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Review

Transseptal puncture — Review of anatomy, techniques, complications and challenges

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ABSTRACT

In recent years, the transseptal puncture approach has enabled passage of increasingly large and complex devices into the left atrium. Traditional tools remain effective in creating and dilating the initial puncture, with an acceptable safety profile. Even for skilled operators, the procedure is technically demanding and requires sound understanding of atrial anatomy. Intracardiac echocardiography is useful in cases of previous septal repair, poorly defined fossa ovalis anatomy or when considering patent foramen ovale portal crossing. Iatrogenic atrial septal defect (iASD) is the most commonly encountered long-term complication and there is increasing evidence that larger devices are leading to symptomatic defects. The size of the sheath crossing the septum is the strongest predictor of iASD formation but other factors such as longer procedure times, significant catheter manipulation and high pulmonary pressures also contribute. Transcatheter mitral valve repair involves the use of large 22 Fr catheters which carry alarmingly high rates of defect persistence with precipitation of symptoms and possible influence on mortality. Long-term follow up data, particularly beyond the 12-month period are lacking and resultantly, evidence to guide management is sparse. Refinements of conventional instruments, as well as innovations to puncture the septum without mechanical pressure, herald a progressively safer future for the transseptal technique.

1. Introduction

During the 1950s, as right-sided catheterisation techniques were refined, focus shifted toward left heart access [1]. Exponential progress in the field of open heart surgery placed increasing demands for accurate preoperative diagnostic data. Initial efforts to catheterise the left heart were technically demanding, highly invasive and carried significant risks [2–5]. In this light, the technique of transseptal puncture emerged and quickly became accepted as standard [6,7]. By the 1970s, the pulmonary artery catheter enabled safer, simpler methods of measuring many left-sided pressure parameters [8]. Indeed, the need for transseptal puncture soon became limited and today, procedural skills have declined outside of specialised centres [9].

Over the last decade, advancements in electrophysiology have driven an increased need for transseptal intervention; mostly for left atrial ablation in the treatment of atrial fibrillation. More recently, structural heart interventions, such as left atrial appendage occlusion and mitral valve repair, have pushed the boundaries in terms of the size and complexity of devices crossing the septum [10]. The transseptal puncture procedure is technically demanding and not without complications. Once considered a benign entity, iatrogenic atrial septal defects (iASD) that follow transseptal crossing have the potential to persist and become symptomatic [11]. Understanding the risks and natural history of iASDs is key to selecting the most appropriate management strategy.

Going forward, as additional therapies such as mitral valve replacement are being considered, it is likely that the expectations and scope for transseptal puncture will be increasingly challenged. Never before has there been a greater need for renewal of knowledge in transseptal intervention. This state of the art review presents current and past perspectives on the transseptal method and critically appraises the data currently available. Anatomical considerations and conventional

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techniques are first discussed, followed by a detailed review of complications and difficulties with contemporary procedures. Novel transseptal techniques are reviewed and future directives are discussed.

2. The Brockenbrough needle

The transseptal puncture technique originated in 1957 when John Ross Jr. was passing balloons of various sizes from the right atrium through atrial septal defects to measure their size. Realizing that this was an easy access route to the left atrium, he subsequently developed a needle to create an access path through intact septa [12]. The initial needle had a curved distal end to allow controlled rotation of the tip and an arrow-shaped proximal handle to define position — both these features remain today. The catheter housing this needle was developed by Edwin Brockenbrough, first reported in his landmark study of 450 left heart catheterizations [13].

The Brockenbrough needle is currently available in a number of configurations through various manufacturers. The standard adult BRK (St Jude Medical, USA) needle has a 19° angle between the distal curved region and the needle shaft, while the adult BRK-1 needle has 53° angle, offering increased curvature, Fig. 1. The needles are made from 18-gauge stainless steel, tapering to 21 gauge at the tip. Both devices are available in adult lengths of 71 cm, 89 cm and 98 cm. Paediatric versions are also available with a length of 56 cm and with intermediate curve options (BRK™ and BRK-2™). Full size versions have a bevel angle of 50° at the tip while an option for sharper angles of 30° are also available (BRK XS and BRK-1 XS). The needles come with a stylet in the lumen to hold it straight within the sheath, thereby avoiding damage of the sheath lumen.

Brockenbrough needles can be used with a wide variety of sheaths, all generally with a dilator extending beyond the sheath tip. The traditional Mullins-style sheath is widely used and is available from several manufacturers. This is approximately 60 cm long with a large 180° curve at the distal tip and is typically available in either 8 Fr or 10 Fr sizes. The Swartz™ SL series are also widely used, providing a broader range of options on distal curvature, again in either 8 Fr or 10 Fr sizes, Fig. 2. Steerable introducer sheaths are available from a number of companies and offer bidirectional deflection.

3. Anatomical considerations

The Brockenbrough needle is passed through the fossa ovalis (FO), an oval-shaped depression in the interatrial septum composed primarily of loose fibroelastic tissue [14]. Two highly detailed cadaveric evaluations of fossa ovalis anatomy have recently been presented [15,16]. Some clinically useful parameters of FO anatomy are presented in Table 1. Understanding the concept of the clinically significant interatrial septum versus the anatomical interatrial septum is crucial. From a structural perspective, the septum is bordered by the ostia of the inferior vena cava, superior vena cava, coronary sinus, tricuspid septal leaflet, right atrial appendage and posterior wall folds. Only a small 'true' segment may be crossed without exiting the heart. This area accounts for only 20% of total septal area and is represented best at the anteroinferior segment of the fossa, Fig. 3 [16].

The true septum is 1–3 mm in diameter and its anatomical properties bear little relationship to age or concurrent cardiac disease [17]. The thin nature of the septum is best appreciated in histological section, shown in Fig. 4 [18]. The muscular limbus which abruptly steps down into the floor of the FO is the most helpful identifying landmark prior to puncture. The prominence of the limbal ridge and redundancy of the FO vary but the relationship between these two structures remains constant [19]. Highly redundant, aneurysmal fossae are relatively common; oftentimes the poorly anchored FO and its surrounding attachments tent across into the left atrium, increasing the risk of perforating the anterolateral wall [20].

