomy, which can be safely used to guide AF ablation.

Introduction :

A precise reconstruction of the left atrium (LA), the pulmonary veins (PV) and the left atrial appendage (LAA) is of critical importance in order to achieve efficient and safe results during atrial fibrillation (AF) ablation. The procedure is currently performed with the guidance of three-dimensional mapping systems. In the CARTO 3 mapping (CARTO System, Biosense Webster, Inc, Diamond Bar, CA) the LA reconstruction methods most frequently used are the Fast Anatomical Mapping (FAM) and cardiac computed tomography angiography (CTA) integration with the electroanatomic mapping (CARTO Merge).[1-6]

The existing FAM algorithm currently used in CARTO constructs a three-dimensional reconstruction of the atrial anatomy by applying a standard ball-pivoting algorithm to the point cloud acquired by the catheter. FAM mapping requires catheter manipulation by a skilled operator and it is frequently time consuming for less experienced operators. The result does not consider the underlying anatomy, provides no information in areas where the catheter has not yet visited, and contains anatomically incorrect artifacts due to deformation of the atria by the catheter during the mapping procedure, such as merging of the appendage and left superior pulmonary vein. Therefore, the raw anatomy obtained with FAM requires post imaging refinement of the LA surfaces, achieved by shaving the image with “sculpting tools” prior to initiation of the ablation and throughout the procedure. In the CARTO Merge, the CTA scan of the left atrium is integrated with the FAM reconstruction. CARTO Merge provides a far better definition of the LA anatomy, including the areas mentioned above, which are critical for a successful ablation and provides a clear definition of anatomical variants, such as PV common ostium, separated branches, or additional PVs. The drawback of CARTO Merge approach is mainly related to the exposure of the patients to contrast media and (low dose) radiation during the cardiac CTA, plus the additional costs of the CTA scan, which are added to the total cost of the procedure.

Model-based FAM (m-FAM) is a novel module recently developed for the CARTO 3 system (Biosense Webster). [7] [8] The scope of the mFAM algorithm is generating an improved, anatomically correct reconstruction of left atrial anatomy, while at the same time requiring fewer samples than are currently needed. This is carried out by defining a parametric model representing a shape of a portion of a heart, and constructing a statistical prior of the shape from a dataset of other instances of the portion. The method is further carried out by fitting the parametric model to the point clouds data and statistical prior to produce an isosurface of the portion of the heart of the subject, which is then display in CARTO. m-FAM applies machine-learning techniques to LA reconstruction using an adaptive model trained from over 300 LA anatomies obtained from CTA scans. Training was performed to define statics of relevant proportions and sizes to represent a "realistic" and anatomically-accurate left atria. Examples of these features are the angle between the PVs, distances from atria center to the valve and PV ostium or the relations of those values to the volume. Having the geometrical primitives associated with any of the left atria anatomical structures, as well as keeping the proportions and sizes trained by a large left atria population, provides a way to represent the most probable left atria even with very limited information. The algorithm selects the model that best fits all the available information: points locations, contact force magnitude and direction, user tagging of anatomical parts, and a statistical score measuring anatomical correctness of the model. The reconstruction adapts smoothly to new points as they are mapped by the catheter, and allows assignment of special points where the catheter is in contact with the LA surface ("magnets"), such as ablation points, that constrain the surface while retaining overall anatomical correctness. The model deforms to best align with those locations and model reconstruction.

Mathematically, the algorithm can be defined as an optimization problem in which model parameters that best fit the data and prior statistical knowledge are estimated in an iterative process. The model is a result of fitting a parametric shape model to the point cloud acquired by catheter positions. The model includes a geometrical primitive for each of the left atria parts, main chamber, pulmonary veins, appendage, and valve. The geometrical primitives are blended to form the atria structure. Once the mapping catheter or the ablation catheter introduced in the LA engage the PVs, their location is tagged on the software and model fitting begins. A few additional force- and respiration-gated points are required to further refine the surface and volume of the LA at key locations, such as the roof, back wall and anterior LA, this tagged points are called magnet points. After acquisition of enough magnet points, the software produces a reconstruction of the LA that includes the LAA ostium and PVs. The model continually self-adjusts with added ablation tags during the procedure. Importantly, the model is trained to adjust for non-classical left atrial and pulmonary veins anatomy as for common ostium or additional side branches. In case of side branches, these branches are incorporated in the PVs of the closest major PV. The potential advantages of the m-FAM include: reduction of the mapping time required to achieve an entire LA reconstruction and better shaping of the LA anatomy compared to FAM.

