

# Use of a novel sharp-tip, J-shaped guidewire to facilitate transseptal catheterization

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## Aims

Transseptal catheterization (TSP-C) is a demanding procedure and at the same time one of the key points of atrial fibrillation ablation, an increasingly diffused procedure. This study prospectively evaluates the usefulness of a novel sharp-tip, J-shaped 0.014" transseptal guidewire (TSP-GW) to facilitate TSP-C in case of resistant atrial septum (AS).

## Methods and results

Consecutive patients undergoing TSP-C for arrhythmia ablation in a single centre were considered for the study. TSP-C was performed according to a standardized technique. The criterion to use the TSP-GW was a resistant AS, defined as inability to perforate the fossa ovalis by applying moderate pressure to a standard Brockenbrough needle. The TSP-GW was inserted in the needle lumen and advanced to puncture the AS and enter the left atrium; subsequently, the transseptal assembly was advanced over the TSP-GW. Double transseptal puncture was routinely performed for ablation of atrial fibrillation. Eighty-one patients (54 males, 27 females; mean age  $54 \pm 17$  years, range 12–81) undergoing TSP-C were enrolled; 132 TSP-C procedures were planned and accomplished. Nineteen patients (23%) in 27 procedures showed a resistant AS. In all these procedures, the TSP-GW was safely and successfully used to accomplish the TSP-C. In patients with a resistant AS, only a significantly lower prevalence of structural heart disease was observed when compared with controls. No complication related to TSP-C was observed.

## Conclusion

The TSP-GW facilitates TSP-C in 23% of the patients, in whom a resistant AS is encountered. In this population, there was no clinical predictor of such anatomy.

## Keywords

Transseptal catheterization • Cardiac arrhythmia ablation • Atrial fibrillation ablation • Atrial septum • Left heart catheterization

## Introduction

Over the last decade, the use of transseptal catheterization (TSP-C) in the electrophysiology laboratory has progressively increased, becoming an essential part of the electrophysiologist's technical armamentarium.<sup>1</sup> Although this technique can be used to map and ablate a variety of arrhythmias originating in the left heart, this unabated increase is mainly related to the increased number of ablations of atrial fibrillation (AF) in the left atrium (LA). In this scenario, TSP-C is the first step of a complex procedure, and, hence, it requires specific training, adequate experience, and a particular care to be accomplished safely, quickly, and successfully. Both in the past<sup>2</sup> and recently,<sup>1,3</sup> in experienced

centres, severe complications are reported in <1% of the procedures. Nevertheless, this is a demanding procedure especially in patients who require an aggressive anticoagulation therapy. Difficulties can be encountered in localizing, puncturing, and crossing the fossa ovalis (FO) and for this reason different imaging tools are used to assist this procedure.<sup>4</sup> In a proportion of cases, the presence of a resistant atrial septum (AS) renders the access to the LA very difficult and in some cases this may result in inability to accomplish the TSP-C using the standard technique<sup>5–8</sup> or in a puncture of inappropriate structures during multiple attempts.<sup>1</sup>

Recently, the use of novel transseptal guidewire (TSP-GW), combined with a standard transseptal sheath and needle, has been described<sup>8</sup> to gain LA access in the case of an AS particularly

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resistant to puncture at the site of the FO. The aim of this study is to evaluate prospectively the usefulness of this new additional tool in a series of consecutive patients undergoing TSP-C for electrophysiological purposes in our institution.

## Methods

### Patient population

Consecutive patients undergoing TSP-C for ablation of a left-sided arrhythmogenic substrate in our institution from 1 January 2009 to 30 June 2009 were prospectively considered. Patients with patent foramen ovale were excluded. All patients underwent routine pre-procedure evaluation including transthoracic echocardiogram. Patients undergoing pulmonary vein ablation had been on oral anticoagulation for at least 2 months before the procedure. Upon admission, this therapy was discontinued and low-molecular weight subcutaneous heparin was initiated. Before the procedure, candidates of AF ablation and any patient, in whom it was considered appropriate, also underwent transoesophageal echocardiogram and computed tomography or magnetic resonance imaging of the LA/pulmonary veins and of the adjacent structures. The study complies with the Declaration of Helsinki and it was approved by the institutional review board; patients participating gave informed consent.