The incidence of TEE-detected patent foramen ovale (PFO) in healthy adult populations is approximately 25% [21], or higher when the fossa is aneurysmal [22]. This congenital lesion is most often asymptomatic, but has been associated with paradoxical embolism and cryptogenic stroke [23–25] with a resultant trend towards increased closure. PFOs are situated in the anterocepahalad margin of the FO and channel length varies considerably, ranging from 1 to 10 mm in diameter. When used as a portal for septal crossing, the proximity of the valve's free margin to the anterior atrial wall, degree of valve overlap and channel orientation should all be appraised; these may limit accessibility and catheter manipulation. Similarly, crossing at an atrial septal defect does not provide as much support to the sheath as a traditional transseptal puncture [26].

4. The transseptal puncture procedure

Pre-procedural transesophageal echocardiography is performed to out rule left atrial thrombi and provide insight into septal anatomy, including the presence of PFO or ASD [27]. Next, a pigtail catheter is placed in the non-coronary sinus as an anatomical marker of the aortic root. The sheath and dilator are advanced over a J-tipped guidewire into the superior vena cava via the femoral vein. The lumen is aspirated and flushed after removal of the guidewire which is then exchanged for the needle, with a protective stylet. After removal of the stylet, the needle is aspirated and continuously flushed with heparinised saline.

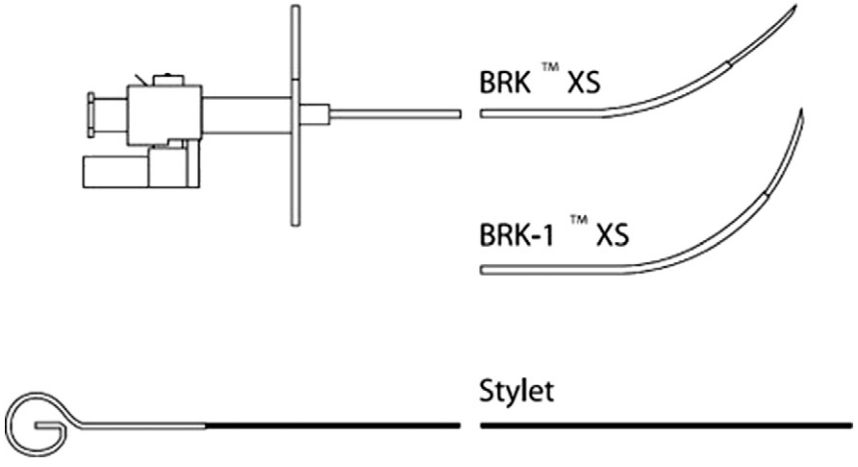

Fig. 1. Schematic of Brockenbrough needles with different curvature [St Jude Medical Spec Sheet 100071962].

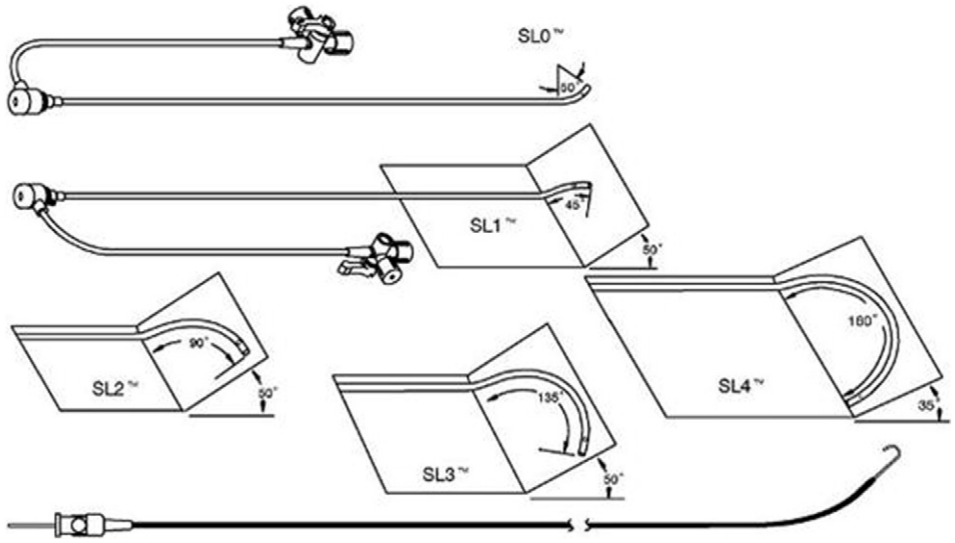

Fig. 2. Schematic of Swartz SL catheters with varying distal curvature options [St Jude Medical – Electrophysiology International Catalogue 2013].

The sheath and dilator are rotated so that both are pointing approximately to the 4–5 o'clock position, as shown in Fig. 5 [28].

The assembly is then withdrawn from the SVC, with an initial movement felt when the assembly falls into the right atrium and again as it contacts the muscular limbus as it falls into the FO. A monophasic pressure waveform confirms contact between the catheter tip and FO, Fig. 6. Failure to localise the FO is the single most common cause of aborted procedures [29]. In the left anterior oblique (LAO) view, the tip is placed below the pigtail catheter and right anterior oblique projections confirm that the tip is posterior to the coronary sinus ostium [28]. Injection of contrast agent through the needle may also be used to verify location and show the degree of septal tenting. A detailed account of the tissue forces required to cross the septum has been described elsewhere [30].

The puncture should be performed using LAO projections. The needle is advanced carefully from the tip and the jump across the septum into the left atrium will be readily felt. A change in the pressure waveform confirms the atrial position. The dilator and sheath are then advanced over the needle, with an increase in resistance as the taper of the dilator crosses the septum and then drops again. The dilator and needle are then fixed while the sheath is advanced into the left atrium and finally, the dilator and needle are withdrawn.

The puncture step can be performed under direct fluoroscopic visualization or with intracardiac echocardiography (ICE) [31]. The ICE probe is positioned in the right atrium and directed to visualize the septum, allowing for subtle changes to optimize the puncture position. Merchant et al. present a useful description of how ICE can be optimized to help select specific locations for puncture on the FO, by using manipulations/rotations of both the ICE catheter and the dilator/needle assembly [32]. Fig. 7, taken from this report, shows ICE images of the mains steps during the puncture sequence.

Table 1
Anatomical measurements of clinically-relevant septal structures [15,16].