In view of the fact that the m-FAM is a totally new feature of the CARTO 3 system, we decided to investigate two different workflows to obtain a m-FAM reconstruction of the LA using either the ablation catheter (3.5mm Smart-Touch or 3.5mm ST-SF ablation catheters, Biosense Webster) or a Pentaray catheter (Biosense Webster) to collect the location tags required by the software. We opted for a mapping using either the ablation catheter or a Pentaray catheter because these are the most commonly catheters used to create the initial LA reconstruction. Of note, m-FAM reconstruction can also be obtained with a Lasso NAV catheter (Biosense Webster) if preferred. The accuracy of the m-FAM reconstruction was confirmed by confirmation of the tagged magnet points both with fluoroscopy and intra-cardiac echocardiography (ICE) at the drop-points of the pulmonary veins to precisely define the pulmonary vein antrum and avoid ablations either too distal or too proximal to the pulmonary veins as well as the roof, anterior and posterior LA. Moreover, the m-FAM reconstruction was compared to a cardiac computed tomography angiography (CTA) of the LA which is routinely performed in our center prior to ablation of AF. Importantly, for the purpose of this study, the operator remained blinded to the CTA scan imaging of the patient during the m-FAM mapping reconstruction and reconstruction confirmation with ICE and fluoroscopy.

The aim of the present study was to evaluated the feasibility and safety of the ablation procedure when guided by the m-FAM reconstruction and the time required to achieve the m-FAM reconstruction and fluoroscopy time. We also compared the LA reconstruction obtained with m-FAM obtained with different catheters to the patient's cardiac CTA.

Methods:

Study patients:

Consecutive patients with symptomatic, drug-refractory paroxysmal or persistent AF referred for ablation were studied. A CTA of the left atrium was performed before the ablation to assess the left atrial size, PV anatomy and to exclude the presence of a left atrial appendage thrombi. The CTA obtained was used as the gold standard to assess the LA anatomy of the patients enrolled in the study.

Atrial fibrillation ablation technique:

The ablations were performed by three different operators (RR, LAS, UC). As previously reported[9], the procedure was performed under uninterrupted warfarin therapy (aiming for an INR of 2 on the day of the procedure) or after skipping a single dose of new oral anticoagulants (NOAC). The ablation procedure was conducted under general anesthesia. One decapolar (Livewire decapolar, St. Jude Medical, Minneapolis, USA) and 1 quadripolar catheter (Biosense Webster, Inc) were positioned in the coronary sinus and the His bundle position through the right femoral vein. An intracardiac echocardiogram (ICE) probe (ACUSON Acunav, Siemens Medical Solutions USA, Inc*)* was positioned in the right atrium through a 9F or 11F sheath introduced in the left femoral vein. One 8.5F long sheath (SL1, St. Jude Medical, Minneapolis, USA) was introduced into the left atrium with a single trans-septal puncture under ICE guidance. Intravenous bolus of heparin was injected intravenously just prior to the trans-septal puncture and repeated as needed to maintain an activated clotting time (ACT) of >350 seconds throughout the procedure. As routine in our department, the PVs were visualized by selective angiography using a N.I.H angiography catheter (N.I.H 6F, Cordis, Miami Lakes, FL, USA).

m-FAM workflow with ablation catheter (group 1) :

