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Original Research

VersaCross Transseptal System for Mitral Transcatheter Edge-To-Edge Repair With the PASCAL Repair Platform

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ABSTRACT

Background: VersaCross is a novel radiofrequency transseptal solution that may improve the efficiency and workflow of transseptal puncture (TSP). The aim of this study was to compare the VersaCross transseptal system with mechanical needle systems during mitral transcatheter edge-to-edge repair (M-TEER) with the PASCAL device.
Methods: This is a single-center retrospective study of consecutive patients who underwent M-TEER with the PASCAL. Transseptal puncture was undertaken with either a mechanical needle or the VersaCross wire. The primary endpoints were success of TSP and successful delivery of the Edwards sheath on the chosen delivery wire. Secondary endpoints included number of wires used, tamponade rate, interval from femoral venous access to TSP and first PASCAL device deployment, procedural death, and stroke.
Results: Thirty-three consecutive patients (10 with mechanical needle, 23 with VersaCross) who underwent M-TEER with the Edwards PASCAL device were identified. All patients had successful TSP. In the mechanical needle group, the Edwards sheath was successfully delivered on the Superstiff Amplatz wire in all cases. In the VersaCross arm, the radiofrequency wire was used successfully for delivery of the sheath in all cases. There were no cases of pericardial effusion/tamponade in either arm. Interval from femoral venous access to TSP and to deployment of the first PASCAL device was shorter with the VersaCross system. Significantly fewer wires were used with VersaCross. There were no procedural deaths or strokes in either group.
Conclusions: VersaCross appears a safe and effective method of TSP and for delivery of the 22Fr sheath for M-TEER with PASCAL.

ABBREVIATIONS

ACT, activating clotting time; GA, general anesthesia; LA, left atrium; M-TEER, mitral valve transcatheter edge-to-edge repair; RF, radiofrequency; SVC, superior vena cava; TEE, transesophageal echocardiography; TSP, transseptal puncture.

Introduction

Transseptal puncture (TSP) is a critical step for a variety of percutaneous procedures including mitral valve transcatheter edge-to-edge repair (M-TEER), mitral balloon valvuloplasty, left atrial appendage closure, insertion of mechanical circulatory support devices and atrial fibrillation ablation.[1] Since its development by Ross, Braunwald, and Morrow and first use in 1959, for direct invasive left atrial pressure measurement, there has been very little change in mechanical needle systems used for TSP, until relatively recently.[2] Only in the last decade have specialized puncture needles, such as the SafeSept wire (Pressure Products Medical Supplies, CA, USA) and dedicated radiofrequency wires, such as the NRG (Baylis, Quebec, Canada) become available.

The traditional mechanical needle system consists of 3 components: a sheath, a dilator, and a hollow transseptal needle. The most widely used mechanical transseptal needles are the Brockenbrough (Medtronic, MN, USA) and the BRK family of needles (Abbott, IL USA). Both are hollow, stainless steel needles with a 21-gauge tip, the central channel of which

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may be used for pressure measurement. The SafeSept wire is an 0.014" J-tipped, nitinol guidewire with a sharp distal tip and is used in conjunction with a standard mechanical needle.[3] The sharp tip of the SafeSept wire requires 77% less force than a mechanical needle and may have an advantage over traditional mechanical needles in fibrotic or aneurysmal septa and improve success rates of TSP after previous TSP. A 0.035" "needle-free" version of the SafeSept wire is also available. The 0.014" tip remains unchanged but the shaft is replaced by a 0.035" wire which obviates the need for support from a mechanical TSP needle.[4] The NRG needle replaces the mechanical needle and has a dedicated radio-frequency (RF) blunt-tipped electrode at the needle tip which ablates the septal tissue at the intended point of puncture on the fossa ovalis, thereby reducing the degree of tenting on the septum and force required for crossing. The NRG needle has been shown to increase crossing success, compared with mechanical needles, and shortened time to TSP in a randomized study.[5] A large registry has shown greater safety with reduced rates of tamponade and greater efficacy than mechanical needles.[6]

A disadvantage of mechanical/RF needles is that a minimum of 2 wires is required. A soft tipped 0.032" "starter" wire is required to navigate the sheath/dilator complex into the superior vena cava (SVC). The starter wire is then removed and exchanged for a mechanical/RF needle and the complex of sheath/dilator/needle is then withdrawn until the fossa ovalis is engaged. Furthermore, if repositioning on the septum is required, the mechanical/RF needle needs to be withdrawn from the dilator and the starter wire reintroduced in order to safely reposition the sheath/dilator complex in the SVC for a reattempt. Such exchanges add time and complexity to the procedure and potentially increase risk.

