ESC European Society of Cardiology

Europace (2023) **25**, 1126–1134
https://doi.org/10.1093/europace/euac262

TECHNICAL ISSUES

Feasibility and safety of a three-dimensional anatomic map–guided transseptal puncture for left-sided catheter ablation procedures

Marius Bohnen *, Jan Minners, Martin Eichenlaub, Reinhold Weber, Hans-Jürgen Allgeier, Amir Jadidi, Franz-Josef Neumann, Dirk Westermann, Thomas Arentz, and Heiko Lehrmann

Department of Cardiology and Angiology (Campus Bad Krozingen), Heart Center, University Hospital Freiburg, Südring 15, 79189 Bad Krozingen, Germany

Received 2 October 2022; accepted after revision 28 November 2022; online publish-ahead-of-print 4 January 2023

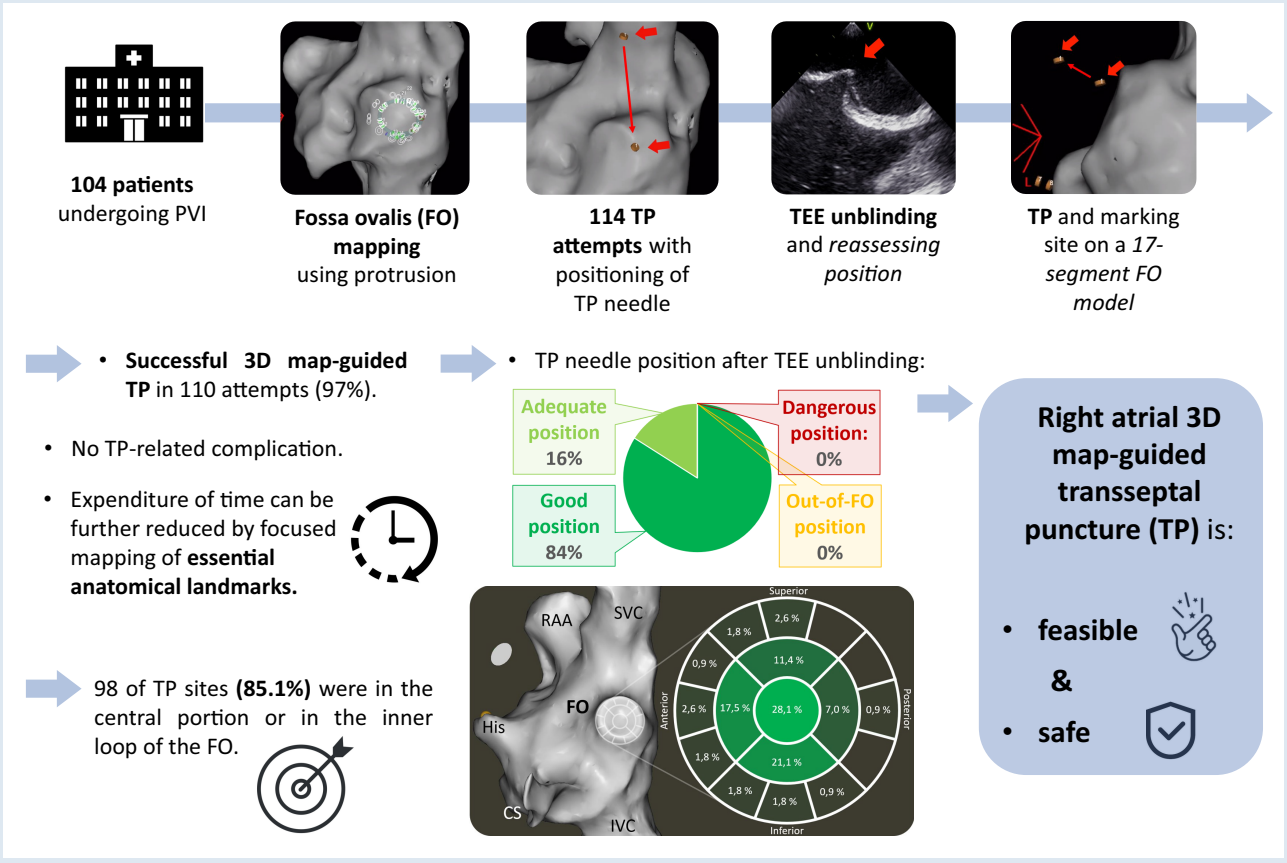
Aims Transseptal puncture (TP) for left-sided catheter ablation procedures is routinely performed under fluoroscopic or echocardiographic guidance [transoesophageal echocardiography (TEE) or intracardiac echocardiography (ICE)], although three-dimensional (3D) mapping systems are readily available in most electrophysiology laboratories. Here, we sought to assess the feasibility and safety of a right atrial (RA) 3D map–guided TP.

Methods and results In 104 patients, 3D RA mapping was performed to identify the fossa ovalis (FO) using the protrusion technique. The radiofrequency transseptal needle was visualized and navigated to the desired potential FO-TP site. Thereafter, the interventionalist was unblinded to TEE and the potential FO-TP site was reassessed regarding its convenience and safety. After TP, the exact TP site was documented using a 17-segment-FO model. Reliable identification of the FO was feasible in 102 patients (98%). In these, 114 3D map–guided TP attempts were performed, of which 96 (84%) patients demonstrated a good position and 18 (16%) an adequate position after TEE unblinding. An out-of-FO or dangerous position did not occur. A successful 3D map–guided TP was performed in 110 attempts (97%). Four attempts (3%) with adequate positions were aborted in order to seek a more convenient TP site. The median time from RA mapping until the end of the TP process was 13 (12–17) min. No TP-related complications occurred. Ninety-eight TP sites (85.1%) were in the central portion or in the inner loop of the FO.