Anatomical parameter	Unit
Mean interatrial septum width	29.3 mm
Mean anteroposterior FO diameter	14.5 mm
Mean craniocaudal FO diameter	12.6 mm
Mean FO area	142.7 mm
Mean PFO channel length	10.5 mm
FO shape: oval v circular	86% v 14%
Limbus morphology: raised v flat	92% v 8%

5. Iatrogenic atrial septal defects

5.1. Atrial fibrillation ablation

Today, transseptal catheterisation is performed most commonly for atrial fibrillation ablation, and it remains the leading cause of significant iASD [33]. The FlexCath steerable catheter used to deliver cryoballoon (CB) ablation has a relatively large outer diameter of 15 Fr in comparison to the 8 Fr puncture used in radiofrequency (RF) ablation. Oftentimes, extensive manipulation of the cryoballoon is required to occlude the right inferior pulmonary vein with resultant septal stretching or tearing. Earliest reports of CB ablation found an iASD rate of 38% at 6 months, with a mean size of 5.5 mm. At 9 months follow-up, 31% had persistent iASD with a reduction in mean defect size to 4.6 mm [34]. Closure rates continue to increase thereafter but approximately 1 in 5 defects will be present at 1 yr follow-up [35].

The iASDs incurred with RF ablation catheters are smaller and follow a more benign course. In one study, with standard twin 8 Fr crossings, iASD was detected in 87% on the day after the procedure, with a mean diameter of 0.75 mm. At 3 month TEE follow-up, the defects had closed in all but one patient [36]. Notably, the passage of two 8 Fr devices through a single puncture carries a higher risk of persistent iASD, with a trend toward right-to-left shunting (RLS) when compared to twin puncture [37].

Rillig et al. [38] report a large combination of devices being passed through an initial 8 Fr puncture. This study used the Sensei Robotic Navigation System (RNS) device for ablation. It consists of a steerable sheath with an outer diameter of 14 Fr in combination with an 8.5 Fr conventional transseptal sheath for a mapping catheter. One day after ablation 95% of patients had an iASD with a mean size of 3.45 mm and 63.2% had left-to-right shunting (LRS). At three months, 50% still had an iASD with an average size of 2.1 mm, while at six months the incidence rate reduced to 21.1% with an average defect size of 1.3 mm. Larger iASD sizes at 3 months correlated with persistence at 6 months. The trend clearly shows that larger defects are caused when higher profile devices are passed through single punctures, Fig. 8. It is interesting to note that iASD in the Rillig study at 6 months were smaller than for the Hammerstingl study at 9 months [37]. Perhaps the robotic system results in less manual manipulation and potentially less tissue trauma.

Cronin et al. [39] published a retrospective analysis comparing iASD outcomes on cryoballoon patients against traditional RF ablation methods. The RF group had two 8 Fr transseptal punctures, for

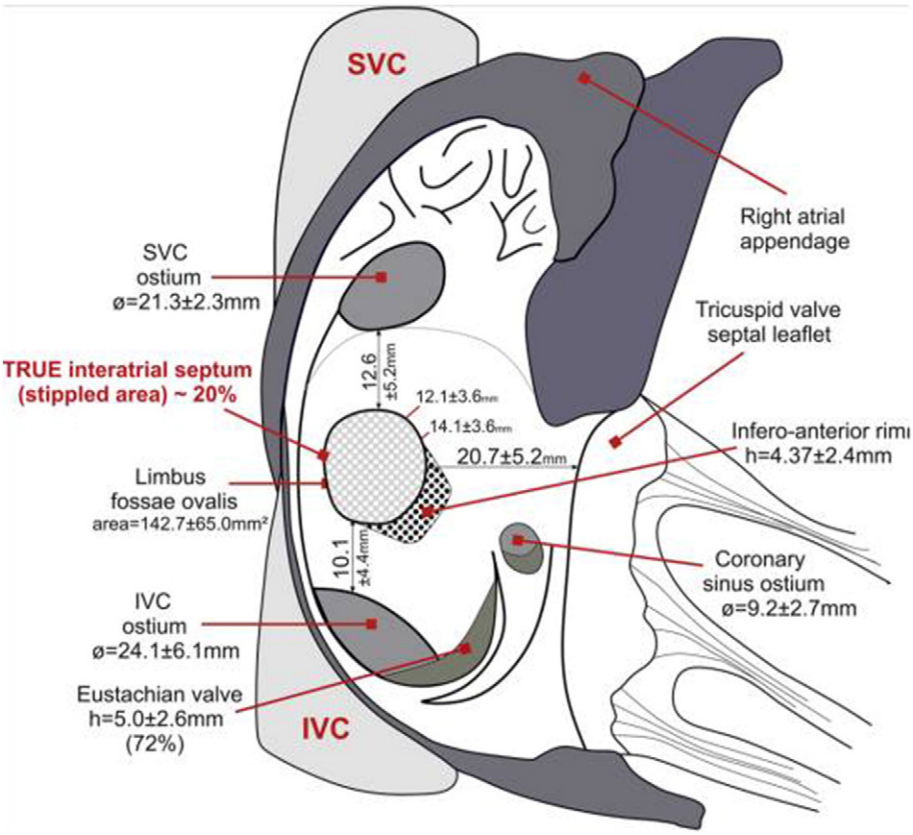

Fig. 3. Schematic view of interatrial septum from the right atrial side [16].

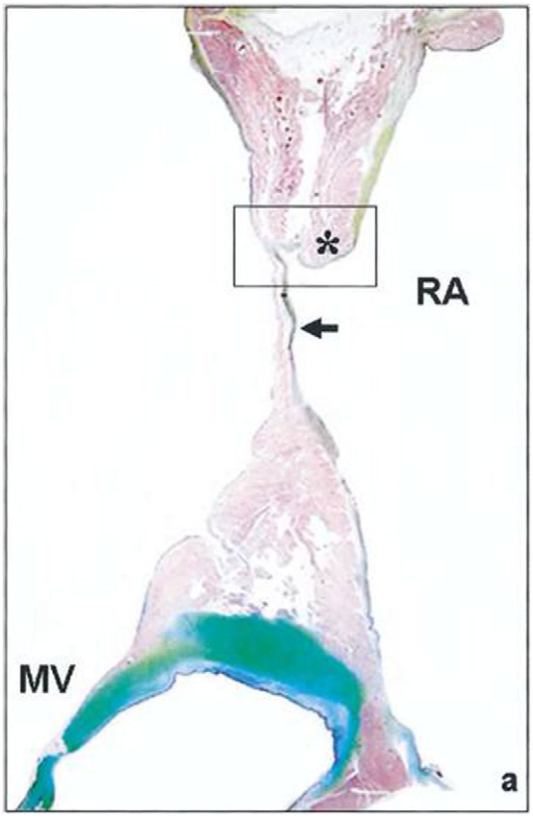

Fig. 4. Posterior longitudinal section of the atrial septum, showing the limbus (*) and part of the mitral valve (MV) [18].

