



Original Research

Collagen-Based Bailout Compared to Suture-Mediated Vascular Closure Alone During Transcatheter Aortic Valve Replacement



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A B S T R A C T

Background: Hemostasis for transfemoral transcatheter aortic valve replacement (TAVR) is typically achieved using a suture-mediated vascular closure device (VCD) prior to large-bore sheath insertion (preclosure technique). Recently, the addition of a hybrid closure technique using a preclose technique with the addition of a collagen-plug VCD after sheath removal in cases of failed hemostasis has been utilized.

Methods: Data were collected from the Northwell TAVR registry, including 3 high-volume TAVR centers. We evaluated a preclose strategy with suture-mediated vascular closure alone ("legacy strategy") and standard bailout techniques versus a contemporary hybrid strategy of suture-mediated closure with collagen-mediated closure bailout. The primary end point was major or minor vascular complications as defined by the VARC-3 criteria.

Results: A total of 1327 patients were included, of which 791 patients underwent TAVR with suture-mediated closure alone and 536 with contemporary strategy. The primary end point (major or minor vascular complication) was lower in the contemporary strategy (5.44% vs 1.31%; $P < .001$). Both minor (3.92% vs 1.12%; $P = .002$) and major (1.14% vs 0.19%; $P = .0196$) vascular complications were reduced and the total length of stay was less in the contemporary strategy (median of 3 days vs 2 days; $P < .0001$). Using multivariable analysis, we observed that vascular management strategy significantly improved the composite primary outcome when adjusted for sheath size, peripheral artery disease, carotid disease, and site of procedure. In the contemporary group, bailout collagen-plug VCD with an Angio-Seal (Terumo Medical) was used in 68 patients (12.69%) and bailout MANTA (Teleflex) was required in 4 patients (0.75%). There were no major or minor vascular complications among the patients who received bailout collagen-plug VCD.

Conclusions: A contemporary hybrid strategy of suture-mediated closure with collagen-mediated closure bailout reduces the risk of vascular complications among patients undergoing transfemoral TAVR.

Introduction

Vascular complications during transfemoral (TF) transcatheter aortic valve replacement (TAVR) procedures are associated with increased length of stay (LOS) and mortality.¹⁻⁴ Hemostasis is typically achieved using a suture-mediated vascular closure device (VCD) such as the

Perclose ProGlide device (Abbott) which is deployed prior to the initial sheath insertion, known as the preclose technique. However, the use of this technique may still result in unsuccessful hemostasis.⁵ Recently, a contemporary hybrid strategy that consists of preclosure in standard fashion and if hemostasis is not obtained after sheath removal, addition of a collagen-mediated VCD such as the Angio-Seal (Terumo Medical) is

Abbreviations: LOS, length of stay; PAD, peripheral arterial disease; TAVR, transcatheter aortic valve replacement; TF, transfemoral; VCD, vascular closure device.

Keywords: Angio-Seal; Perclose; transcatheter aortic valve replacement; vascular complications.

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<https://doi.org/10.1016/j.jscai.2024.101929>

Received 19 December 2023; Received in revised form 22 February 2024; Accepted 1 March 2024

Available online 3 April 2024

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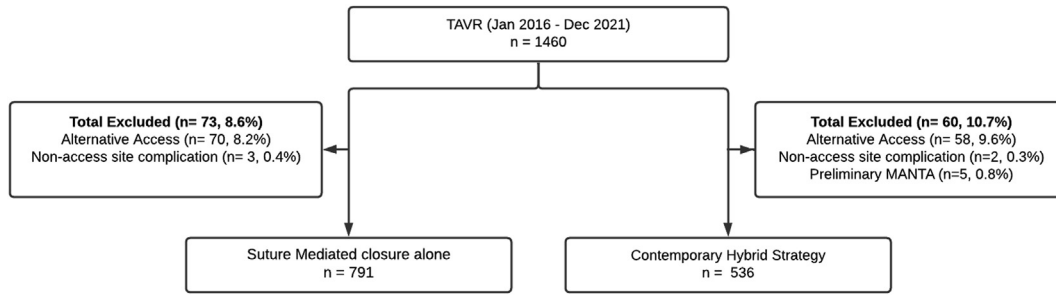


Figure 1. Schematics of study design. TAVR, transcatheter aortic valve replacement.

used as bailout.⁶ We therefore evaluated a preclose strategy with standard bailout (suture-mediated closure alone) vs a contemporary hybrid strategy (suture-mediated with collagen-mediated closure bailout).