Conclusion A 3D map–guided TP is feasible and safe. It may assist to decrease radiation exposure and the need for TEE/ICE during left-sided catheter ablation procedures.

* Corresponding author. Tel: +49 7633 402 0. *E-mail address*: marius.bohnen@uniklinik-freiburg.de

Graphical Abstract



Keywords Transseptal puncture technique • 3D mapping system • Catheter ablation • Zero-fluoro • Pulmonary vein isolation • Atrial fibrillation

What's new?

- This study sought to assess the feasibility and safety of a right atrial three-dimensional 3D map–guided transseptal puncture (TP) by identifying the fossa ovalis (FO) using the protrusion technique.
- The majority of 3D map–guided TP attempts demonstrated a good position (84%), and the remainder demonstrated an adequate position after TEE unblinding (prior to TP). An out-of-FO or even dangerous position was not seen.
- A successful 3D map–guided TP was performed in almost all attempts (97%). Four attempts (3%) with adequate positions after TEE unblinding were aborted in order to seek a more convenient TP site.
- No TP-related complications occurred.
- Right atrial mapping increased the time for the TP process, but this can be further reduced by focusing on the essential anatomical landmarks.
- Assessment of the actual TP sites on the 3D map showed that 85.1% of the 3D map–guided TP sites were in the central portion or in the inner loop of the FO.

Introduction

Transseptal puncture (TP) for left-sided catheter ablation procedures is routinely performed under fluoroscopic or echocardiographic guidance [transoesophageal echocardiography (TEE) or intracardiac echocardiography(ICE)].

Fluoroscopy still is the cornerstone of imaging during catheter ablation procedures; however, its adverse effects on patients and staff are well known.[1] Additionally, a purely fluoroscopy-based TP involves the risk of inadvertent puncture of the aorta and pericardial space.[2,3] When performing catheter ablation under general anaesthesia, TEE is a useful technique to decrease radiation exposure and safely guide TP.[4] However, using TEE during catheter ablation procedures under analgosedation may reduce patient comfort and safety, namely by increasing the risk of aspiration.

To decrease radiation exposure and increase safety, as well as patient comfort, alternative imaging techniques are desirable. Intracardiac echocardiography would comply with these requisites;[5] however, in Europe, its use is currently associated with high costs.

Since its introduction in invasive electrophysiology in 1996,[6] 3D mapping systems have become a well-established imaging technique with

high precision and accuracy.[7] Thus, they have the potential to guide TP without any auxiliary means; however, their routine use for a purely 3D map–guided TP is not established. This study sought to assess the feasibility and safety of a right atrial (RA) 3D map–guided transseptal puncture.

Methods

Study design

This was a prospective, single-centre, feasibility study. From July 2021 to May 2022, 104 consecutive patients undergoing radiofrequency (RF) catheter ablation for paroxysmal or persistent atrial fibrillation (AF) by a single operator (H.L.; invasive electrophysiology since 2011) were prospectively included in the analysis. Patients with interventional or surgical closure of a persistent foramen ovale (PFO) or atrial septal defect were excluded. The study protocol was reviewed and approved by our institutional review board (registration number 461/19; www.drks.de, DRKS-ID: DRKS00025560). All patients gave written informed consent.

Catheter placement (Step 1)

The ablation procedures were carried out under general anaesthesia, as previously described.[8] In brief, after obtaining access to the right femoral vein using ultrasound guidance, two 63 cm, standard 8 Fr-long sheaths (Swartz™ Braided Transseptal Series Guiding Introducer, LAMP™ 45°, Abbott, USA) were introduced. A 20-polar circular mapping catheter (Lasso®, Biosense Webster, USA, spacing 2–6–2, electrode size 1 mm) and a 7 Fr, 3.5 mm tip, open-irrigated ablation catheter (ThermoCool Smarttouch®, Biosense Webster, USA) were visualized on the CARTO® 3D electroanatomic mapping system (CARTO® 3 System, Biosense Webster, USA) as soon as they had reached the end of each long guiding sheath. From the patients' pelvic area, the catheters were further advanced to the right atrium (RA) solely by using the 3D mapping system.

Time for catheter placement (Step 1) was measured from the first skin puncture until the circular mapping and the ablation catheter had reached the RA.

Right atrial anatomic mapping (Step 2)

Again, without the use of any fluoroscopy, a fast anatomical map of the RA and its adjacent caval veins using the circular mapping catheter was acquired (*Figure 1A*). The goal was to reliably identify the fossa ovalis (FO) with the circular mapping catheter using the protrusion technique (*Figure 1B*).[9] To outline the RA anatomy, the regional detail level was set to '11'. When mapping the septal portion of the RA including the FO, the regional detail level was set to '15', focusing on a precise delineation and protrusion of the FO with the circular mapping catheter. Furthermore, the His-bundle region as well as the presence of a PFO were marked. To prevent entrapment of the circular mapping catheter in the tricuspid valve, mapping of the right ventricle or dislodgement of the mapping catheter in the right ventricle must be implicitly avoided at all time. Using the ablation catheter, the coronary sinus (CS) was included in the 3D anatomic map.

At last, the circular mapping catheter was placed in the superior vena cava (SVC), the circle was minimized, and the guiding sheath was advanced until resistance was appreciated. Thereafter, the circular mapping catheter was exchanged for a 0.035 inch, 180 cm, J-tip guidewire and dilator, which were both sequentially further advanced into the SVC until fully exposed. Finally, the guidewire was withdrawn.