### Transseptal catheterization

The TSP-C procedure was carried out according to the simplified method already described,<sup>9</sup> with some modifications. Briefly, after positioning of the coronary sinus and His bundle catheters, a 0.032" 150 cm-long guidewire was introduced through the right femoral vein and advanced into the superior vena cava. Then, a transseptal introducer (sheath + dilator) was advanced over the wire into the superior vena cava. An 8 F 60 cm-long sheath with a 180° distal curve (Transseptal Adult 8591, Medtronic Inc., Minneapolis, MN, USA) was used in case of left-sided accessory pathways or ventricular tachycardia, while an 8 F 62 cm-long sheath with a multipurpose curve (Preface 301803M, Biosense-Webster, Inc., Diamond Bar, CA, USA) was used in all the other cases. After removal of the guidewire and flush of the dilator lumen, a 71 cm-long transseptal needle (EP 003994S, Medtronic Inc., Minneapolis, MN, USA) was introduced and kept roughly 1 cm inside the dilator. In case of enlarged atria, the distal part of the needle was manually reshaped to increase the curve and facilitate engagement into the FO. On antero-posterior fluoroscopic view and keeping the needle indicator at 4–5 o'clock, the transseptal assembly was withdrawn from the superior vena cava into the right atrium until a leftward jump of its distal part suggesting

engagement of the FO was observed. In case no jump was observed, the manoeuvre was repeated changing the orientation and/or shape of the needle. After engagement into the FO, in 30° right and left anterior oblique views, the correct position of the distal of the assembly was checked. Optionally, the septum was stained with injection of a small amount of dye. Subsequently, the needle was protruded and a gentle pressure was applied to perforate the AS. Once the needle tip crossed the AS, as observed on fluoroscopy, its positioning in the LA was confirmed by aspiration of arterial blood from the needle lumen and by dye injection through its lumen to visualize the left atrial cavity. If resistance to needle advancement was felt after applying a moderate pressure and dye injection through the needle lumen confirmed that septal perforation was not obtained, application of more pressure to the needle in an attempt to perforate the AS was avoided and this was the criterion to use the TSP-GW (see over).

After perforation of the septum by the needle, the dilator was advanced in the LA over the needle and, subsequently, the sheath was advanced over the dilator, keeping both the needle and dilator in place, to avoid their further advancement. After positioning of the dilator first and of the sheath afterwards, their correct positioning in the LA was checked by dye injection through the lumen. Finally, after having carefully flushed the sheath lumen, the diagnostic or ablation catheter was inserted into the sheath and the LA.

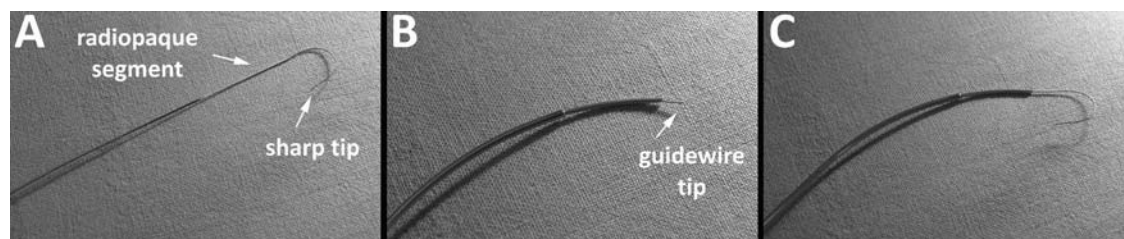
In patients undergoing AF ablation, a double transseptal puncture was routinely performed to insert the circular mapping catheter and the mapping/ablation catheter independently into the LA. Every effort was made to perform both punctures as close as possible.