Following successful TSP with mechanical/RF needles, a second more supportive wire, such as an Amplatz Superstiff (Boston Scientific, MA, USA), is required to deliver therapy sheaths to the left atrium. TSP carries a risk of major life-threatening complications of around 2%, due mainly to tamponade and injury to the aorta.[7,8]

M-TEER has evolved as a cost effective alternative to open heart surgery in symptomatic patients with degenerative or functional mitral regurgitation on guideline-directed medical management at high or prohibitive surgical risk.[9,10] The PASCAL device (Edwards Lifesciences, CA, USA) is a nitinol framed edge-to-edge leaflet repair system indicated for degenerative and functional mitral regurgitation which has shown good outcomes in clinical trials.[11,12] After TSP, a supportive 0.035" wire is required for delivery of the 22Fr Edwards sheath required for advancement of the implant catheter into the LA.

The VersaCross Radiofrequency Transseptal Solution (Baylis, Montreal, Quebec, Canada) is a novel device that became available in Europe in late 2021. The key innovation of the device is incorporation of a multipurpose 0.035" wire that functions as a starter wire, to navigate the sheath/dilator complex into the SVC, as the radiofrequency needle for TSP, and finally as a supportive guidewire for delivery of large caliber therapy sheaths to the LA. As such, VersaCross may eliminate the need for any additional wires for many structural heart procedures.

As yet there are only limited data on the VersaCross system. To date, there are no reports of the effectiveness of the VersaCross wire in delivery of the 22Fr sheath required for M-TEER procedures with the PASCAL mitral leaflet repair system. In this study, we report our experience with the VersaCross compared with standard mechanical needle systems.

Material and Methods

Patient and Public Involvement

This was a single-center, retrospective study of consecutive patients who underwent TSP for M-TEER with PASCAL at our institution between March 2021 and October 2022. Case details were retrieved from our institutional database and electronic patient records system. All cases were fully anonymized and the study fully complied with the principles set by the Declaration of Helsinki. The first 10 cases were undertaken with mechanical needles (BRK1) with either a Mullins (Medtronic, Dublin, Ireland) or SL1 introducer sheath (Abbott Vascular, IL, USA). From September 2021 onwards, all cases were undertaken with the VersaCross system. All procedures were performed under general anesthesia (GA) and transesophageal echocardiographic (TEE) guidance. After endotracheal intubation, a TEE probe was advanced into the esophagus and vascular access was gained to the right femoral vein under ultrasound guidance and with micropuncture needle. Hemodynamic monitoring was undertaken via a 4Fr radial cannula. A 7Fr femoral sheath was initially placed in the femoral vein. Under fluoroscopy, a 150-cm soft J-tipped 0.032" guidewire was advanced in the SVC for advancement of the introducer sheath/dilator of mechanical needle systems. For the VersaCross system, the VersaCross 0.035" pigtail guidewire was directly passed up into the SVC via the 7Fr femoral venous sheath for advancement of the sheath/dilator.

Device Description

The VersaCross system includes a 0.035", 24 mm curve diameter pigtail (180/230 cm) guidewire, an 8.5Fr sheath (63/81 cm), and a shapeable TRUform dilator (67/85 cm). The TRUform dilator comes in 45° but can be molded by hand to attain a greater curvature if required for large atria. An 8.5Fr steerable version of the sheath is also available. The proximal end of the guidewire is connected via a proprietary cable to the RF generator which delivers up to 50W energy for a prespecified time of up to 3 seconds, although the device is preset to deliver energy for 1 second. Energy delivery is controlled by a button on the console or via a foot pedal controlled by the operator. The VersaCross guidewire can be used as a starter wire, to navigate the VersaCross sheath and introducer into the superior vena cava, for the TSP puncture, and as a supportive wire over which devices such as septostomy balloons or delivery sheaths can be introduced.