Time for RA mapping (Step 2) was defined as the time between the mapping and the ablation catheter had reached the RA, and the TP needle was introduced in the sheath positioned in the SVC.

Transseptal puncture (Step 3)

The radiofrequency (RF) transseptal (TS) needle (NRG® Transseptal Needle, Baylis Medical) with a rounded, atraumatic tip was connected via a pinbox (CARTO® 3 System, Biosense Webster, USA) to the 3D mapping system and was defined as a bipolar catheter. The TS needle was introduced into the dilator/sheath positioned in the SVC and was advanced until ~1 cm before reaching the end of the dilator. By retracting the dilator/sheath while securing the TS needle in position, the tip of the needle was passively exposed into the SVC and appeared on the 3D anatomic map [*Figure 1C* (red arrows)]. We would like to emphasize that the TS needle itself must not be advanced actively outside the dilator/sheath into the SVC, due to the increased risk of perforation. For the transseptal puncture manoeuver, we used a biplane mapping system view of the FO, one showing a direct plane view of the FO and the other an orthogonal posterior view.

The entire assembly, consisting of the exposed TS needle, visualized on the 3D map, and dilator/guiding sheath, was slowly dragged down from the SVC and was navigated towards the desired portion of the FO, always visualized in real time on the 3D anatomic map (*Figure 1C*). For the reason of maximizing patient safety while investigating this new TP approach and its precision in navigation, the goal was to puncture the septum in the centre of the FO. After positioning the TS needle/sheath, the interventionalist was required to commit oneself to the desired potential FO-TP site.

Thereafter, the interventionalist was unblinded to transoesophageal echocardiography (TEE) and the potential FO-TP site was reassessed regarding its position, precision, and safety using a scoring system (good, adequate, out-of-FO, dangerous; *Figure 1D*).

A good position was defined as a centrally placed TS needle/sheath apparatus within the FO, enabling safe transseptal access at the precise site the interventionalist was aiming for. An adequate position was defined as a position in the outer parts of the FO but still within its margins. An adequate TP position would still ensure a safe and suitable TP. However, precision would rather be adequate since the TP is still within the FO but not its centre. An out-of-FO position was a TP position just outside the FO (the rim of the FO or septum secundum), requiring a new TP attempt but without the criteria of a dangerous position. TP at a dangerous site (position and direction of puncture) would lead to the puncture of adjacent structures, namely the aorta or the epicardial space, and would potentially result in a severe complication.

After a good or adequate position was confirmed by TEE (*Figure 1E*), RF energy was applied to the needle, and TP was performed. For technical reasons, visualization of the needle tip was interrupted during RF energy delivery. Successful access to the left atrium (LA) was confirmed by tactile feedback of the sudden loss of resistance of the TP needle, recording of an LA pressure pattern, and visualization of the TP needle tip now outside the RA geometry (orthogonal RA view; *Figure 1F*). Thereafter, the TS needle was exchanged for the guidewire, which was positioned in either of the left pulmonary veins (PVs) as confirmed by TEE or fluoroscopy. The ablation catheter was advanced into the LA by probing the FO at the same site as the prior position of the TS needle. Following the successful crossing of the septum with the catheter probing technique,[10] the TP site was marked on the RA 3D map by acquiring additional high-resolution geometry (regional detail level '20') via the ablation catheter. Then the second sheath was advanced over the still-in-place guidewire and subsequently the circular mapping catheter was introduced into the LA.

Time for each TP attempt (Step 3) was taken from introducing the TP needle in the sheath positioned in the SVC until ablation and circular mapping catheter had reached the LA or a second TP attempt was started.

Post-procedural analysis and anatomic measurements

Using the 3D anatomic map and the TEE (bicaval view and perpendicular *x*-plane view), the height and width of the FO were measured and the elliptic FO area was calculated. Measurements were made with the CARTO® 3 software, using the 'distance measurement' or 'design line' tool. The exact TP site as depicted on the RA map was analysed using a 17-segment model of the FO ('clock' scheme; Supplementary material online, *Figure S1*).

Statistical analysis

The normality of data distribution was tested using the Kolmogorov–Smirnov and Shapiro–Wilk test. If formal testing was not significant normality was accepted, otherwise, graphs, skewness, and kurtosis were used to confirm non-normality. Categorical variables are expressed as numbers (percentage). Continuous variables are expressed as mean ± standard deviation (SD) or median [interquartile range (IQR)] as appropriate. SPSS Statistics 25 (IBM Corporation, Armonk, NY, USA) was used for statistical analysis.