Methods

Retrospective data were collected from the Northwell TAVR registry, including 3 high-volume TAVR centers. A total of 1460 consecutive patients who underwent TF TAVR between September 2016 and December 2021 were reviewed. The study excluded patients who underwent alternative access TAVR, planned primary closure with the MANTA (Teleflex) instead of a preclose strategy, and/or patients who had a nonprimary access site vascular complication. From November 2020, vascular management protocols changed across our health system to include bailout with small (ie, Angio-Seal) or large (ie, MANTA) collagen-mediated VCD (Figure 1). We compared this contemporary hybrid strategy (n = 791) to the “suture-mediated closure alone” strategy (n = 536) (Central Illustration). Our study received proper ethical oversight and IRB approval.

The suture-mediated closure alone vascular management strategy involves preclosure with 2 suture-mediated VCDs prior to insertion of the large-bore sheath. The TAVR procedure is performed under heparin (goal-activated clotting time >250 seconds) and protamine is administered after the procedure is completed. The sheath is removed and the Perclose sutures are secured with a safety wire in place. If hemostasis is not obtained, additional Proglide device(s) may be placed. If the postclosure device also does not obtain adequate hemostasis, then

a peripheral crossover technique is typically performed with balloon tamponade ± covered stent placement. In November 2020, there was a protocol switch at 2 institutions that included the use of small or large collagen-plug VCDs for bailout. This contemporary hybrid vascular management strategy includes preclosure in standard fashion and if hemostasis is not obtained after sheath removal, a small (6F-8F) or large (14F-22F) collagen-plug VCD is used as a bailout. Collagen-based plug size is chosen based on the sheath size that allows for hemostasis. For example, if hemostasis is not obtained after securing sutures, then an 8F sheath is reinserted in the arteriotomy. If hemostasis is obtained with an 8F sheath with minimal oozing around the sheath, then an 8F Angio-Seal is deployed. If the operator is unable to obtain hemostasis and there is residual bleeding around an 8F sheath, then bailout with a MANTA VCD may be performed. Figure 2 illustrates the protocol for both suture-mediated closure alone and contemporary hybrid strategy.

Outcomes

The primary end point was in-hospital major or minor vascular complications due to the access site. Vascular complication was defined based on the Valve Academic Research Consortium-3 (VARC) classification of vascular access site and access-related complications.⁷ Minor vascular complications were defined as vascular injury at the access site (ie, perforation, rupture, dissection, etc.) not resulting in death, VARC type ≥2 bleeding, limb or visceral ischemia, or irreversible neurologic impairment. Major vascular complications were defined as vascular injury at the access site resulting in death, VARC type ≥2 bleeding, limb

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PARTICIPANTS	RESULTS
<div style="text-align: center;"> <p>TAVR Sept 2016-Dec 2021 N=1327</p> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="background-color: #003366; color: white; padding: 5px; border-radius: 10px; width: 45%;"> <p style="text-align: center;">--- LEGACY ---</p> <p style="text-align: center;">Suture-mediated closure alone N = 791</p> </div> <div style="background-color: #003366; color: white; padding: 5px; border-radius: 10px; width: 45%;"> <p style="text-align: center;">--- HYBRID ---</p> <p style="text-align: center;">Contemporary hybrid vascular strategy N = 536</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="background-color: #003366; color: white; padding: 5px; border-radius: 10px; width: 45%;"> <p style="text-align: center;">Suture-mediated VCD +/- percutaneous intervention/cutdown as bailout</p> </div> <div style="background-color: #003366; color: white; padding: 5px; border-radius: 10px; width: 45%;"> <p style="text-align: center;">Collagen based VCD as bailout</p> </div> </div>	<p style="background-color: #003366; color: white; padding: 5px; text-align: center; margin-bottom: 10px;">PRIMARY ENDPOINT</p> <p style="text-align: center;">Primary endpoint (major and minor vascular complications) lower with hybrid strategy [1.31% vs 5.44%; P< 0.001].</p> <p style="background-color: #003366; color: white; padding: 5px; text-align: center; margin-bottom: 10px;">PREDICTORS OF ENDPOINT ON MULTIVARIATE LOGISTIC REGRESSION</p> <p style="text-align: center;">Vascular strategy (legacy) and presence of peripheral arterial disease.</p> <p style="background-color: #003366; color: white; padding: 5px; text-align: center; margin-bottom: 10px;">CONCLUSION</p> <p style="text-align: center;">Improved vascular outcomes with hybrid vascular strategy compared to legacy strategy.</p>