The ablation catheter was introduced through the original SL1 sheath into the left atrium. In case of difficulties in manipulation the ablation catheter in the left atrium, the SL-1 sheath was replaced with a steerable sheath (Agilis 8.5F, St. Jude Medical, Minneapolis, USA). The ablation catheter was first introduced deep into the PVs. Then the catheter was withdrawn and specific landmarks at the pulmonary vein ostium were tagged (magnet points) on the system for reconstruction. These magnet points are represented by the drop-point from the left superior to the left inferior and from the left inferior back to the left superior (i.e carina), the drop-point from the left inferior to the left atrium, the drop-point from the left superior to the left atrial appendage, the anterior and posterior borders of the left inferior pulmonary vein were tagged. On the septal side, we tagged the anterior and posterior drop point from the right superior pulmonary vein to the left atrium, the drop-point from the right superior to the right inferior pulmonary vein (i.e carina), the drop-point from the from the right inferior pulmonary vein to the left atrium and the anterior and posterior borders of the right inferior pulmonary vein at the ostium. Additional magnet points were tagged at the anterior and posterior left atrium and at the mid roof. These magnet points are needed to better define the shape and volume of the left atrial body. At this moment the m-FAM algorithm was initiated to create a three-dimensional reconstruction of the left atrium.

Upon acquisition of the m-FAM reconstruction, the accuracy of the m-FAM reconstruction and location of the specific landmarks at the pulmonary veins ostium were checked with fluoroscopy and ICE visualization (Figures 1 and 2).

m-FAM workflow with Pentaray/ablation catheter (group 2):

The Pentaray catheter was introduced through an SL1 sheath or steerable Agilis sheath into the left atrium. The Pentaray catheter was first introduced deep in the PVs and then positioned at the PV ostium. The Pentaray mapping catheter was replaced with the ablation catheter. To better define the pulmonary vein antrum, the ablation catheter was used to tag magnet points at the pulmonary vein ostium represented by the drop point from the left superior to the left inferior and vice versa, the drop point from the left superior to the left atrial appendage at the ridge, the drop point from the lower quadrant of the left inferior to the left atrium and the drop point from the right superior to the right inferior on the septal side. At this moment the m-FAM algorithm was initiated to create a three-dimensional reconstruction of the left atrium. The accuracy of the m-FAM reconstruction and location of the specific landmarks at the pulmonary vein ostium were checked with fluoroscopy and ICE visualization (fig. 1 and 2).

In case of lack of accuracy of the initial m-FAM reconstruction, re acquisition of the magnet points at the pulmonary veins drop-points and LA body was performed and the software algorithm was reinitiated.

The time required to achieve the M-FAM reconstruction and fluoroscopy time were also compared between the ablation and Pentaray workflows.

Visual inspection of the m-FAM reconstruction and comparison with the CTA:

The three-dimensional reconstructions of the LA obtained with the m-FAM module were shown to the operator prior to the initiation of the ablation and visually compared to the matching CT scan and to Carto location points and VisiTag's. Importantly the operator was blinded to the CT scan of the patient during the LA mapping and m-FAM reconstruction. The comparison between the m-FAM reconstruction and the cardiac CTA of the same patient included:

-the LA body morphology

-the presence of common os pulmonary veins

-the PV antrum at the level of WACA

The comparison between the m-FAM and the cardiac CTA was graded as good or poor.

Ablation:

Ablation was performed using a "point by point" technique. Settings were: catheter irrigation-flow rate of 18 mL/min, target temperature 45° and maximal energy of 50 W. During the ablation we aimed to achieve a contact force of 10 to 20 grams at all times. Radiofrequency energy (RF) was applied at each ablation site using the automated lesion tagging ablation-index module (Biosense Webster) to mark the location and efficacy of each lesion. The ablation-index settings were: catheter stability position minimum-time of 5 seconds, and maximum range 3-4 mm, minimum force 3 g, (the blue and yellow marks give two different contact force values) and lesion tag of 3 mm. The maximal RF time at each ablation site was 10 seconds for the posterior wall and 25 seconds for the anterior quadrants. We aimed for an ablation-index value of 400 for the back wall and 500 for the anterior quadrants. Upon completion of the wide antral circumferential ablation (WACA), the ablation catheter was withdrawn from the left atrium and replaced by a lasso circular mapping catheter (Lasso, Biosense Webster, Inc). The acute end-point of the procedure was PV isolation demonstrated by disappearance of local PV electrograms and confirmed by standard pacing maneuvers, to confirm entrance and exit block, with a lasso circular mapping catheter. In case of lack of first pass isolation the residual PV-LA connections were tagged on the CARTO system and additional RF was delivered until PV isolation was achieved. After a waiting period of 20 minutes, each pulmonary vein was assessed for entrance and exit block. Each vein was also assessed for the presence of dormant pulmonary vein-left atrium connection with intravenous adenosine 18 mg injection. Patients with evidence of dormant connections revealed by adenosine challenge, received additional ablations according to the mapping catheter until the connections were completely abolished.

Post-procedure Care:

After the ablation procedure, patients on warfarin received low molecular weight heparin until an INR of 2.0–3.0 was achieved. Patients previously treated with NOACs, underwent the ablation after skipping one dose. The NOAC therapy was restarted between 3-5 hours post procedure. Anticoagulation was continued for at least 3 months in patients with CHA2DS2VASc 0–1 score or indefinitely in patients with CHA2DS2VASc of 2 or more. Antiarrhythmic therapy was restarted immediately after the procedure and continued for 1 month.

The study protocol was approved by the local ethical committee and registered in the Israel Ministry of Health (MOH 2020-06-22_009053). Written informed consent was obtained from all study subjects. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Statistical methods:

Continuous, normally distributed variables are presented as mean ± SD and compared using the Student's t test. Ordinal and/or non-normally distributed variables were compared using the Wilcoxon rank-sum test. Normality was assessed using the Shapiro-Wilk test and visual inspection of quantile-quantile (QQ) plots and skews. Categorical variables were compared using the Chi-square test. All analyses were made using "R" program language platform (version 3.5.3, 2019-03-11).

Results:

A total of 32 consecutive patients with drug refractory paroxysmal or persistent atrial fibrillation referred for a first or redo ablation were enrolled in the present study (Table 1). In 18 patients the m-FAM reconstruction was conducted with the use of the ablation catheter only (Group 1), while a Pentaray and ablation catheter were used in 14 patients (Group 2). The CTA of the patients enrolled showed a classical anatomy with 4 pulmonary veins in 66% of the patients, while a left common ostium and a right middle branch was seen in 25% and 21% patients, respectively (table 2).

The m-FAM time was significantly shorter in group 2 while the m-Fam fluoroscopy time was similar for the two groups. In 4 out of 32 patients (12%) enrolled, regardless the mapping catheter used for the reconstruction re acquisition of the magnet points at the PV ostium and LA body was required to optimize the reconstruction.

The m-FAM reconstruction accuracy was accurate also in patients with left common pulmonary veins or right middle branches as in patients with a classical left atrial anatomy. In case of a right middle branch, the m-FAM reconstruction displayed the additional branches as part of the right superior right inferior PV. Regardless to the pulmonary vein anatomy, the PV antrum at the level of the WACA was accurately reconstructed.

The visual comparison between the m-FAM and the CT scan was good in all patients before initiating the ablation. In the four patients in whom the initial m-FAM reconstruction was inaccurate based on the confirmation of the PV landmarks with fluoroscopy and ICE, the comparison with the CT scan was also poor and became good after re acquisition of the magnet landmarks and re initiation of the m-FAM software.

All pulmonary vein ablated were successfully isolated. The fluoroscopy time, dwell time, procedural time and radiofrequency time were similar for the two groups (Table 2).

No significant complications occurred during or after the procedure.