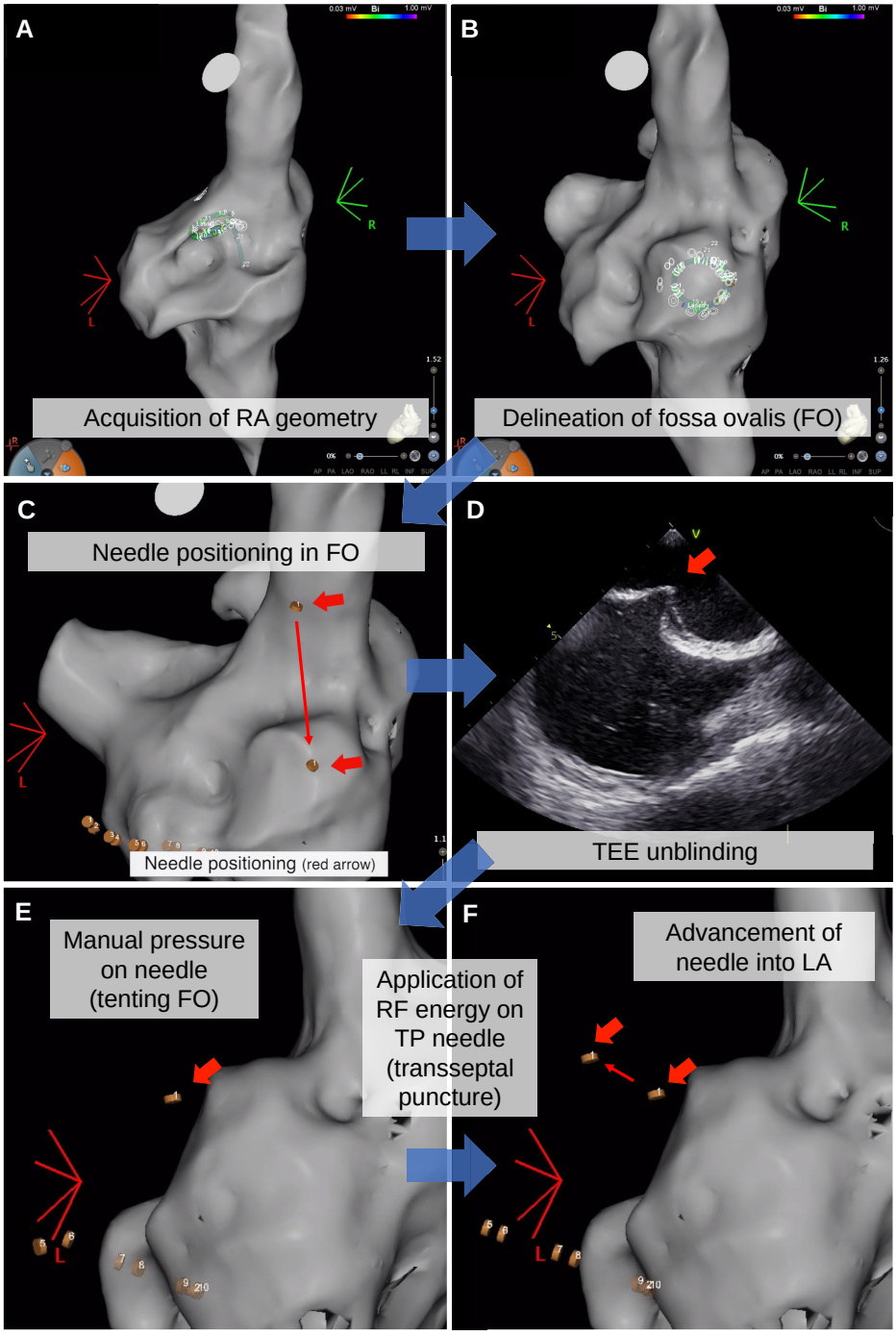


Figure 1 Image sequence (*A*–*F*) of the process of a 3D map–guided transseptal puncture (for video, see Supplementary material online). The red, bold arrows point to the tip of a TP needle. FO, fossa ovalis; LA, left atrium; RA, right atrium; RF, radiofrequency; TEE, transoesophageal echocardiography; TP, transseptal puncture.

Results

One hundred and four consecutive patients who underwent catheter ablation for AF were included in the analysis (*Table 1*). Patients were 63 ± 10 years old, predominantly male, and having a history of arterial hypertension but only few having structural heart disease. About one-half of the patients presented with paroxysmal (48%), and the other half presented with persistent AF (52%). Notably, five (5%) patients did have a cardiac implantable electronic device (CIED).

Anatomic parameters

Anatomical parameters of the interatrial septum are summarized in *Table 2A*. The calculated FO area using the 3D anatomic map

Table 1 Clinical parameters

Parameter	$n = 104$
Age (years)	63 ± 10
Male gender	65 (61)
Arterial hypertension	72 (68)
LVEF in SR (%)	59 (56–61)
Cardiac implantable electronic device	5 (5)
LA diameter (mm)	41 ± 5
Atrial fibrillation type	
Paroxysmal	51 (48)
Persistent	55 (52)

Data are presented as *n* (%) or mean ± SD/median (IQR).
LA, left atrium; LVEF, left ventricular ejection fraction; SR, sinus rhythm.

Table 2 Anatomical and procedural parameters

(A) Anatomical parameters	$n = 104$
3D map calculated FO area (mm^2)	34.5 ± 11.7
TEE calculated FO area (mm^2)	29.4 ± 17.5
Atrial septal aneurysm	5 (5)
Patent foramen ovale	14 (13)
(B) Procedural parameters	**$n = 104$**
Re-do	33 (31)
Total procedure time (min)	130 (117–160)
Catheter placement time (min)	8 (7–10)
Fluoroless catheter placement	103 (99)
If fluoro for CP was used ($n = 1$)	
Fluoro time (min)	0,9
Fluoro dose ($cGy \times cm^2$)	43.7
Right atrial mapping time (min)	6 (5–8)
Fluoroless right atrial mapping	104 (100)
3D map–guided TP feasible	102 (98)

Data are presented as *n* (%) or mean ± SD/median (IQR).
CP, catheter placement; FO, fossa ovalis; TEE, transoesophageal echocardiography.