individual mapping and ablation catheters. Transthoracic echocardiography (TTE) follow-up was at an average of 118 days for 42 patients in each group, with iASD detected in seven (16.7%) of the cryoballoon group versus one (2.4%) in the RF group. Mugnai et al. [40] also present a recent comparison of iASD incidence; the CB and RF ablation groups had 45 and 82 patients respectively. At 1-year follow-up, 22% of the CB group had iASD compared to only 8.5% in the RF group. The mean maximum dimension for the defects was 6.0 mm in the cryoballoon group compared to 4.4 mm in the RF group ($p > 0.05$). While these incidence rates and trend are consistent with earlier reports, patients had TEE at 1 year specifically due to AF recurrence and the need for repeat

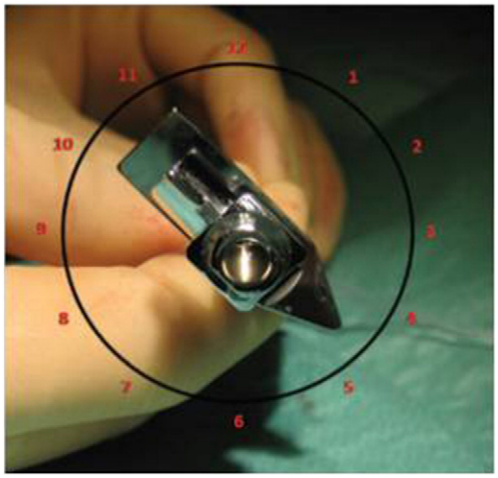

Fig. 5. Orientation of the needle for the sheath-needle retraction step [28].

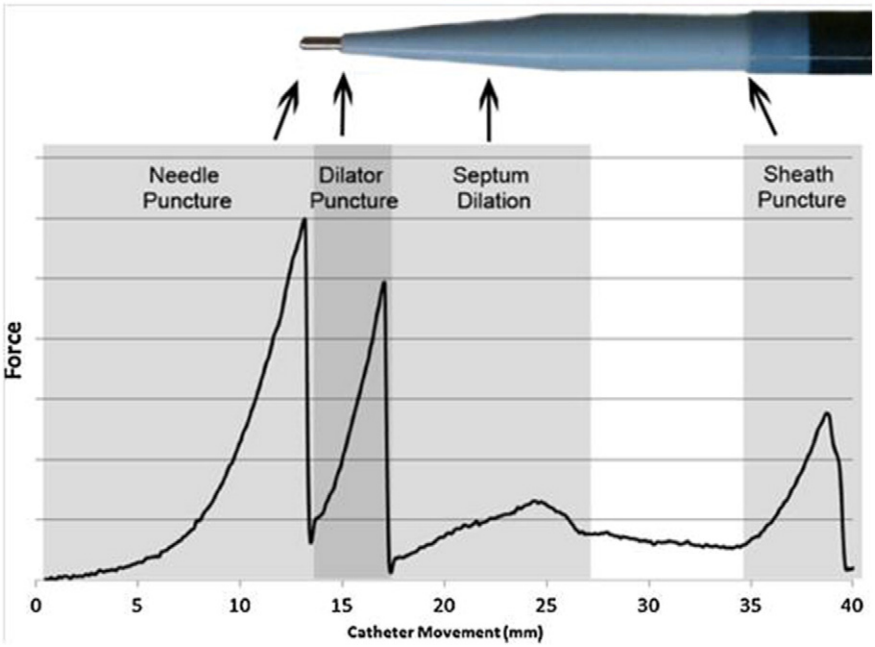

Fig. 6. Typical force distance graph from FO puncture [30].