Central Illustration. A contemporary hybrid strategy of suture-mediated closure with collagen-mediated closure bailout compared to suture-mediated closure alone reduces the risk of vascular complications among patients undergoing transfemoral TAVR.

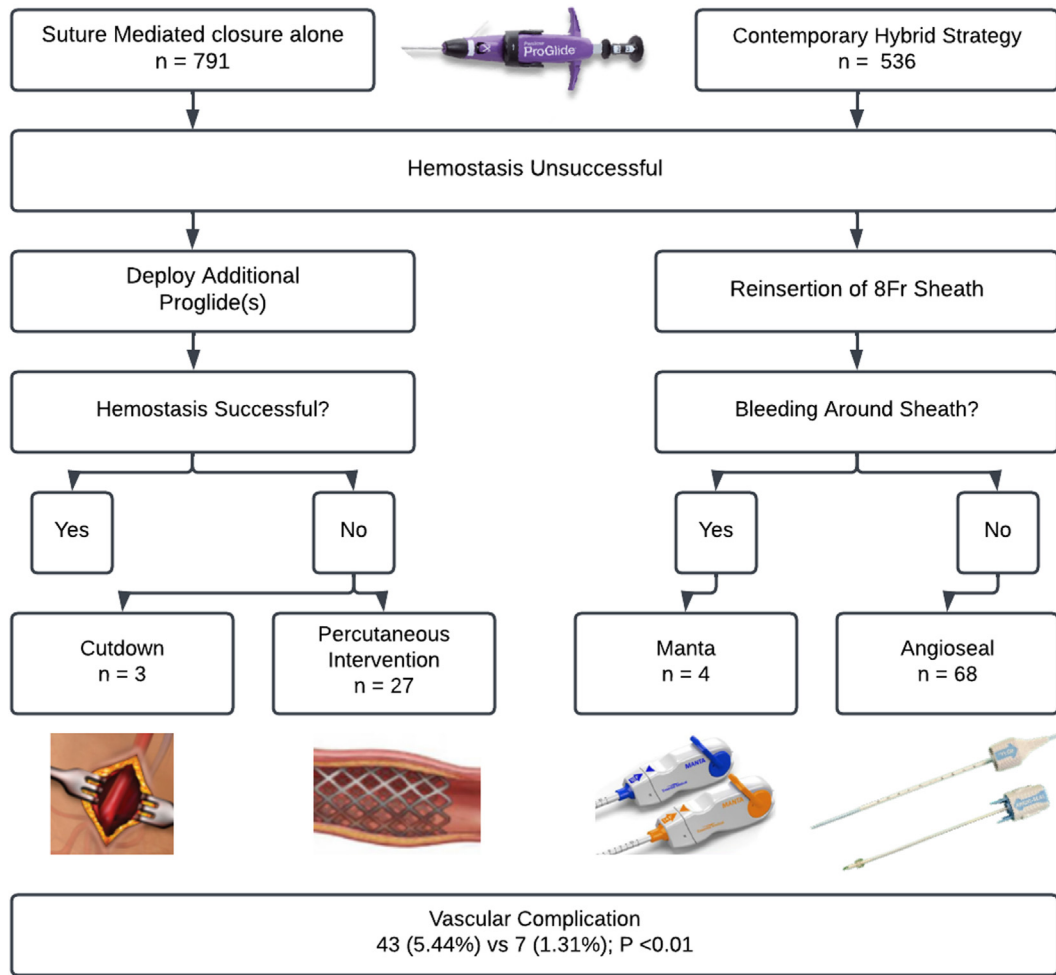


Figure 2. Graphical illustration of suture-mediated closure alone vs contemporary hybrid strategy. VCD, vascular closure device.

or visceral ischemia, or irreversible neurologic impairment. All complications were reviewed to ensure they met VARC-3 criteria. Secondary outcomes included the treatments for vascular injury (ie, stent, balloon tamponade), LOS, and discharge alive. The use of bailout equipment (Perclose, Angio-Seal, MANTA) was also reported.