(34.5 ± 11.7 mm^2) was significantly larger than the calculated FO area using TEE (29.4 ± 17.5 mm^2; $P = 0.025$). On TEE, five (5%) patients demonstrated an atrial septal aneurysm. Using fast anatomic mapping and TEE, a patent foramen ovale (PFO) was present in 14 (13%) patients.

Procedural parameters

Procedural characteristics are summarized in *Table 2B*. About one-third (31%) of cases were re-do procedures with a previous transseptal puncture. Catheter placement time (including femoral venous access) and RA mapping time were 8 (7–10) and 6 (5–8) min, respectively. Right atrial mapping times did not differ between the first and second half of patients in our study cohort [6 (5–8) min, 6 (5–9) min, $P = 0.943$]. Reliable identification of the FO using the protrusion technique was feasible in 102 (98%) patients. In the remaining two (2%) patients, the protrusion technique failed to identify the FO and TEE revealed the interatrial septum to be markedly thickened and fibrous.

Table 3 Transseptal puncture parameters

Parameter	Value
Number of TP attempts in 102 patients	$n = 114$
Time per TP attempt (min)	7 (6–9)
Successful 3D map–guided TP attempts	110 (97)
Aborted 3D map–guided TP attempts	4 (3)
TP-related complications	0
Needle position after TEE unblinding	
Good position	96 (84)
Adequate position	18 (16)
Out-of-FO position	0
Dangerous position	0
Fluoro-use for TP process	
None	49 (43)
For actual TP	1 (1)
For wire visualization in left PVs	64 (56)
If fluoro during TP process was used:	
Fluoro time per TP attempt (min)	0.00 (0.00–0.05)
Fluoro dose per TP attempt ($cGy \times cm^2$)	0.00 (0.00–0.09)

Data are presented as *n* (%) or median (IQR).
FO, fossa ovalis; PV, pulmonary vein; TEE, transoesophageal echocardiography; TP, transseptal puncture.

Transseptal puncture parameters

In the 102 patients demonstrating reliable identification of the FO, 114 TP attempts were performed (*Table 3*). A successful 3D map–guided TP (*Figure 2*) was performed in 110 attempts (97%). Four attempts (3%) with adequate position after TEE unblinding were aborted in order to seek a more convenient TP site (operator's decision). The median time per TP attempt was 7 min (IQR: 6–9 min), which included the time for TEE confirmation of a suitable position and placement of both catheters (mapping and ablation) and transseptal sheaths into the LA. Time per TP attempt did not differ between the first and second half of the study cohort [7 (5–9) vs. 7 (6–8) min, $P = 0.790$].

There were no TP-related complications. Specifically, there were no cases of pericardial tamponade or effusion, aortic intramural haematoma, aortic dissection, cerebral or systemic thromboembolism, catheter entrapment in heart valves, or new/progressive regurgitation of heart valves. In addition, there was no case of lead dislodgement in the five CIED patients. Pre- and post-procedural device interrogation revealed stable sensing and pacing parameters.

Prior to the actual TP, TEE unblinding revealed a good TP position in 96 (84%) attempts and an adequate position in 18 (16%) attempts (*Table 3*). An out-of-FO or even dangerous position was not seen after TEE unblinding.

The TP itself was performed without the use of any fluoroscopy in 113 (99%) attempts. Only one (1%) TP attempt needed the conjunctive use of fluoroscopy for the actual puncture, to confirm the presence of unusual anatomy. A secure guidewire position in the left PVs was confirmed by fluoroscopy in 65 (57%) attempts and by TEE in 49 (43%) attempts. The entire TP process being fluoroless was significantly more common in the second half of our cohort [16/57 (28%) attempts vs. 33/57 (60%) attempts, $P = 0.003$].

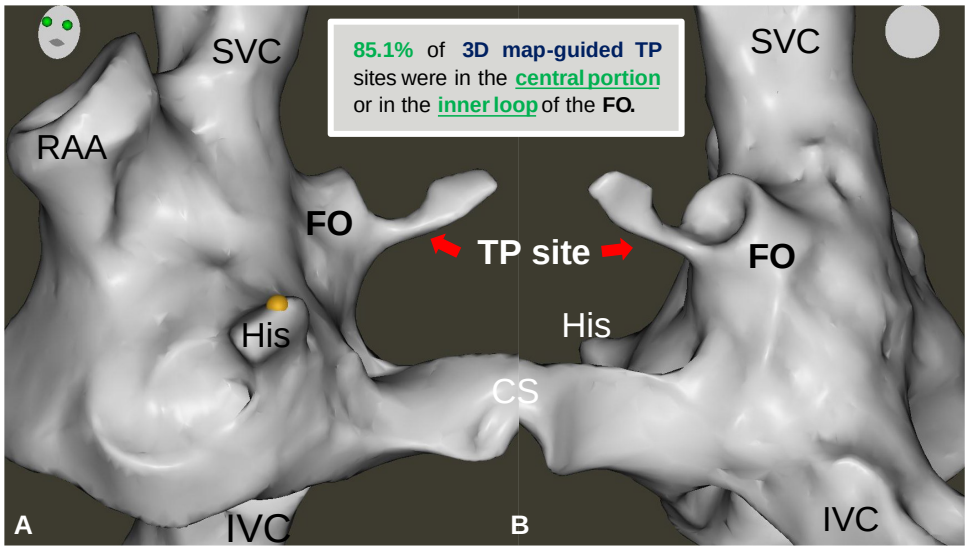


Figure 2 Three-dimensional anatomic map of the right atrium after a successful 3D map–guided TP viewed from (*A*) LAO 40° and (*B*) posterior. CS, coronary sinus; FO, fossa ovalis; His, bundle of His; IVC, inferior vena cava; LAO, left anterior oblique; RAA, right atrial appendage; SVC, superior vena cava; TP, transseptal puncture.