Transseptal Puncture

The TEE probe was advanced to the midesophageal level. The anatomy of the interatrial septum as well as the severity of the mitral regurgitation was confirmed and the atrial appendage examined to confirm absence of thrombus. The sheath/dilator complex was then advanced over the guidewire (VersaCross/0.032" wire) into the SVC (Figure 1a, Supplemental Video 1). For mechanical needle systems, the 0.032" guidewire was then withdrawn and replaced with a mechanical TSP needle. With the VersaCross system, the multipurpose wire was withdrawn into the dilator until the RF tip was a short distance from the dilator tip. The sheath/dilator/needle complex was then withdrawn under fluoroscopy with the tip of the dilator pointing to the left shoulder until the fossa ovalis was engaged (Figure 1b, Supplemental Video 2). In the case of mechanical, needle-based systems we used a similar technique. The introducer/sheath complex was advanced in the SVC with the dilator tip facing the left shoulder. The guidewire was then exchanged for the BRK1 with the needle tip positioned a few millimeters short of the dilator tip. The system was then slowly withdrawn until the dilator tip engaged the fossa ovalis. On TEE a bicaval view was obtained initially to position on the superior-inferior axis. When tenting on the fossa was obtained, a short axis view was gained to position the tip of the dilator on the anterior-posterior axis for the desired height above the mitral valve annulus. Generally, a mid superior/inferior and posterior site was selected for the TSP. Before puncture, the vertical height from the tenting point to the mitral coaptation point was assessed from the 4-chamber view. A height of 3.5-5 cm was deemed satisfactory. In the case of mechanical needle systems, TSP was performed by advancing the needle briskly into the dilator. In the case of the VersaCross wire, TSP was undertaken by gentle tenting with the rounded electrode tip slightly protruding from the dilator whilst delivering radiofrequency energy and simultaneously pushing forward