Intravenous heparin was administered soon after completing the TSP-C in an initial bolus of 50 IU/kg and, subsequently, throughout the procedure to maintain the activated clotting time to be >300 s.

All the TSP-C procedures were performed by two experienced electrophysiologists (R.D.P. and R.M.) as the first operator. Ultrasounds to assist septal puncture were not routinely used.

### Use of the TSP-GW

The sharp-tip, J-shaped TSP-GW (SafeSept, Pressure Products, Inc., San Pedro, CA, USA) is 120 cm long and 0.014" in diameter for use in adults. It has a sharp specially designed tip and a radiopaque coil in the proximity of its distal end (*Figure 1A*). Being made by nitinol, its J-shaped part remains straight when the distal part of the TSP-GW is in the needle lumen (*Figure 1B*), but it resumes its original J-shape as soon as it protrudes from the needle (*Figure 1C*). With these peculiar characteristics, it is possible to easily perforate a resistant structure by the TSP-GW tip, when the J-shaped part is straight inside the needle and just the tip is protruding, while inadvertent

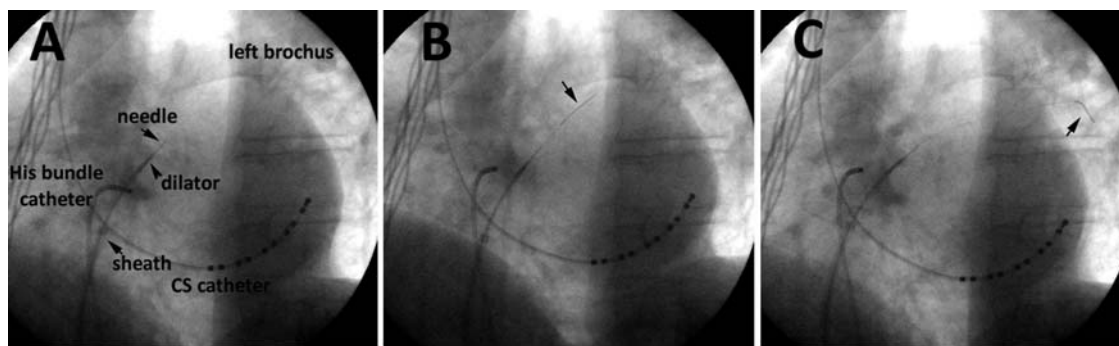


**Figure 1** The characteristics of the 0.014" transseptal guidewire (TSP-GW) are shown. In (A), the J-shaped, sharp tip, and radiopaque segment close to its distal end are evident. In (B), the sharp tip protrudes straight from the needle and, in this way, it is able to penetrate and puncture the AS. In (C), as the TSP-GW is further advanced, it promptly resumes the J-shape and becomes completely atraumatic.

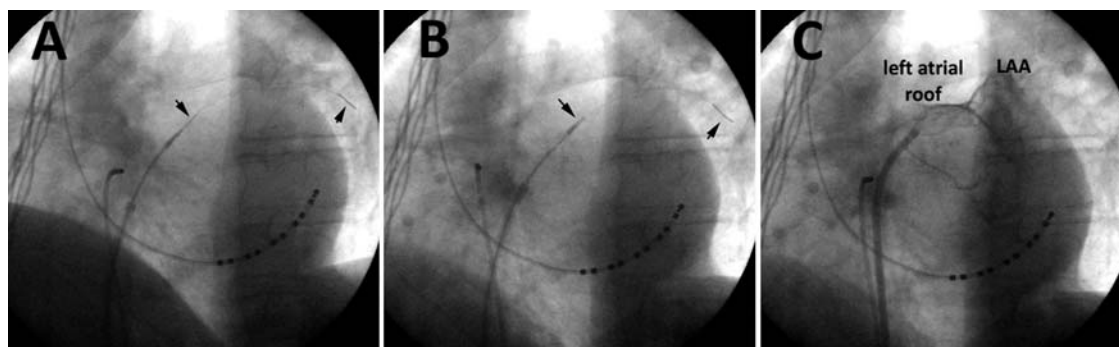
perforation of inappropriate structure is prevented by resumption of the J-shape immediately after its complete exit from the needle lumen. The TSP-GW has also a proximal marker 72 cm from the tip. When the TSP-GW is inserted in the needle lumen during the procedure, this marker indicates that the TSP-GW tip is about to exit from the needle lumen, since the TSP-GW cannot be visualized by fluoroscopy, when it is inside the needle.