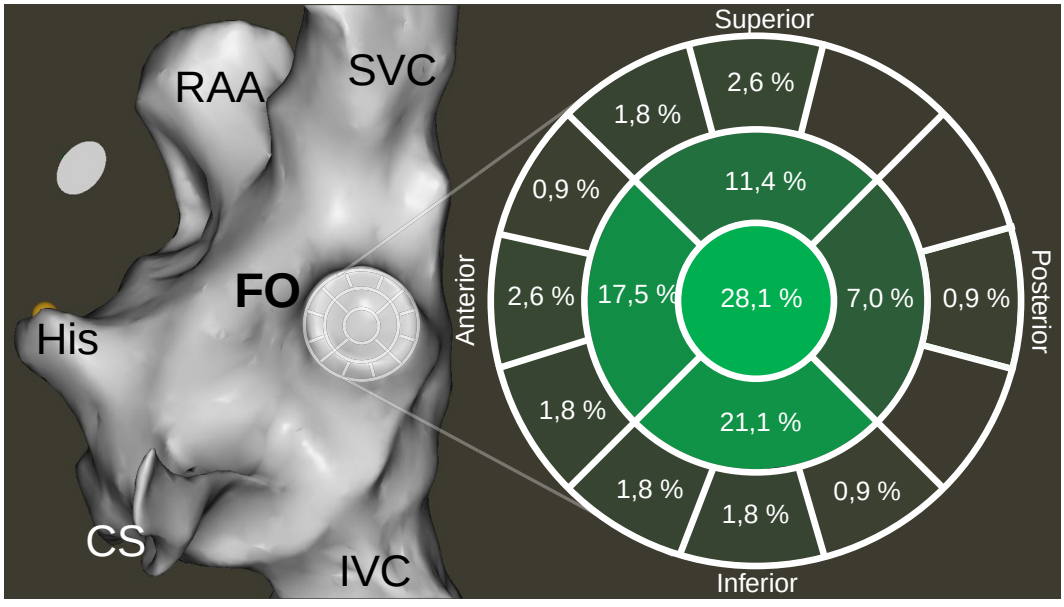


Figure 3 Spatial distribution of transseptal puncture sites within FO (outer loop, inner loop, central portion). The goal was to puncture the FO in its centre. As a result, 100% of 3D map–guided TP sites were within the FO and 85.1% within the central portion or in the inner loop. CS, coronary sinus; FO, fossa ovalis; His, bundle of His; IVC, inferior vena cava; RAA, right atrial appendage; SVC, superior vena cava; TP, transseptal puncture.

If fluoroscopy was used during the TP process (mainly guidewire visualization in left PVs), the fluoro time and fluoro dose per TP attempt were 0.00 (0.00–0.05) min and 0.00 (0.00–0.09) cGy cm^2, respectively.

Plotting the exact TP sites using the 17-segment model of the FO, 85.1% of 3D map–guided TP sites were in the central portion or in the inner loop of the FO (*Figure 3*; central portion 28.1%; inner loop 57.0%).

Discussion

In this study, we have shown that a right atrial 3D map–guided transseptal puncture is feasible and safe.

The main findings are as follows: (i) the majority of 3D map–guided TP attempts demonstrated a good position (84%), and the remainder demonstrated an adequate position after TEE unblinding (prior to

TP). An out-of-FO or even dangerous position was not seen. (ii) A successful 3D map–guided TP was performed in almost all attempts (97%). Four attempts (3%) with an adequate position after TEE unblinding were aborted in order to seek a more convenient TP site. (iii) No TP-related complications occurred. (iv) Right atrial mapping increased the time for TP process but can be further reduced by focusing on the essential anatomical landmarks. (v) Assessment of actual TP site on the 3D map showed that 85.1% of 3D map–guided TP sites were in the central portion or in the inner loop of the FO.

Strength and weakness of our study

The described method of 3D map–guided TP is applicable in every EP laboratory. It is based on the FO protrusion technique[9] utilizing a multielectrode mapping catheter, routinely used especially for radiofrequency PV isolation procedures. In only 2 of 104 patients (2%) of our study cohort, identification of the FO, a prerequisite of our 3D map–guided TP method, was not feasible.

Most importantly, the application of the 3D map–guided TP technique resulted in a safe puncture site within the FO in 100% of attempts. Only 3% of attempts were aborted at the operator's discretion, most notably not for safety reasons but to obtain a more central puncture site. In those patients, the following TP attempt was again guided via the 3D map with consecutive successful TP.

Mainly due to the necessity for prior RA mapping (median 6 min), expenditure of time for 3D map–guided TP [13 (12–17) min] is increased in our study in comparison to a purely fluoroscopy-guided approach. The actual time for TP (median 7 min) is consistent with previously reported data.[11,12] The following two aspects might explain the relatively long time period in the context of this study.

First, as this was a feasibility and safety study, a detailed geometry of the entire RA was acquired, also including the right atrial appendage, the RA sidewall, and inferior vena cava (IVC) to get a complete overview of the RA anatomy. Although retrospectively, this detailed mapping would not have been necessary, while conducting the study, the main focus was set on the highest possible safety of this new, yet uninvestigated TP approach. After completion of the study, we have come to the conclusion that focusing on the most important RA anatomical landmarks is absolutely sufficient, reducing the time duration while still maintaining the highest safety requirements.