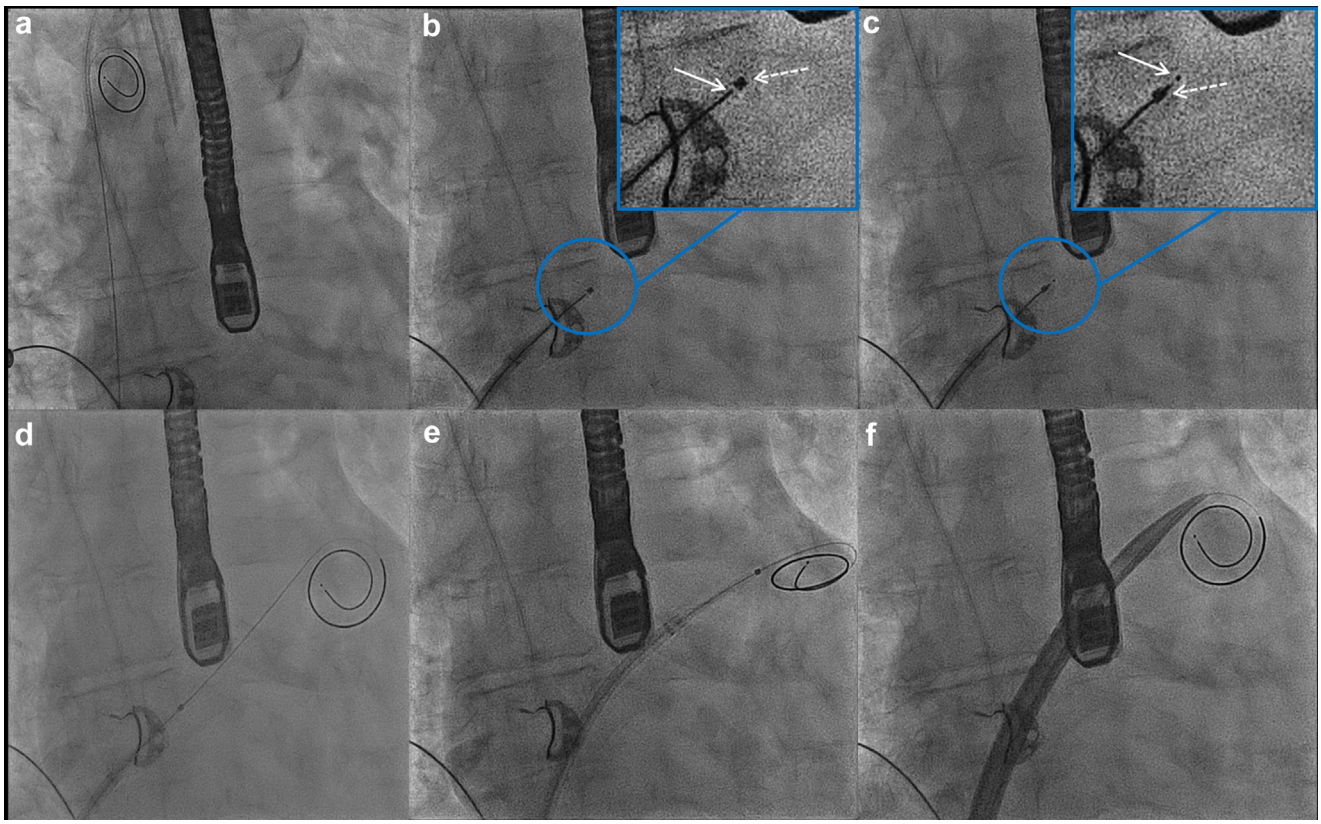

Figure. 1(a) VersaCross positioned directly into the SVC as a "starter wire". (b) Dilator/sheath engaged in the fossa ovalis. Magnified panel shows the tip of the VersaCross wire (continuous arrow) close to the tip of the dilator (dashed arrow). (c) Tip of the VersaCross wire (continuous arrow in magnified panel) slightly protruding from the tip of the dilator (dashed arrow) at the time of TSP while applying RF energy. (d) VersaCross wire advanced in the LA and confirmation of satisfactory entry point and position of wire in LA assessed by TEE. (e) Dilator and sheath passed over VersaCross wire through interatrial septum and into the LA. (f) 22Fr PASCAL delivery catheter across the interatrial septum and into the LA on the VersaCross wire.
Abbreviations: LA, left atrium; RF, radiofrequency; SVC, superior vena cava; TEE, transesophageal echocardiography; TSP, transseptal puncture.

gently with the wire (Figure 1c, Supplemental Video 3). Wire/needle advancement was monitored on fluoroscopy (Figure 1d, Supplemental Video 3). After confirming entry to the LA on fluoroscopy and TEE the sheath/dilator was advanced into the LA (Figure 1e, Supplemental Video 4). With the mechanical systems, the dilator and needle were removed and an Amplatz Superstiff (180 cm) was positioned in the LA for advancement of the 22Fr Edwards sheath.

With the VersaCross system, the dilator/sheath were removed and the 22Fr Edwards sheath advanced into the LA directly on the VersaCross multipurpose wire (Figure 1f, Supplemental Video 5). If repositioning was required, the sheath/dilator/VersaCross was withdrawn to the cavo-atrial junction and the VersaCross wire was redirected in the SVC over which the sheath/dilator was readvanced for a further descent on the septum (Supplemental Video 6). At the conclusion of the procedure and after retrieval of equipment from the LA, TEE was used to evaluate the septal defect and color Doppler was used to assess the magnitude and direction of the shunt.

Procedural Details

The Superstiff Amplatz/VersaCross 0.035" guidewire was used as a rail for delivery of the 22Fr sheath for the PASCAL repair system (Edwards Lifesciences, CA, USA). The details of the repair system have been previously described in detail.[13] After successful TSP and a satisfactory access point on the septum was confirmed, intravenous unfractionated heparin was administered at an initial dose of 100 IU/kg and activating clotting times (ACT) monitored to achieve an ACT target >300 sec. LA pressure was measured continuously via the side port of the steerable sheath of the PASCAL system.