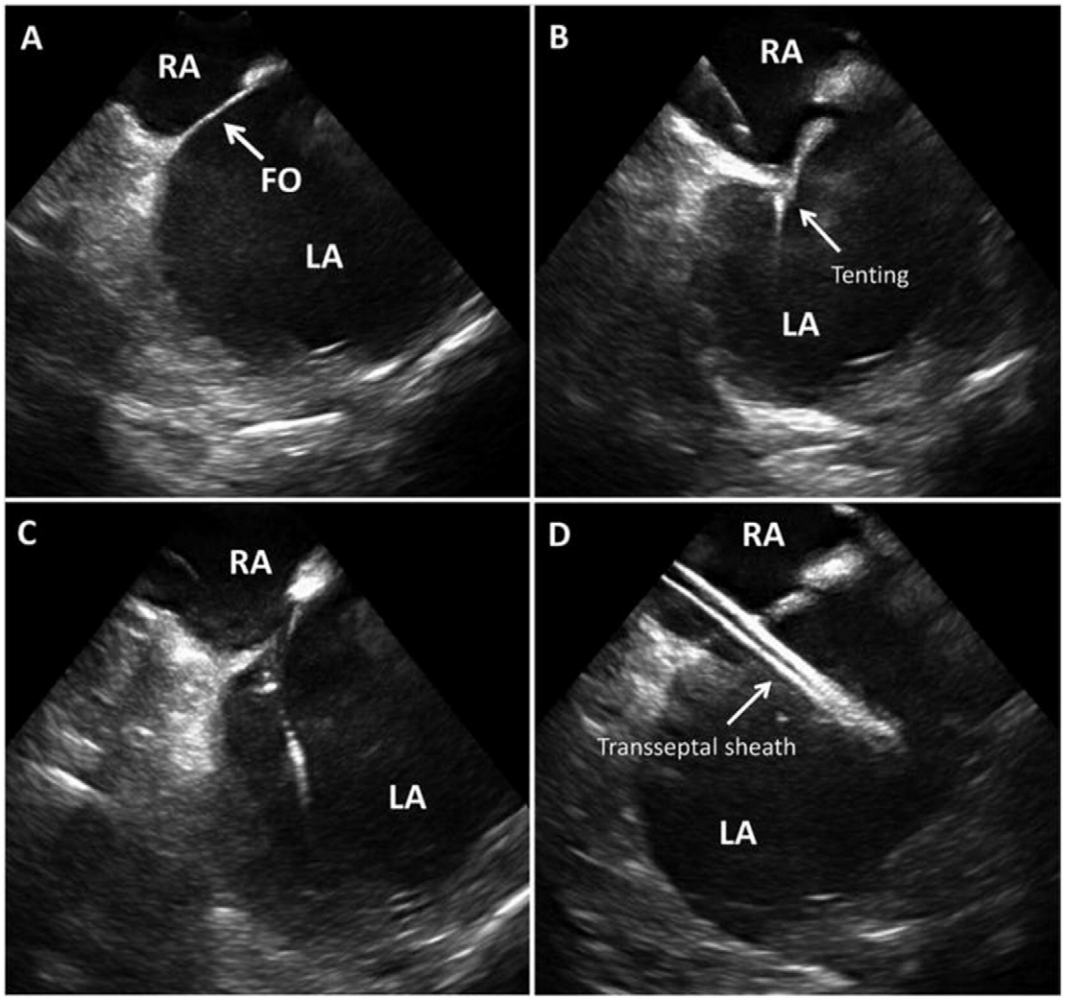

Fig. 7. ICE- guided puncture showing septum and fossa ovalis (A), septal tenting into the left atrium as the needle engages (B), loss of tenting as the needle crosses (C) and transseptal sheath in the left atrium(D) [32].

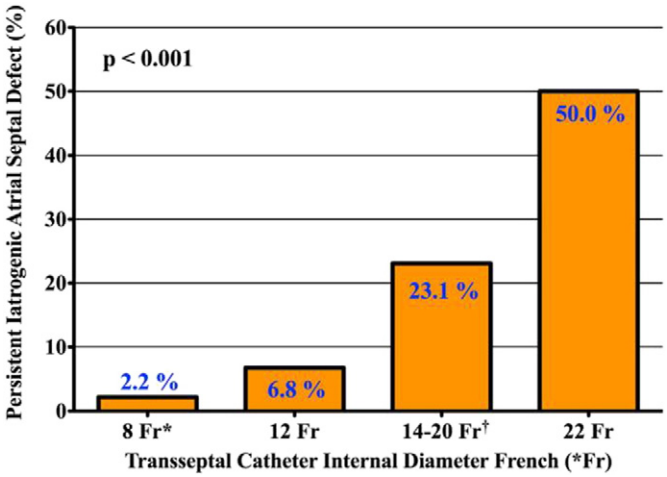

Fig. 8. Relationship between transseptal sheath size and the incidence of persistent IASDs [33].

procedures. Perceivably persistent iASD is a risk factor for AF recurrence although prospective data are lacking.

Although the FO remains the standard puncture location for CB crossing, an interesting alternative at the inferior limbus (IL) has been described. The IL puncture site is approximately 1 cm below the conventional FO site and in a more anterior location. A study comparing the two sites showed acute LRS in 100% of the FO group while LRS was detected in only 33% of the IL group [41]. The thicker and more muscular septum at the IL site allows for more compression and re-closure of tissue compared to the thin walled FO location. Additionally, pushing the large 15 Fr device through the more rigid IL location may be technically easier than trying to cross at the FO.

5.2. Left atrial appendage occlusion

The WATCHMAN left atrial appendage closure device is delivered to the left atrium through a transseptal sheath with a 14 Fr outer diameter [42]. Singh et al. [43] report on a group of 253 patients who underwent TEE evaluation immediately after LAA closure. A conventional 8.5 Fr sheath was used for crossing the septum, which was then exchanged over a guidewire for the 12 Fr transseptal sheath of the WATCHMAN device — with a 14 Fr outer diameter. The incidence of iASD was 87% post-procedure, dropping to 34%, 11% and 7% at 45 days, 6 months and 12 months respectively. Defect sizes were identified as being either ≤3 mm or >3 mm. While 61% of the defects were >3 mm immediately post procedure, this proportion had dropped to 28%, 24% and 29% at 45 days, 6 months and 12 months respectively. A remarkably low level of RLS was identified in patients with iASD. There was no increase in risk of stroke or embolism over patients that did not have an iASD; importantly anticoagulation regimes and $CHADS_2$ scores were matched. However, a relationship between the presence of an iASD and elevated left atrial pressures on the day of the procedure was identified.

5.3. Mitral valve repair

As more data on septal defects following TMVR becomes available, the natural history and clinical impact of these defects are being better delineated. Firstly, it is notable that iASD data were neither reported in the initial MitraClip safety trial [44] nor at 5 years of EVEREST follow-up [45]. Hence, our appreciation of iASDs in the MitraClip setting lags behind other periprocedural safety data. This first-in-class system requires a 22Fr sheath at the septal crossing — undoubtedly the largest in routine use. The sudden formation of an iatrogenic LRS in the setting of MR reduces left atrial output, significantly contributing to the hemodynamic improvements seen immediately post-procedure [46]. However the intermediate and long term outcomes are seemingly deleterious. Smith et al. were the first to raise concern about MitraClip iASD; reporting a rate of 43% after 30 days, declining to 27% at 6 months but without any further closures at 12 months [47]. The average diameter at 30 days was 6.0 mm and 6.6 mm at 12 months. The authors also suggested the link between the grade of MR at follow-up and the persistence of iASD. The severity of MitraClip iASDs was then ascertained in a more comprehensive study of 66 patients, each receiving TOE at 6 months [48]. This intriguing study reported iASD in 50% of patients, with evidence of spontaneous RLS in all patients. Most critical was that the presence of iASD influenced clinical outcomes and mortality. Patients with iASD had worse heart failure, higher N-terminal pro-brain natriuretic peptide levels and less improvement in 6 min walk test. Multivariate regression identified persistence of iASD as the only predictor of 6 month survival. Real time 3-dimensional (3D) TOE has been used to study iASD morphology after the MitraClip procedure [49], as illustrated in Fig. 9. These images suggest that tearing of the atrial septum beyond the initial puncture orifice is common.