Secondly, some of the relatively long time period may be explained by our definition 'end of TP process', which was defined as point in time when ablation and circular mapping catheter had reached the LA. This included (i) blinded positioning of the TP apparatus in the oval fossa, (ii) validation of its position by TEE (only necessary during this study), (iii) primary transseptal puncture, (iv) probing of the TP site with the ablation catheter and advancing it into the LA, (v) positioning of the circular mapping catheter within the LA. For post-study everyday usage, without the need for TEE validation and with the endpoint of having one catheter in the LA, the expenditure of time for a single TP would be clearly less.

A completely zero-fluoro transseptal needle access into the LA was possible in **99%** of attempts, but in 56%, the position of the transseptal guidewire within the left PVs had to be confirmed by fluoroscopy in order to assure safe septum crossing of the sheath. Due to the X-ray settings with a pulse rate of 0.5/s, the resulting fluoroscopy dose was not measurable by the X-ray system (median 0.00 cGy cm^2).

Choice of transseptal needle for visualization on 3D map

In principle, any other transseptal needle can be visualized on a 3D mapping system by using two alligator clips connected to a pinbox and subsequently the patient interface unit. In the mapping system, the TP needle again needs to be set up as a bipolar catheter. However, we chose to use the RF needle based on the following grounds.

First, in order to be visualized on the 3D anatomic map, the tip of the needle has to be exposed out of the sheath. For the TP manoeuver itself, the entire assembly is then dragged down the SVC towards the FO. The rounded atraumatic tip of the RF needle seems clearly favourable during this procedural step in terms of safety compared with a conventional TP needle with its sharp tip. Alternatively, a visualized guiding sheath (e.g. VIZIGO™, Biosense Webster) could be used to target the desired FO position with subsequent exposure of a conventional TP needle in that position. To our knowledge, this alternative 'visualized sheath' TP approach, however, has yet not been validated in a prospective study.

Secondly, for the RF needle, the actual tip of the needle is visualized at any time, regardless of how far the needle is being advanced out of the sheath (due to electrical isolation of the TS needle shaft). This circumstance is particularly relevant for reliable localization of the needle immediately after TP puncture. If a conventional TS needle (lacking electrical isolation) is used, the midpoint of the exposed needle part (midpoint between tip and end of the sheath) will be visualized instead of its tip.

Lastly, the RF needle is directly connected to the mapping system via cable and connector box, making a fast and reliable 3D map visualization possible.

Needle visualization on the 3D map and within the 'matrix' A sufficient map of the FO is a requisite for a safe and effective 3D map–guided TP. In this study, we performed a rather detailed mapping of the entire RA; however, in everyday practice, this may be restricted to important anatomical landmarks, focusing especially on the FO.

Visualization beyond the acquired geometry is possible by the concomitant 'matrix', which is always larger than the anatomical map itself. In fact, the tip of the needle was visible at all times, including during tenting of the FO. This maybe another advantage of the protrusion technique: by protruding the FO for its identification, the 'matrix' is expanded to the left side as well. Even after crossing the septum and carefully advancing the needle into LA, the tip of the needle remained visible within a radius of about 2 cm from the protruded FO.

The only exception of needle visualization was at the time of RF energy delivery over the TS needle (needle disappears for ~2 s); however, this is due to the lack of a simultaneous mapping capacity while applying RF energy to the needle and not due to insufficient 'matrix'.

General anaesthesia or analgosedation?

By using general anaesthesia in this study, we were able to validate this method towards the well-established TP approach using TEE guidance. But this approach could very well be transferred to procedures under analgosedation since visualization of the TS needle and acquisition of a RA map is not dependent upon general anaesthesia. However, patient movement with insufficiently deep analgosedation and subsequent map shift would possibly displace the gathered anatomical landmarks and would require the reacquisition of RA/FO geometry. Keeping this in mind, the proposed 3D map–guided TP method is also applicable under adequate analgosedation.

Comparison to previous studies

A purely fluoroscopy-guided TP has been a routine procedure for many years, but still carries a risk of cardiac tamponade (0.72%)[2] and rarely even aortic puncture (0.03%),[3] both of which are potentially life-threatening complications and may need open-heart surgery. Combining a fluoroscopy-guided TP with the here presented approach would lead to clear identification of the FO and the transseptal needle position in the vast majority of patients and could therefore further increase safety, especially in anatomically challenging cases.

A zero-fluoroscopy TP may also be performed with the use of ICE.[5,13] The disadvantages of this approach are as follows: first, the high additional costs of the ICE catheter with its concomitant

reimbursement issues in various European countries. Secondly, the risk of additional complications related to venous access or mishandling of the ICE probe with subsequent vascular or cardiac perforation. The advantage over the presented technique is the direct visualization of the LA cavity, which allows direct visual guiding of the transseptal wire into the left PVs. This enables the transseptal sheath to cross safely the interatrial septum into the LA.

Another echocardiographic modality with the potential for TP without fluoroscopy is TEE (transoesophageal echocardiography).[14] To date only limited data have been published on this topic, most likely because most pulmonary vein isolation (PVI) procedures are performed under conscious sedation. Insertion of a TEE probe into a non-intubated, supine patient carries the risk of aspiration, resulting in frequent coughing during the procedure and a post-procedural risk of pneumonia. In addition, injuries to the teeth, throat and oesophagus may occur.[15] Moreover, the need for additional staffing (echocardiographer) increases procedural costs.