As mentioned above, the criterion to use the TSP-GW was a resistance felt during the attempt of puncturing the AS, while dye injection through the needle lumen after proper aspiration confirmed that the needle tip was tenting the FO, yet still without perforating the septum. While the first operator kept in place the transseptal assembly, the second operator inserted and advanced the TSP-GW in the needle lumen. While the needle tip was tenting the FO (Figure 2A), in 30° left anterior oblique view, the TSP-GW was further advanced to exit from the distal end of the needle, perforate the septum, and enter the LA (Figure 2B). From here, the TSP-GW

was positioned into the left superior pulmonary vein (Figure 2C), so that its radiopaque marker exited the cardiac silhouette on fluoroscopy. If needed, minimal clockwise rotation was applied to the transseptal assembly to direct posteriorly the TSP-GW and facilitate engagement of the os of the left superior vein by the TSP-GW. No other positioning of the distal part of the TSP-GW was considered appropriate. In fact, if the TSP-GW is positioned in the left atrial appendage, the distal marker does not exit the cardiac silhouette and, theoretically, it cannot be excluded that the guidewire is in the pericardial space after perforation of an inappropriate site. If the TSP-GW is positioned in the left inferior pulmonary vein, it might not provide enough support to advance the transseptal assembly over the wire. After this step, the needle was gently advanced over the wire and if a resistance to its advancement was still encountered, more pressure could be applied safely since the needle proceeded over the wire (Figure 3A). Subsequently, after checking by dye injection the correct position of the needle tip in the LA, once the



**Figure 2** Sequence of images of the AS puncture by the transseptal guidewire (TSP-GW) in a 30° left anterior oblique fluoroscopic view in a patient undergoing transseptal catheterization for atrial fibrillation ablation. In (A), the coronary sinus and the His bundle catheters are in place, while the transseptal assembly tip is engaging the fossa ovalis. The needle tip is advanced outside the dilatator without puncturing the atrial septum (AS). Therefore, the TSP-GW is inserted in the needle lumen and advanced beyond its distal end, so that it punctures the AS, penetrates into the left atrial cavity (arrow in B) and can be positioned in an inferior branch of the left superior pulmonary vein (arrow in C).



**Figure 3** Sequence of images of the accomplishment of the transseptal catheterization in the same fluoroscopic projection and patient as in the previous figure. While the distal part of the transseptal guidewire (TSP-GW) remains in the left superior pulmonary vein (arrow on the right-end side in A and B), the needle tip is now advanced over the TSP-GW, so that, although a resistance is still encountered, it is possible to safely cross the AS with the needle (A). In (B), after temporary withdrawal of the TSP-GW and dye injection through the needle lumen to check its correct position, the distal end of the dilatator is now advanced in the left atrium (LA), over the needle and the TSP-GW, still positioned in the left superior pulmonary vein. Finally, the sheath is advanced across the septum into the LA and, after withdrawal of the TSP-GW, needle, and dilatator, its positioning in the LA is finally checked by dye injection (C).