Endpoints and Statistical Analysis

The primary endpoints were success of TSP and successful delivery of the 22Fr Edwards sheath into the LA on the chosen 0.035" delivery wire (Amplatz/VersaCross). Secondary endpoints included number of wires used, pericardial effusion/tamponade rate, interval from femoral venous access to TSP, interval from femoral venous access to first PASCAL device deployment, procedural death and stroke. Categorical data are presented as absolute numbers (n) and frequencies (%) and were compared using the chi square test. Continuous variables are presented as median and interquartile range and were compared with the Mann–Whitney U-test. All statistical tests were 2-sided and p values < 0.05 were considered statistically significant. Statistical analyses were performed using R version 4.1.1 (R Foundation for Statistical Computing). We used the STROBE cross-sectional checklist when writing our report.[14]

Results

Between March 2021 and October 2022, 33 consecutive M-TEER cases were identified. The first 10 cases underwent TSP with a mechanical needle system and the following 23 cases underwent TSP with the VersaCross system. Baseline demographics are presented in Table 1.

Procedural characteristics are presented in Table 2.

There were no differences between the groups bar the presence of coronary artery disease. There was 1 case of septal aneurysm in the VersaCross group (0 vs. 4%; $p = 0.5$). TSP was successful for all cases in both groups (Table 2). In both groups, delivery of the 22Fr PASCAL sheath was successful over the intended guidewire (Amplatz Superstiff/VersaCross). The median time from venous access in the right groin to the

Table 1
Baseline characteristics

Characteristic	Mechanical N = 10	VersaCross N = 23	*p*
Age (years)	80 (76-82)	81 (79-86)	0.29
Gender, male, n (%)	9 (90)	13 (57)	0.06
Diabetes, n (%)	3 (30)	3 (13)	0.25
Hypertension, n (%)	4 (40)	6 (26)	0.42
Coronary artery disease, n (%)	8 (80)	7 (30)	**0.009**
Atrial fibrillation, n (%)	6 (60)	13 (57)	0.85
Degenerative MR, n (%)	7 (70)	14 (61)	0.62
Functional MR, n (%)	2 (20)	5 (22)	0.91
Mixed MR, n (%)	1 (10)	4 (17)	0.59
LV ejection fraction (%)	60 (52-65)	62 (53-65)	0.65
Left atrial size			
Volume (mL)	110 (107-154)	137 (98-181)	0.46
Volume indexed	62 (61-85)	76 (52-81)	0.81
Septal characteristics			
Presence of patent foramen ovale	0	0	1
Septal aneurysm, n (%)	0	1 (4)	0.5
Height (cm)	4.5 (3.8-4.9)	4.5 (4.2-4.8)	0.49

Baseline characteristics and comparison between the 2 groups. Continuous data are presented as median and interquartile range. Categorical data are presented as absolute numbers and frequencies. Bold values indicate p value <0.05.

TSP was shorter in the VersaCross group (40 mins (25-46) vs. 18 mins (10-27); $p = 0.048$). Additionally, the median time from venous access in the right groin to release of the first PASCAL device was shorter in the VersaCross group (146 mins (115-175) vs. 94 (73-130); $p = 0.029$). There was no pericardial effusion/tamponade in either group. In the mechanical needle group, significantly more guidewires were required in the procedure. There were no procedural strokes or deaths. One late stroke occurred in the VersaCross group at 36 hrs post M-TEER. The same patient subsequently died before discharge. The embolic stroke was not deemed to be related to the VersaCross device and was attributed to atrial fibrillation, a difficult procedure with multiple repositionings, and the Pascal device itself.

Discussion

In this study of 33 patients undergoing M-TEER with the PASCAL repair system with either the VersaCross or traditional mechanical needles for TSP we observed the following: 1. The VersaCross system appeared safe and effective for TSP. 2. The VersaCross wire provided *sufficient* support to deliver the 22Fr PASCAL delivery sheath. 3. The VersaCross system reduced the interval between femoral venous access and TSP or deployment of the first PASCAL device. 4. The VersaCross system significantly simplified the procedure by eliminating the need for additional wires and obviating the need to remove the VersaCross wire when repositioning the sheath/dilator in the SVC for a further descent onto the septum. A particular advantage of the VersaCross radiofrequency wire over mechanical systems is the reduced force needed to tent on the septum at the time of crossing. As the actual crossing is achieved by ablation rather than mechanical force, there is less tendency to slip on the septum, thus allowing more precise crossing to be achieved.