An alternative TP approach without auxiliary tools was published by Yu *et al.*[16] In contrast to our study, the FO was not identified by protrusion but by voltage mapping, with the central portion showing a strongly attenuated signal, a finding being independent of the underlying rhythm (AF or SR). On the contrary, previously published data from our group, comparing different methods for identifying the FO, did not find voltage mapping to be useful.[9] The discrepancy between the studies might be explained by the method the voltage signals were acquired. In our study, mapping was performed with a 20-pole circular mapping catheter, whereas in the study by Yu *et al.*,[16] a pinpoint ablation catheter was used. The shape of the circular mapping catheter may have led to a circular signal acquisition within the FO, with the sparing of its centre. Nevertheless, pre-existing septal fibrosis might hamper FO identification by voltage mapping alone, whereas the here proposed method is independent of voltage gradients.

Clinical implications

(A) For everyday clinical usage, we suggest the following simplified landmark approach: start mapping with the circular catheter at the left aspect of the SVC and drag it down towards the interatrial septum. Then we recommend outlining the borders of the septum and the IVC. With the ablation catheter, the His region and the septal tricuspid annulus should be marked. Subsequently, the ostium of the CS, as well as its course towards the left side, should be mapped. Afterwards, the CS catheter may be navigated to its position. Finally, using the circular mapping catheter again, the FO should be identified by a careful protrusion of the septum, thoroughly mapping its limbus but also its centre.

(B) The method described allows the clinician to perform a TP safely based on an already available 3D mapping system, obviating the need for additional costly tools such as TEE and ICE. As the TP is currently the major obstacle to a zero-fluoro PVI procedure, the here-described method would help overcome this problem in a majority of patients. The advantages of zero-fluoro procedures, particularly in terms of radiation exposure reduction, apply to patients and staff alike. Moreover, orthopaedic sequelae can be reduced by the abolition of lead aprons.[1] Pregnant cath lab staff may have the possibility to still work in their usual working environment. In the long term, even an electrophysiological laboratory without an X-ray system seems conceivable, implying an enormous cost reduction.

(C) Apart from fluoroscopy reduction, a 3D map–guided TP may also play a role in challenging fluoroscopy-guided TPs with difficult anatomical conditions such as patients with pectus excavatum, where it may help to guide the needle–sheath apparatus safely into the FO, even if typical anatomical landmarks are distorted.

Future research

Although a 3D map–guided TP was possible in all patients in our study cohort, placement of the transseptal wire into the left superiore pulmonary vein (LSPV) and safe access of the sheath into the LA required fluoroscopy in 56% of patients. In the future, this limitation may potentially be overcome by using 'visualized' wires within the 3D mapping system, e.g. the VisionWire (Biotronik) or the VersaCross transseptal wire (Baylis Medical).

The method of 3D map–guided TP should be transferred to other ablation procedures using a 3D mapping system, such as ablation of left-sided accessory pathways, especially in paediatric patients. However, since multipolar mapping catheters (circular or pentaspline catheters) are not routinely used during these procedures, further research on whether a reliable protrusion of the FO (a prerequisite of the described technique) is possible with the ablation catheter alone is needed.

Limitations

This is a single-centre study with all procedures being performed by a single experienced operator, which is a limitation in terms of replicability. The presented method should be validated in a larger multicentre cohort.

For safety reasons, the goal was to puncture the septum in the central portion of the FO: 100% of the 3D map–guided TP sites were in the FO, and 85.1% were in the central portion or in the inner loop, demonstrating excellent safety. However, whether other TP sites within the FO may be targeted as per operators' preference remains unknown.

In this study, containing five CIED patients, no case of lead dislodgement was seen. However, this low number of CIED cases prohibits drawing any reliable conclusions, implying the need for further studies for this special patient cohort. Until then, a routine fluoroless 3D map–guided approach in CIED patients should be dispensed.

Similarly, if a reliable protrusion of the FO is not possible, the here-described approach using solely the 3D map for TP guidance is not applicable. In such a case, a complementary imaging technique, such as fluoroscopy or preferably echocardiography (TEE, ICE), is mandatory to assure a safe and successful TP.

Conclusions

Right atrial 3D map–guided transseptal puncture is feasible and safe. Guiding the PVI procedure solely using the 3D mapping system seems achievable in the near future.

Supplementary material

Supplementary material is available at *Europace* online.

Authors' contributions

M.B. and H.L. planned and designed the study, acquired the data, interpreted the data, and wrote the manuscript. M.B. analysed the data. R.W., J.M., M.E., A.J., F.-J.N., D.W., and T.A. interpreted the data, revised the manuscript, and substantially contributed to the inaugural draft. All authors approved the final submitted version.

Funding

The funder (University Hospital Freiburg) had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results. This study was performed and designed without the input or support of any pharmaceutical or medical company, or other commercial interests. We acknowledge support by the Open Access Publication Fund of the University of Freiburg.

Conflict of interest: D.W. reports lecture fees paid from Abiomed, AstraZeneca, Bayer Healthcare, Boehringer Ingelheim, Edwards LiveScience, Novartis, and Medtronic. F.-J.N. reports lecture fees paid to his institution from Amgen, Bayer Healthcare, Boehringer Ingelheim,

Boston Scientific, Daiichi Sankyo, Edwards Lifesciences, Ferrer, Pfizer, and Novartis; consultancy fees paid to his institution from Boehringer Ingelheim and Novartis; and grant support from Bayer Healthcare, Boston Scientific, Biotronik, Edwards Lifesciences, GlaxoSmithKline, Medtronic, Pfizer, and Abbot Vascular. All remaining authors have no conflicts to disclose.

Data availability

The data that support the findings of this study are available from the corresponding author (M.B.) upon reasonable request.

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