**Table 1** Characteristics of the patients with resistant AS when compared with controls

	Patient with resistant AS, group I	Control patients, group II	P-value
Number of patients	19	62	
Number of TSP-C procedures	31	101	
Age (years)	49 ± 19	56 ± 16	n.s.
Sex (male)	12 (63%)	42 (68%)	n.s.
Presence of structural heart disease	3 (16%)	32 (52%)	0.0039
Presence of diabetes	1 (5%)	4 (6%)	n.s.
Previous TSP-C procedures	3 (16%)	11 (18%)	n.s.
Body surface area (m <sup>2</sup> )	1.88 ± 0.22	1.88 ± 0.23	n.s.
Cardiac arrhythmia			
AF	12 (63%)	38 (61%)	n.s.
Others	7 (37%)	24 (39%)	n.s.

TSP-GW was temporarily withdrawn, both the dilator (Figure 3B) and the transseptal sheath (Figure 3C) were advanced into the LA and the procedure completed.

In case of double TSP-C, the TSP-GW was used in both procedures only if the criterion to use this tool was met in both punctures.

## Statistics

Continuous variables are expressed as mean ± standard deviation, while categorical variables are presented as percentage. Statistical analysis of the continuous variables in the group with a resistant AS vs. the remaining patient population was made by means of Student's *t*-test. To evaluate the association of a resistant AS and continuous and categorical variables, logistic regression was used. A *P*-value < 0.05 was considered statistically significant.

## Results

### General population undergoing TSP-C

In the considered time period, 81 patients underwent TSP-C in our institution for treatment of cardiac arrhythmias. Fifty-four (67%) were male; the mean age was 54 ± 17, range 12–81 years.

In 50 patients (62%), the procedure was performed for electrical disconnection of the pulmonary veins in patients with AF. In the remaining 31 patients (38%), the procedure was performed to ablate a left-sided atrioventricular accessory pathway in 23 patients, a left atrial flutter/tachycardia in 7, and a ventricular tachycardia in 1. Since in all patients undergoing pulmonary vein ablation and in one patient with post-ablation atypical atrial flutter a double AS puncture was performed, the overall number of TSP-Cs accomplished in this patient population was 132. Transoesophageal or intracardiac ultrasounds were used in no case to assist the TSP-C procedure.

Thirty-five patients (43%) had a structural heart disease and specifically 20 had hypertensive heart disease, 7 ischaemic heart disease, 3 dilated cardiomyopathy, 3 mitral valve disease (with mechanical prosthesis in 2), and 2 hypertrophic cardiomyopathy. Four patients had prior heart surgery and another two had an implantable cardioverter/defibrillator. In 14 patients (17%) one previous TSP-C was performed in our or in another centre.

There was no complication related to TSP-C. One patient had mild pericardial effusion at the end of a procedure for pulmonary vein isolation; before the effusion developed, a cavitation sound was heard during the last radiofrequency energy application. No sign of tamponade was observed at transthoracic echocardiogram and no other countermeasure was necessary other than intensive observation. In two patients, who required aggressive anticoagulation, a femoral artero-venous fistula was observed; surgical repair was necessary in one.

### Patient with resistant AS requiring the use of the TSP-GW

Nineteen patients (23%) met the criterion to use the TSP-GW. This subset of patients represents group I, while the remaining patients are considered controls (group II). In Table 1, a comparison of the clinical characteristics of group I and group II patients is shown. Among these variables, no significant difference was noted between the two groups, with the exception of a smaller proportion of patients with structural heart disease in group I, associated with a non-significant trend towards a lower age in the same group.

Among cases undergoing double TSP-C, in four patients the criterion to use the TSP-GW was met only in one transseptal procedure: the first in two patients and the second in the other two. Therefore, the overall number of procedures, in which the TSP-GW was used, is 27.

In all cases, perforation of the AS by the TSP-GW, while the needle tip was tenting the FO, was easily obtained at the first attempt and the subsequent steps of the TSP-C procedure could be successfully accomplished with no complication.