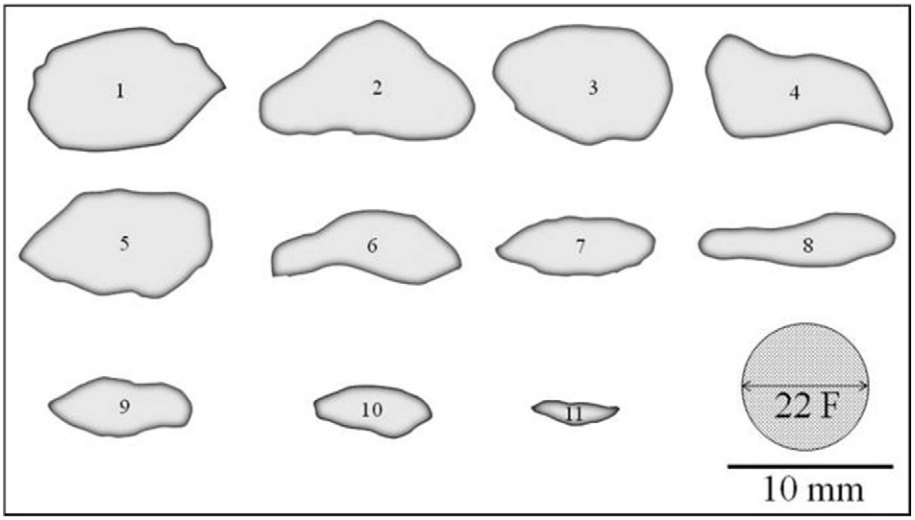

Fig. 9. Representations of defects at end-systole in relation to the 22 Fr sheath [49].

5.4. Transcatheter annuloplasty devices

The Cardioband annuloplasty system is a transcatheter mitral valve repair device, developed by Valtech Cardio (OrYehuda, Israel). The device is delivered through a 25 Fr steerable transseptal delivery system, secured on the mitral annulus using 12–16 anchors along the implant. Despite the large 25 Fr sheath size, neither the 1 month [50] nor 6 month [51] reports present data on iASDs.

5.5. Percutaneous mitral balloon valvuloplasty

Percutaneous mitral balloon valvuloplasty (PBMV) is most often performed using the Inoue device; models in current use carry a maximum sheath diameter of 14 Fr [52,53]. Korkmaz et al. [54] report on a group of 63 patients with TTE follow-up at 5 years. Although iASD was observed in 23% of patients, there was no difference in NYHA functional status when compared to patients without iASD. No specific procedural or patient characteristics predictive of iASD persistence were identified. Failure to sufficiently deflate the balloon during withdrawal, multiple balloon passes and extensive manipulation across a calcific valve are possible contributors. An interesting study compared the iASD incidence rate for diagnostic left-sided catheterization, atrial fibrillation and PMBV at a single centre; the transseptal sheaths used were 6 Fr, 7 Fr and 14 Fr respectively [55]. All groups had iASD at immediate follow-up but at long-term follow-up only the valvuloplasty group had residual iASD — at a rate of approximately 25%, mirroring that of older reports [56,57]. This outcome is again attributed to larger sheaths, more manipulation and possibly older patients who have less elastic septa.

5.6. Closure of iatrogenic atrial septal defects

The lack of long-term follow up in patients undergoing transseptal intervention has limited our understanding of the natural history of iASDs. Current evidence can only support a reactive approach whereby defects are closed if symptomatic; for example, worsening of heart failure, development of refractory hypoxemia, cryptogenic stroke or other paradoxical embolic phenomena [58]. In this light it is important to remember that patients with intracardiac devices may be at higher risk of systemic embolism [59]. There is some argument for prophylactic iASD closure in all patients undergoing MitraClip procedures, but this remains unsupported [60]. Defined echocardiographic parameters, perhaps as part of a clinical prediction tool, to select which iASDs should be pre-emptively closed, is highly desirable. Typically, iASDs have favourable anatomical characteristics to facilitate percutaneous closure with the Amplatzer device [49]. In rare cases where there the prerequisite 5 mm landing zone is unavailable or when the septum is particularly aneurysmal, a patch-type device for example, CardioSEAL may be used.

6. Periprocedural complications

Cardiac tamponade is the most common life threatening complication of transseptal puncture and the incidence is approximately 1 per 100 cases [61–63], although others report significantly lower rates [29]. The typical mechanism of injury is misdirected transseptal puncture performed too posteriorly and subsequent catheter exit [64]. Less commonly, catheter exit occurs through-and-through at the left atrial posterolateral wall, left atrial roof or left atrial appendage. Atrial fibrillation ablation procedures are higher risk, because of the need for multiple punctures, extensive catheter manipulation and systemic anticoagulation [62]. When compared to pulmonary vein isolation (PVI) techniques, RF procedures carry the additional possibility of perforating the left atrial wall from high energy or popping [63]. It is likely that penetration more commonly leads to pericardial effusion without tamponade but such data are lacking, perhaps due to reporting bias.

Acute unstable iASD may occur with large-sheath devices in the setting of severely reduced ejection fraction. The acute LRS causes an abrupt drop in preload with the potential for severe hypotension, or even cardiogenic shock and death [65]. Indeed, centres performing transseptal puncture should have the 24 h capability to perform acute iASD closure. Entry of the catheter into the aorta is a rare but potentially life-threatening complication of the transseptal puncture. Wasmer et al. have complied the most comprehensive study to date, reporting on over four thousand transseptal punctures during a 10 year period [66]. Aortic puncture occurred in 0.05% of procedures ($n = 2$), with neither patient requiring device closure nor cardiac surgery. Leaving a guidewire in place is recommended with slow retraction after an observational period.

ST-segment changes in the setting of transseptal puncture is an intriguing phenomenon; it is very uncommon, transient and without sequelae. To date, our characterisation of this curiosity is drawn from one single-centre retrospective study [67] and a small number of case reports [68–72]. The ST-elevation occurs in the inferior leads and is typically accompanied by a pronounced vagal response with bradycardia, hypotension and diaphoresis. Recovery over 3–5 min without troponin rise is the norm. In the study by Tang et al., baseline demographics were similar between groups but the investigators noted a smaller left atrial size in the group with transient ST-segment changes [67]. The atrial septum is home to high densities of parasympathetic fibres, which preferentially innervate the right coronary artery leaving it vulnerable to cholinergic vasospasm [73]. Perhaps the nerve fibre distribution in the smaller atria lends itself vulnerable to reflex activation by the transseptal catheter.