Statistical methods

Categorical variables are presented as counts and/or percentages and were compared using the Fisher exact test. Continuous variables are presented as the mean ± SD and the median (lower quartile, upper quartile) and were compared using the t test or Mann-Whitney U test as the Shapiro–Wilk test shows these variables are not normally distributed. A P value <.05 was considered statistically significant. All statistical tests were 2-tailed and performed using Prism 9.2.0 (GraphPad Software). Multivariable logistic regression model was used to observe the effect of contemporary or legacy vascular management strategy on composite end point adjusted for peripheral arterial disease (PAD) (yes vs no), carotid artery disease (yes vs no), and sheath size (large [>14F] vs small [14F]).

Results

Baseline characteristics

Baseline characteristics were similar among the groups (Table 1). There was no difference between sex, smoking, hypertension, or body

surface area; however, the suture-mediated closure alone arm had higher rates of carotid artery disease and PAD. Patients in the contemporary hybrid arm had less diabetes and the average age was 1 year younger. The use of self-expandable TAVR was similar in both groups.

Primary/secondary end points

The primary end point (including both major and minor vascular complications) was lower in the contemporary hybrid strategy (5.44% vs

Table 1. Baseline characteristics.

	Suture-mediated closure alone (n = 791)	Contemporary hybrid strategy (n = 536)	P value
Age, y	81 (75-86)	80 (73-85)	.0003
Female sex	381 (48.17)	241 (44.96)	.2624
Current smoker	38 (4.80)	24 (4.48)	.8947
Carotid disease	146 (18.46)	58 (10.82)	.0001
Hypertension	720 (91.02)	474 (88.43)	.1361
Diabetes	286 (36.16)	160 (29.85)	.0179
Body surface area, m ²	1.87 (1.70-2.04)	1.87 (1.70-2.06)	.7650
Peripheral artery disease	97 (12.26)	30 (5.60)	<.0001
Self-expanding transcatheter valve	301 (38.05)	187 (34.89)	.2465

Values are n (%) or median (IQR).

Table 2. Primary and secondary end points.

	Suture-mediated closure alone (n = 791)	Contemporary hybrid strategy (n = 536)	P value
Primary end point (major and minor vascular complications)	43 (5.44)	7 (1.31)	<.001
Minor vascular complications	31 (3.92)	6 (1.12)	.002
Major vascular complications	12 (1.52)	1 (0.19)	.0196
Pseudoaneurysm	2 (0.25)	0 (0)	.518
Balloon tamponade	26 (3.29)	3 (0.56)	.0005
Percutaneous stent	16 (2.02)	2 (0.37)	.0133
Surgical repair (cutdown)	3 (0.38)	1 (0.19)	.652
Total length of stay, d	3 (2-5)	2 (2-3)	<.001
Discharge alive	789 (99.75)	533 (99.44)	.3988

Values are n (%) or median (IQR).

1.31%; $P < .001$) (Table 2). Both minor (3.92% vs 1.12%; $P = .002$) and major (1.14% vs 0.19%; $P = .0196$) vascular complications were reduced in the contemporary strategy (Table 2, Figure 2). Pseudoaneurysm was rare, occurring in only 2 patients (both in the suture-mediated closure alone arm). The total LOS was less in the contemporary hybrid strategy (median of 2 days vs median of 3 days in the legacy strategy). Discharge alive occurred in >99% of patients in both arms and was not statistically significant. To account for operator experience, complications in the contemporary group were divided into pre-2018 and post-2018, with no significant difference observed between the 2 (5.5% vs 5.4%; $P = .97$).

Multivariable analysis

Multivariable analysis was performed to determine the effects of case type, PAD, sheath size, carotid disease, and site location on the combined end point for vascular complications (Table 3). The default patient was assumed to be in the legacy closure strategy group, with no PAD, small sheath size (14F), and no carotid disease. Under this analysis, only the closure strategy and the presence of PAD had a statistically significant effect on the combined end point. All else being constant, using the contemporary closure strategy will reduce the odds ratio of vascular complication by a multiplicative factor of 0.17 and the presence of PAD will increase the odds ratio of vascular complications by a multiplicative factor of 4.23. Vascular management strategy has a significant effect on composite outcome when adjusted for PAD, carotid disease, sheath size, and site of the procedure ($P = .02$).