## Discussion

### Main findings

In this prospective study, a novel TSP-GW was used to facilitate transseptal puncture in patients with a resistant AS. This was encountered in roughly 20% of the cases in an unselected patient population. In these cases, the use of the TSP-GW

allowed perforation of the AS and facilitated the following steps of the procedure with no need of ultrasound guidance and no complication. Interestingly, there was no well-defined clinical variable predicting the presence of an AS resistant to puncture. However, the group of patients with a resistant AS showed a lower percentage of structural heart disease in general, associated with a non-significant trend towards a younger age.

### Use of the TSP-GW to facilitate TSP-C

Although a variable amount of fibrous tissue and different arrangements of the muscular strands in the area of the FO have been reported,<sup>10</sup> to our knowledge no systematic anatomic data on different morphological types of FO, which might result in resistance to AS puncture are available. A previous study<sup>7</sup> evidenced that none of the pre-procedure echocardiographic data can predict the presence of a resistant AS, which was found to be always <2 mm in thickness even in cases of inability to perform transeptal puncture by the standard technique. Generally, an AS resistant to puncture for any reason, especially when associated with an elastic and over-compliant FO, which dislocates leftward under the pressure applied to the needle, may result in a prolonged TSP-C procedure and even in complications. In fact, multiple attempts to locate and perforate the FO together with an excessive pressure applied to the transeptal needle may lead to puncture of inappropriate structures, such as the right atrial free wall, the aortic root, or even the left atrial free wall when abrupt penetration in the LA of the transeptal assembly occurs after application of an increased pressure by the operator. This difficulty, encountered in about one-fifth of the patients in our series, can be overcome by experienced operators in the vast majority of the cases. However, even in experienced hands, this may result in severe complications and/or inability to accomplish the procedure using the standard technique in a proportion of cases varying from 1.7 to 5%.<sup>1,7</sup> In the present study, the use of the TSP-GW proved safe and effective in perforating a resistant AS in a series of consecutive patients. This also prevented perforation of the free wall of the LA by an unprotected needle tip and, ultimately, facilitated the insertion of the needle, dilator, and sheath in the LA to finally accomplish the transeptal procedure. This is particularly important, considering the increasing and widespread use of the TSP-C, especially related to ablation of AF in the LA. This is definitely a demanding procedure in each step, and facilitating the initial part of transeptal puncture is an important contribution to expedite the whole procedure.

In a small number of cases undergoing double TSP-C, resistance to AS perforation was encountered only in the first or second puncture. Provided that all the efforts were made to perform both punctures very close together in the FO, this finding is open for speculation. It could be that in these cases the FO was structurally inhomogeneous and one of the two punctures was made in a weaker area, whereas the other was performed in a resistant site. It could be also speculated that in some cases positioning of the first transeptal sheath may facilitate the second puncture, even in cases of resistant AS. This could explain the need for TSP-GW only in the first TSP-C.

Two previous studies<sup>11,12</sup> showed that difficulties in TSP-C are mainly related to a repeat procedure, possibly owing to atrial

septal thickening and/or upward displacement of the AS puncture site. Another study<sup>7</sup> demonstrated that the only parameter associated with a resistant septum was the total number of prior TSP-C procedures. A further study<sup>13</sup> reported that, although FO thickening is observed after a first TSP-C procedure for AF ablation, this is not predictive of difficulty during redo procedures. In this study, the only significant predictor found in 33% of those with difficult redo TSP-C procedure was diabetes. Such correlations were not found in our study. Conversely, although no clear predictor was found in our series, a resistant AS can be found in younger age people and in patients without structural heart disease. This can be explained based on the assumption that preserved heart structures may be more resistant to perforation in some cases.

To our knowledge, the prevalence of a resistant AS in a series of consecutive patients undergoing TSP-C has not been previously reported. In a previous study,<sup>12</sup> difficult puncture was encountered in 7% of the cases in the first TSP-C procedure and in 28% during a repeat procedure. In the consecutive patients considered in our series, a resistant AS was present in roughly 20% of the cases. This prevalence seems reasonable, considering the strict criterion used to define this finding and to use the TSP-GW.