Discussion:

The m-FAM is a novel algorithm that was recently added to the CARTO 3 system. It allows the easy and fast creation of a 3-dimensional reconstruction of the LA based on very limited FAM mapping. The system applies machine learning techniques for LA reconstruction using an adaptive model trained from over 300 LA anatomies obtained from CTA scans. However, the accuracy of this reconstruction has not been verified as well as the feasibility and safety of atrial fibrillation ablation guided by the m-FAM reconstruction.

In the present study, we also evaluated the m-FAM reconstruction to the CTA of the LA in the same patient. We found that a precise reconstruction of the LA can be obtained within 4 minutes (including the algorithm reconstruction time) and with less than 2 minutes of fluoroscopy-time regardless to the mapping catheter used. In a minority of patients, adjustments are needed to improve the accuracy of the reconstruction. The algorithm performed just as well in patients with LA anatomy different from the classical four PV anatomy (Figure 5). The fastest m-FAM reconstruction was obtained with the use of a Pentaray for mapping. This approach might be preferable in patients in which a substrate mapping of the left atrium is also required, like patients with long standing persistent AF. Importantly, the voltage map of the left atrium can be displayed on the shell of the M-FAM reconstruction when needed (Figure 5). Despite the shortest mapping time required when using a Pentaray catheter, the accuracy of the m-FAM map was similar in patients in whom the maps were created solely with the ablation catheter. The m-FAM reconstruction closely resembled the LA anatomy obtained from cardiac CTA in all patients. Pulmonary veins angiography is routinely performed in our lab during AF ablation and therefore it was included in the two workflows analyzed in our study. Nevertheless we believe this step is not mandatory for operators who are not comfortable with it. The ablation guided with the use of the m-FAM reconstruction was effective with isolation of 100% of the pulmonary veins ablated. No complications occurred in any of the patients treated who underwent an m-FAM based ablation.

Limitations:

1. Some, but not all variations in PV number and anatomy were represented in the study. Accordingly, one should not assume that the accurate performance achieved in the few patients with PV variations will be reproduced in patients with more uncommon PV anatomy.
2. A major limitation of the study is that the gold standard to define the accuracy of the LA reconstruction by m-FAM was a visual comparison with the CTA of the same patient rather than a computerized “pattern recognition” formal comparison.
3. This is a single center study and our center was involved in the early phases of developments of the m-FAM algorithm. Indeed, we performed approximately 40 previous cases using the m-FAM as research tool before initiating the current clinical study. The large experience with the m-FAM algorithm may have influenced our results. Nevertheless, our impression is that the learning curve in using the m-FAM is very short.

Conclusions:

We describe the first clinical experience of atrial fibrillation ablation guided by reconstruction of the left atrium obtained with the novel, machine-learning based software m-FAM for the CARTO system. The m-FAM allows for an accurate and rapid reconstruction of the left atrium which can be safely used for guidance during the ablation**.**

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Figure legends:

Fig.1: m-FAM workflow in group 1 (A) and group 2 (D). Posterior-anterior and anterior-posterior views of the m-FAM reconstruction compared to the cardiac CTA of the same patient (B-C in group 1 and E-F in group 2). Note the minimal FAM required by the system to create a m-FAM reconstruction

Fig.2: Confirmation of the ablation catheter location with intracardiac echocardiogram at different landmarks on the m-FAM reconstruction. Ablation (Abl), left superior pulmonary vein (LSPV), left atrial appendage (LAA), left interior pulmonary vein (LIPV), right superior pulmonary vein (RSPV), right inferior pulmonary vein (RIPV)

Fig 3. Example of m-FAM reconstruction. In A and D antero-posterior and posterior-anterior FAM required for m-FAM reconstruction. B-C antero-posterior view of the m-FAM reconstruction and cardiac CTA. E-F posterior-anterior view of the m-FAM reconstruction and cardiac CTA.

Fig.4: In A m-FAM vs cardiac CTA of the LA in a patient with left common ostium and right middle branch. The substrate analysis mapping is displayed on the m-FAM reconstruction. In B and C the ablation set of the WACA in the sane patient displayed on the m-FAM and FAM reconstruction in posterior anterior view (B) and anterior posterior view (C)

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