Bailout techniques

Among patients in the suture-mediated closure alone arm, the need for an additional Perclose for failed hemostasis was attempted in 12.14% of patients. In the contemporary hybrid strategy, an extra Perclose was used only 3.17% of the time. Angio-Seal was used in 12.69% of patients in the contemporary arm for bailout. The MANTA device was used in 4 patients (0.75%) for bailout. No patients with Angio-Seal or MANTA bailout had major or minor vascular complications; however,

Table 3. Multivariable logistic regression analysis.

Variables	Odds ratio (95% CI)	P value
Closure strategy	0.17 (0.04-0.71)	.015
Peripheral artery disease	4.22 (2.10-8.48)	<.01
Sheath size	0.99 (0.45-2.16)	.97
Carotid disease	1.38 (0.70-2.73)	.39
Site		.22
Site 1 vs site 2	1.51 (0.29-7.89)	.63
Site 1 vs site 3	0.53 (0.25-1.12)	.097

Table 4. Bailout technique and rates of vascular complications.

Bailout technique	Total number attempted	Vascular complications
Extra Proglide attempted	113	24 (21.2%)
Angio-Seal	68	0
MANTA	4	0

Values are n (%).

19.8% of patients who required an extra Proglide in the suture-mediated closure alone had vascular complications. Bailout with a Proglide was only attempted in 17 patients in the contemporary strategy (many of those cases being early in the protocol switch), and 5 of those patients (29.4%) had a major or minor vascular complication. Table 4 reports the bailout techniques used and associated rates of vascular complications. Table 5 summarizes the patient/procedural details that required MANTA bailout.

Discussion

Our study is the first to compare a contemporary hybrid vascular strategy that involves the use of a small or large collagen-plug VCD for bailout to a suture-mediated closure alone approach utilizing only suture-based VCD for bailout. We found that the use of a contemporary hybrid strategy reduces the risk of vascular complications among patients undergoing TF TAVR. The ability to perform TAVR as a fully percutaneous procedure enables faster ambulation, shorter LOS, and reduced morbidity.⁸ However, failure of VCD to achieve hemostasis results in bleeding and possible limb ischemia.⁹ Furthermore, vascular complications are associated with both short- and long-term morbidity and mortality.¹⁰

Standard vascular management for TF TAVR involves the deployment of 1 or 2 suture-mediated VCD prior to sheath insertion. After the TAVR is performed, the sutures are fastened following sheath removal. In cases with smaller residual bleeding, protamine sulfate and manual pressure may be adequate to achieve hemostasis.¹¹ For larger residual bleeding, additional Proglides may be used; however, VCD failure with the preclose technique may still occur in ~5% to 12% of cases.¹²

More recently, the use of collagen-plug VCDs has been proposed as an option for failed preclose technique. For cases of moderate residual bleeding (in which reinsertion of an 8F sheath seals the hole), a smaller collagen-plug VCD can be used. In cases of excess bleeding (whereby an 8F sheath does not seal), a large-bore collagen plug VCD could be used. The MANTA device is approved for closure for up to 22F.^{13,14} The MANTA device has been compared to a preclose technique, however, there are no data on the use of MANTA for "bailout" after preclose failure.¹⁵ Our study is the first to show that in a series of patients ($n = 4$), the MANTA device was able to obtain hemostasis as a bailout option without any insult. All patients who underwent MANTA closure for bailout had digital subtraction imaging of the access site immediately after and were found to have no bleeding and/or iatrogenic stenosis (Table 4).

Bailout equipment was required in ~12% to 15% of patients in our study. However, our suture-mediated closure alone strategy of deploying an additional Proglide in cases of inadequate hemostasis resulted in vascular injury in ~1 of every 5 attempts. In the contemporary hybrid strategy, the use of a collagen-plug VCD for bailout was successful in every case ($n = 72$). This contemporary strategy improved both minor and major vascular complication rates. The median LOS in the contemporary strategy group was 1 day shorter, but there was no difference in discharge alive. A shorter LOS may be attributed to fewer vascular complications; however, it is also likely a reflection on the trend toward LOS reduction for TAVR over the past few years.¹⁶

Table 5. Case summary of patients who received MANTA bailout.