The high incidence of thrombus formation and systemic thromboembolism in the setting of left atrial ablation is not related to the transseptal puncture per se but rather the combination of left atrial stasis, use of heat energy and the catheter activating the coagulation cascade. Evidence on the detection of left atrial thrombi and optimal anticoagulation strategies in this setting have been presented elsewhere [74–77]. During standard needle puncture, thrombus may form suddenly at the site of puncture- most often on the right atrial side. Endothelial disruption is the coagulopathic mechanism here and conservative management is appropriate. In patients with implanted intracardiac devices, thrombus formation on endovascular leads should not be ignored. In matched cohorts post-ablation, the risk of stroke appears to be increased- likely due to mobile thrombi on leads juxtaposing the iASD [59]. Notably this risk is attenuated in anticoagulated patients. Although the relative risk is small, the role of anticoagulation in post-transseptal ablation patients needs to be prospectively evaluated.

7. Prior septal repair or instrumentation

Operators are increasingly encountered with an interatrial septum that has been previously punctured, surgically repaired or is fitted with a closure device. The reason for this is two-fold; firstly, ablation procedures have increased exponentially on a global basis and second, patients with ASD are at higher risk for atrial fibrillation, even after repair [78]. The altered septal anatomy in these cases requires modification of the traditional technique and carries the added risk of device dislodgement or embolization. Transseptal access is still feasible and safe in this population.

Lakkireddy present an intriguing prospective cohort study in which patients with prior septal repair ($n = 45$) were compared with matched controls ($n = 45$) for ICE-guided radiofrequency ablation [79]. Although recurrence of AF was higher in the repair group, there were no differences in periprocedural complications or procedure time, including the time spent executing transseptal puncture. Patients with ASDs had either a pericardial patch, synthetic patch, septal stitches or a CardioSEAL device. PFOs had been repaired by CardioSEAL or Amplatzer devices. Atrial occlusion devices typically sit anterosuperiorly in the septum, leaving room inferoposteriorly for puncture, as depicted in

Fig. 10. ICE is helpful in accurately localising the interatrial device or patch and delineating the secondary puncture site. Where more than one device is present, preprocedural computed tomography (CT) is useful in identifying native areas of the interatrial septum amenable to puncture [80]. Direct puncture is achievable through pericardial or standard polyethylene patches (e.g. Dacron) but tougher PTFE Gore-Tex patches are resistant to penetration. Operators should consider the possibility of detritus embolization in heavily calcified surgical patches and proceed based on clinical judgment [79].

Chen et al. [81] describe access through a 45 mm ASD closure device that covered the true septum in its entirety. A standard 8 Fr transseptal sheath and dilator were used with a Brockenbrough needle. The needle penetrated through the waist of the device, but the sheath could not be advanced. An angioplasty balloon was inflated to create an opening through which the 8 Fr sheath readily passed. Ablation was successfully completed and the access point spontaneously closed by virtue of the flexible nitinol wire mesh. Clearly this approach would have limitations for larger profile transseptal sheaths and is dependent on the closure device structure, but exemplifies what can be achieved in difficult circumstances.

Puncture at a prior transseptal crossing brings fourth another group of challenges. Common to all comparative studies is that repeat puncture is technically more difficult with higher rates of failure [82–85]. That this is accompanied by higher complication rates remains possible, and large safety studies are warranted. The local inflammatory response over the first puncture site(s) leads to scarring of the surrounding tissue and toughening of the interatrial septum. Repeat TOE measurements have demonstrated 25% increase in interatrial FO thickness following twin puncture but septal thickness alone does not predict puncture difficulty [84]. Rather, the authors propose that tissue stiffness may be the prognostic factor. In this context they note diabetes was associated with difficult puncture, perhaps attributable to the accelerated fibrotic reaction in these patients. As such longer duration of the initial procedure bears relationship to the extent of scarring, as does the interval between first and repeat procedures [83]. Similarly, the use of the PFO as a crossing portal makes for more difficult instrumentation on repeat procedure and total loss of patency may occur [82]. Puncturing thickened septa is oftentimes easier with wide angle needles e.g. the BRK-1 needle with 53° of curvature. This reduces upward slipping and directs the driving force perpendicular to the septum [86]. Advancing the sheath across a fibrotic septum may be difficult given the atraumatic tip designs, but this can almost always be overcome with manual pressure. Should this fail, an angioplasty balloon provides an effective method of controlled puncture dilation to facilitate easy crossing [87]. Care should be taken in using the smallest calibre balloon possible to minimise defect persistence.

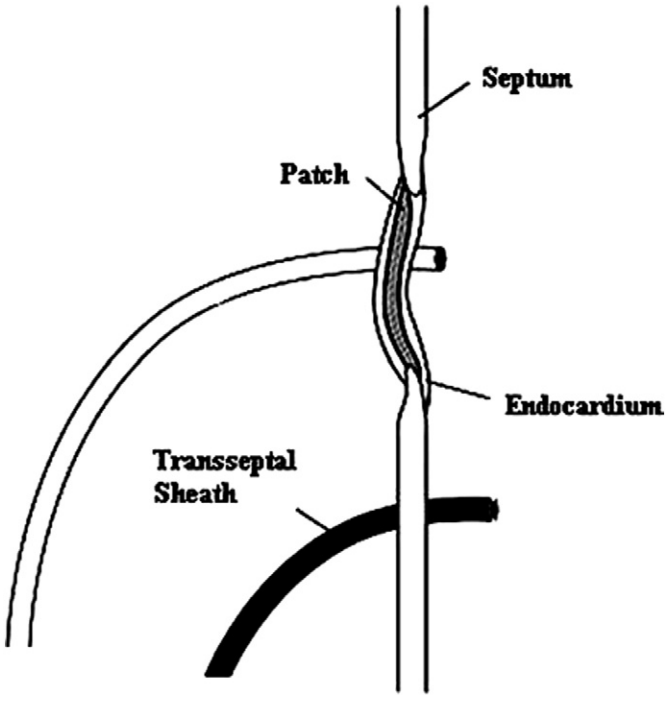

Fig. 10. Cross section of the interatrial septum showing placement of a second sheath inferoposteriorly to the repaired septal defect [79].