### Alternative methods to accomplish TSP-C in case of a resistant AS

The use of surgical electrocautery<sup>5,14</sup> or the ablation catheter<sup>7</sup> applied to the proximal part of the standard transeptal needle or the use of a powered radiofrequency energy transeptal needle<sup>6,15</sup> have been described to achieve AS perforation in case of a resistant AS for electrophysiological procedures in humans. Except for one study<sup>7</sup> these methods have never been tested prospectively in a series of consecutive patients. Importantly, when radiofrequency energy is used to perforate the septum, the use of ultrasounds is highly recommended<sup>5,6,14</sup> to clearly assess the position of the transeptal assembly tip in the FO and to carefully monitor the effect of electrocautery on the septum. In fact, electrocautery of inappropriate structures may cause cardiac perforation with loss of tissue and of elastic recoil at the site of puncture and this may result in a severe complication, especially if the aorta is punctured. Other concerns of using radiofrequency energy to perforate the AS in difficult cases are the possibility of persistent iatrogenic atrial septal defects or, conversely, the development of greater fibrosis and scarring, when compared with the conventional technique, which may render further access to the LA even more difficult.<sup>5</sup>

In our study the use of the TSP-GW to perforate a resistant AS did not require the use of ultrasounds, since assessment of the needle tip position by fluoroscopy and optionally by dye injection was considered satisfactory enough and no complication was observed. On the other hand, if an appropriate structure is punctured by the TSP-GW, the damage caused by this very thin tool can be presumably minimal. Moreover, for its design and shape, the possibility of puncturing the aortic root by this TSP-GW is very unlikely. Nevertheless, it has to be underlined that intracardiac ultrasounds are very helpful<sup>16</sup> and widely used<sup>17</sup> in the electrophysiology laboratory to assist TSP-C and the following phases of a complex procedure such as pulmonary vein isolation,

maximizing the procedure safety. Their use practically eliminates the risk of puncturing inappropriate structures and allows subselection of the puncture site in the FO according to the type of ablation procedure. Moreover, during atrial septal tenting in case of a resistant AS, ultrasounds allow evaluation of the distance between the posterior left atrial wall and the needle tip, so that inadvertent puncture of the posterior LA can be avoided. On the other hand, the usefulness of intracardiac ultrasounds has to be counterbalanced by the fact that their use requires a dedicated venous access and personnel, implies a learning curve, and not negligible extra costs. Moreover, even under ultrasound guidance, inability to perforate a particularly resistant AS with the standard technique has been reported.<sup>6,8</sup> Therefore, the TSP-GW can be useful also in combination with the use of intracardiac ultrasounds.

The use of a 0.014" coronary angioplasty guidewire introduced through the needle lumen and positioned in a left pulmonary vein to help advancing the transseptal dilator and sheath in the LA has also been described.<sup>18,19</sup> Although this technique can be very helpful in some cases to facilitate accomplishment of TSP-C, it can be used only when the septum has already been punctured by the needle, which is the most crucial part of the procedure in case of a resistant AS.

## Limitation

This is a single centre study and the technique has been prospectively tested in a relatively limited number of cases, being the first report of this method in a patient series. A larger patient cohort and multicentre experience are required to confirm these results.

## Conclusions

The use of the TSP-GW allows easy perforation of a resistant AS during TSP-C. It facilitates and expedites the procedure and, at the same time, it is expected to contribute to procedure safety. In our series of consecutive patients, an AS resistant to puncture was encountered in roughly one-fifth of the cases; there was no clear clinical predictor of such anatomy.

## Addendum

At the time of manuscript revision, the experience in the use of the TSP-GW has increased. So far, it has been used in 29 patients in 42 TSP-C procedures out of 125 consecutive patients without patent foramen ovale undergoing TSP-C for electrophysiological purposes. This further experience confirms previous data with ability to perforate a resistant AS at the first attempt using this device.

**Conflict of interest:** none declared.

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