Patient #	Age/pertinent medical history	Pertinent medications	Transcatheter heart valve type/access size	Repeat imaging	Details
1	77 y Recent PCI, obesity (BMI 33 kg/m ²)	Dual antiplatelet therapy	Evolut PRO+ 34 mm/18F	Post-MANTA DSA of the primary access site showed no iatrogenic stenosis or bleeding	Significant bleeding after securing of Proglide sutures, another Proglide attempted but still significant bleeding, bailout with 18F MANTA
2	79 y Diabetes, mild obesity (BMI 29 kg/m ²)	Aspirin	Evolut PRO+ 26 mm/14F	Post-MANTA DSA of the primary access site showed no iatrogenic stenosis or bleeding	Significant bleeding after securing of Proglide sutures, bailout with 14F MANTA
3	92 y Diabetes	Aspirin	SAPIEN 3 Ultra 29 mm/16F	Post-MANTA DSA of the primary access site showed no iatrogenic stenosis or bleeding	Significant bleeding after securing of Proglide sutures, bailout with 18F MANTA
4	89 y Thrombocytopenia, COPD	Aspirin, midodrine, prednisone	Evolut PRO+ 29 mm/14F	Post-MANTA DSA of the primary access site showed no iatrogenic stenosis or bleeding	Significant bleeding after securing of Proglide sutures, bailout with 14F MANTA

BMI, body mass index; COPD, chronic obstructive pulmonary disease; DSA, digital subtraction angiography; PCI, percutaneous coronary intervention.

Limitations

This study has several limitations, including a retrospective design. As the contemporary cases were done more recently, it is possible that operator vascular management strategies (including the preclose technique) have improved. We chose to evaluate patients from 2016 onwards. At that point, all operators involved in the study had several years of experience with large-bore access and the TAVR sheaths/delivery systems have maintained their lowest profile to date.

Our protocol is to place 2 Proglide sutures prior to sheath insertion; however, there are centers that only use 1 Proglide suture for preclosure. This technique has been associated with improved clinical outcomes.¹⁷ This study did not evaluate the option for 1 preclosure suture with or without collagen-plug VCD. Prior data show that the use of 1 preclosure requires a greater percentage of Angio-Seal use for hemostasis but was not associated with more vascular complications.⁶ We also do not have angiographic or sonographic follow-up data of our patients. Only 1 of the 3 TAVR sites participating in our registry performed consistent post-TAVR angiography. Therefore, we cannot exclude the possibility of iatrogenic injury or stenosis. However, pulses both below the site of entry and distally prior to leaving the procedure room are routinely checked for possible complications.

The use of ultrasound for guidance was not included in the study but has been the standard of care for cases since 2016 at all involved institutions. There was more baseline PAD in the legacy group than in the contemporary group. PAD is a known risk factor for VCD failure.¹⁸ This may be related to the fact that TAVR has expanded to the lower-risk patients.² Therefore, patients receiving TAVR since the initiation of our contemporary strategy may have fewer comorbidities (lower risk) than when a suture-mediated closure alone strategy was used. However, we observed that the contemporary vascular strategy still had a significant effect on the composite outcome when adjusted for PAD.

Conclusion

A hybrid closure technique using suture-mediated VCD preclose with collagen-mediated VCD for bailout improved vascular outcomes compared to standard suture-mediated VCD alone.

Declaration of competing interest

Chad A. Kliger is a consultant and receives speaking honoraria from Edwards Lifesciences and Medtronic. Luigi Pirelli is a consultant and receives speaking honoraria from Edwards Lifesciences and Medtronic. Bruce Rutkin is a consultant and receives speaking honoraria from

Edwards Lifesciences and Medtronic. None of the other authors have anything to disclose.

Funding sources

This work was not supported by funding agencies in the public, commercial, or not-for-profit sectors.

Ethics statement and patient consent

The research reported has adhered to all the relevant ethical guidelines. The need for patient consent was waived as per the institutional review board.

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