8. Alternative transseptal devices

8.1. RF needle

The NRG transseptal needle (Baylis Medical, Canada) delivers RF energy through a closed-tip device to facilitate left atrial access. The main advantage is negation of mechanical pressure, potentially reducing excessive 'jump' and the subsequent complications of catheter exit. Side holes located 2 mm proximal to the radiopaque tip allow for central lumen flushing and pressure measurement. The manufacturer's recommended setting for septal crossing is a single10W pulse delivered over a period of 2 s. Smelley et al. [88] report on an early safety and efficacy study in a group of 35 patients, including 12 with previous transseptal access. Successful crossing was achieved in 98% of cases, with 85% requiring one RF energy application; five cases required two or three applications. The single failed case was converted to a Brockenbrough needle as the blunt RF tip repeatedly slipped out of the FO. Safety outcomes were consistent with that reported in conventional series and the investigators suggested an easier crossing in cases of scarred or thickened septa. Following this preliminary report, the RF needle was prospectively compared to a conventional Brockenbrough needle in approximately 150 patients attending a single centre [89]. The RF needle afforded reduced puncture time (4.8 min versus 7.5 min, $p = 0.045$) and reduced total fluoroscopy time (1.8 min versus 2.9mins, $p = 0.043$). Repeat transseptal crossing took longer with conventional needles but the same was not observed for the RF device. Reduced instrumentation time has since been observed in a large retrospective study [90] and a randomised controlled trial [91]. While safety data is satisfactory overall, superiority of the RF device for preventing any complication has not been reported.

The RF transseptal device is also useful in the setting of previous ASD repair, with successful crossings in both synthetic and pericardial patches [92]. That the RF needle successfully punctured both calcified pericardial patches and Gore-Tex® material is notable since conventional needles are known to fail in these situations [79]. A separate bench study suggests that the RF device has benefits in terms of reduced particulate embolization from the sheath and dilator [93]. Even when a stylet was used with the Brockenbrough BRK-1XS needle, skiving of particles from the inner wall of the dilator was identified, while no visible particles were detected with the NRG needle. An equivalent clinical outcomes study has not been published. The Toronto transseptal catheter (Baylis Medical, Canada) is a more flexible version of the first-generation RF needle. The device essentially behaves like a guidewire, tapering into a large J-shaped floppy distal end. It therefore needs a stiffer dilator; TorFlex Superstrong (Baylis Medical, Canada). Once crossed into the left atrium, it returns to its floppy J-shape reducing the likelihood of damaging intracardiac structures. It may then be used to support septal crossing of the dilator and sheath. Jauvert et al. [94] report on successful use of this device including patients with aneurysmal and fibrotic septa.

RF energy has also been applied to conventional Brockenbrough needles in an effort to reduce the mechanical forces required at the septum. In its simplest form, standard monopolar electrocautery can be applied to the proximal end of the needle, with grounding patches on the patient [95,96]. When a brief 1–2 s pulse at 15–20 W is applied to the needle as it exits the dilator, very low forces are needed to cross the

septum. However, concern has been raised about the risk of complications due to tissue coring when using these unconventional arrangements [97]. Tissue coring refers to the creation of a small plug of cardiac tissue inside the open-ended tip of the Brockenbrough needle — with the risk of systemic embolization. With regard to all forms of RF needles, long term data are lacking, particularly in the area of iASD follow-up. The sizes of the defects, rates of closure and echocardiographic observations in general are unknown. Given the inevitable damage to the tissues surrounding defects created by RF energy, it is plausible that normal means of the septum closing are interrupted.

8.2. Laser puncture

Laser technology has been applied to transseptal access, although its entry into the clinical arena has received little attention. The advantages heralded by this technology are similar to that of RF techniques, namely avoiding the risks of mechanical probing. Porcine studies using commercially available excimer lasers offered safe and accurate transseptal access, as evidenced at necropsy. Bench testing indicated that the laser required ten times less force than a standard Brockenbrough needle to puncture the septum [98]. The TransLas catheter (LasCor GmbH, Germany) has a 600 μm optical fibre core and a 2 s pulse at 10 W is used to perforate the FO, after the fibre is advanced from the dilator tip. The fibre is then withdrawn and replaced by a guidewire. Weber et al. [99] have reported on initial clinical use of the device in a group of 45 patients. All crossings were completed successfully without complications though no follow-up data were presented.

8.3. SafeSept guidewire

Aside from the introduction of novel energy sources such as RF and laser, the only notable change to the original mechanical puncture has been the development of the SafeSept transseptal device (Pressure Products, USA). The SafeSept nitinol guidewire has J-shaped terminal ending with a sharpened end that holds linear conformation when constrained within the lumen of the dilator. To puncture using the SafeSept device, the dilator tents the FO and then the guidewire is pushed through to create the puncture. The manufacturer reports a 77% lower force requirement when compared to conventional needles. After crossing, the wire returns to the J-shape, making it safe against any further tissue penetration. The dilator is then tracked over the wire to open the puncture. A similar refinement, using a smaller J-shaped needle within a Brockenbrough needle has been evaluated as a bail-out approach in resistant, aneurysmal or thick atrial septa [100]. The authors report on 19 patients in whom this additional wire was successful following failure to penetrate with the Brockenbrough needle. Others have used the technique as the initial approach [101]. Both techniques of guidewire-initiated punctures are theoretically safer and as larger studies emerge the next step will be to evaluate safety in the absence of ICE, with the desired outcome of reduced procedural time.

9. Conclusion

Advances in left-sided interventional procedures have renewed interest in the transseptal puncture technique and novel indications are emerging rapidly. Clinicians have now surpassed 50 years of experience with the standard Brockenbrough needle. Although safe in experienced hands, newer tools have eliminated the need for mechanical pressure, in an effort to prevent the rare but life threatening complications of catheter exit. Sound understanding of atrial anatomy in conjunction with ICE is key to safely executing difficult punctures, for example, in the presence of a repaired ASD or fibrotic septa from previous puncture.

A major ongoing concern is that larger catheters are leading to iASDs which persist, become symptomatic and possibly influence survival. Large catheters passed for CB ablation and TMVR are the most common culprits, but other predictors of defect persistence may exist, such as elevated pulmonary venous pressures. Long-term follow up data, particularly beyond the 12-month period are lacking and clinicians are in urgent need of these data. To date there is no guidance available from cardiovascular societies on the management of iASD. Current evidence can only support a reactive approach whereby defects are closed if symptomatic, for example worsening heart failure or hypoxemia. As the natural history of iASDs become better defined, we may see closures performed pre-emptively based on echocardiographic features such as degree of shunting, left atrial pressures and defect size.

Conflict of interest

We declare that there is no conflict of interest for any author.

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