Table 2
Procedural characteristics

Characteristic	Mechanical N = 10	VersaCross N = 23	*p*
Transseptal success, n (%)	10 (100)	23 (100)	1
Delivery of Edwards sheath over Amplatz/VersaCross wire, n (%)	10 (100)	23 (100)	1
Number of wires used, n (%)	2 (2-2)	1 (1-1)	**<0.005**
Femoral vein access to TSP (mins)	40 (25-46)	18 (10-27)	**0.048**
Femoral vein access to first Pascal device release (mins)	146 (115-176)	94 (73-130)	**0.029**
Pericardial effusion/cardiac tamponade	0	0	1
Periprocedural stroke	0	0	1
Periprocedural mortality	0	0	1

Procedural characteristics. Continuous data are presented as median and interquartile range. Categorical data are presented as absolute numbers and frequencies.
Abbreviation: TSP, transseptal puncture

There are limited data on experience with VersaCross in structural heart procedures requiring TSP. In a study comparing VersaCross TSP with traditional mechanical needles in 20 patients undergoing LA appendage occlusion, TSP with VersaCross was considerably faster, reducing the time from femoral access to TSP, with no safety concerns. Furthermore, the VersaCross wire provided sufficient support for delivery of the large bore sheaths required for the Watchman (Boston Scientific, Natick, MA) and the Amulet (St. Jude Medical, St Paul, MN) devices. The VersaCross system has also been examined in a consecutive series of 25 patients undergoing M-TEER with the MitraClip (Abbott Vascular, IL, USA). In this study, TSP was successful in all cases with no safety concerns and a short time to TSP.[15,16] In both studies, use of VersaCross was credited with improving procedural efficiency by reducing the numbers of wires and wire exchanges and by simplifying the steps required for repositioning the sheath/-dilator in the SVC for a further descent on the fossa ovalis. With the expansion of indications for transcatheter percutaneous procedures requiring TSP, there is a continuous need for refinement and improvement of the procedural steps which enhance safety and improve efficiency and work flow.

The present study confirms the finding of earlier reports that the VersaCross system has significant advantages over traditional mechanical needle systems and may have a particular advantage in structural heart interventions that require supportive guidewires for delivery of large bore sheaths to the left atrium. Our study showed that the VersaCross wire provides sufficient support for delivery of the 22Fr Edwards sheath for the PASCAL mitral repair system, and that it is safe, effective, reduces the number of wires and wire exchanges required, and significantly shortens time to TSP and first device deployment.

Our study furthers the experience with this novel transseptal solution and confirms its safety, efficacy, and ease of use.

Limitations

This is a retrospective, single-center, all-comers study which has the inherent limitations of studies with similar design. The 2 groups comprised a relatively small number of cases; therefore, observations from this study may not be generalizable to all patients referred for M-TEER. Accumulated operator experience and other nonmeasurable factors may have also contributed to the significantly shorter procedure interval to first Pascal device in the VersaCross group.

Conclusion

The VersaCross system is an effective, safe, easy to use platform which streamlines the TSP procedure and has many advantages over traditional mechanical needles. The particular innovative feature of the device is a multipurpose 0.035" RF wire that serves as a starter wire, undertakes TSP, and is sufficiently supportive to deliver large bore therapy sheaths to the LA, thus eliminating the need for multiple wires and wire exchanges.

Data Availability Statement

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

The manuscript has been read and approved by all authors, the requirements for authorship have been met, and each author believes that the manuscript represents honest work.

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Ethics Statement

Authors report adherence to the relevant ethical guidlines.

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Disclosure Statement

Dr Sagar N Doshi is a proctor for Edwards LifeSciences and Boston Scientific and has received speaker fees from Boston Scientific, Medtronic and Abiomed. Dr Nadir has received speaker honoraria from Baylis Corporation. The remaining authors have no conflicts to disclose.

Supplementary Material

Supplemental data for this article can be accessed on the publisher's website.

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