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Factors in ProGlide® Vascular Closure Failure in Sheath Arteriotomies Greater than 16 French

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WHAT THIS PAPER ADDS

Although the use of the ProGlide® device for femoral arterial closure after percutaneous endovascular aneurysm repair is associated with a good clinical success rate, factors such as body mass index, the presence of certain comorbidities, the depth of the skin puncture site, and sheath size are significantly associated with device failure. Therefore, it is prudent to ensure careful patient and device selection and to follow an appropriate operating procedure to achieve successful outcomes.

Objectives: The ProGlide® vascular closure device (Abbott Vascular, Redwood City, CA, USA) is approved for the closure of arterial punctures (typically 5–21 Fr sheath; maximum outer diameter, 26 Fr). However, a failure rate of about 2–8% is reported. This study was conducted to analyse factors predisposing to failure when the devices were used for the closure of large hole (16–26 Fr) arteriotomies, and to determine the predictive cut off values of predisposing factors.

Methods: In this retrospective study, the ProGlide® device was used to achieve vascular access site closure in 458 patients undergoing repair of abdominal aortic aneurysm, thoracic aortic aneurysm, type B aortic dissection, or transcatheter aortic valve implantation. The primary endpoint was device failure, defined as inability to achieve common femoral artery (CFA) closure; successful repair, development of acute lower limb ischaemia and haemodynamic compromise; or delayed pseudoaneurysm formation during the follow up period, requiring open repair.

Results: Overall, ProGlide® failure occurred in 7.6% of cases. Factors that predisposed to failure included a history of peripheral arterial disease (PAD) ($p < .001$), the presence of CFA calcification ($p < .001$), the depth of the skin puncture site $\geq$ 33 mm ($p < .001$), body mass index (BMI) of $\geq$28.7 kg/m^2 ($p < .001$), and use of sheath size $\geq$ 19 Fr ($p < .001$).

Conclusion: Factors such as BMI, history of PAD, the presence of CFA calcification, the depth of the skin puncture site, and sheath size are significantly associated with ProGlide® failure. Hence, careful patient and device selection and operating procedure are paramount to achieve successful outcomes.

Keywords: ProGlide®, Common femoral artery, Large hole arterial access, Sheath size, Risk factors
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INTRODUCTION

Endovascular therapy has emerged as the first choice for treating several aortic diseases in the thorax and abdomen,[1] and for transcatheter aortic valve implantation.[2] Earlier, stent grafts were delivered through the common femoral artery (CFA) using an open femoral cut down approach, mainly due to the large sheath size. Currently, however, the total percutaneous approach is being used increasingly to repair aortic pathology, owing to the advent of smaller sheath sizes and less invasive techniques.[3] When compared with the open femoral cut down approach, the percutaneous approach is associated with reduced operating time, need for general anaesthesia, total in-room anaesthesia, groin complications, post-operative pain, and quicker ambulation.[4–6]

Traditionally, small sheath size arteriotomy (<8 Fr) sites were closed using manual compression.[3,7,8] However, manual compression needs close observation, as well as being associated with patient discomfort and other drawbacks.[8,9] Consequently in 1995, arteriotomy closure devices were introduced to reduce vascular complications and the time to achieve haemostasis; to improve patient comfort;

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and to ensure faster ambulation and hospital discharge.[7,9] Commonly used vascular closure devices are categorised into plug based and suture mediated.[1,9,10]

The introduction of the pre-close technique using suture mediated closure devices has led to an increase in the popularity of the percutaneous approach for endovascular aortic repair.[11] Suture mediated closure devices reduce the need for open arteriotomy and thus are associated with reduced morbidity and procedural cost.[9] Two suture mediated closure devices, ProGlide® and Prostar XL (Abbott Vascular, Redwood City, CA, USA), are available for the closure of large bore arteriotomies.[10] ProGlide® is a 6 Fr profile, second generation suture mediated vascular closure device containing a single 3-0 monofilament polypropylene suture with an unbraided, pre-formed slipknot.[12,13] It is indicated for the percutaneous delivery of the suture to close the CFA access site during diagnostic or interventional catheterisation procedures using 5—21 Fr sheaths (maximum outer diameter, 26 Fr). For sheath sizes >8 Fr, a minimum of two devices and the pre-close technique are required.[13,14] When used with the pre-close technique, ProGlide® helps suture large calibre openings in vessels.[12]

Evidence indicates that the pre-close technique with the ProGlide® device is associated with a technical success rate of 92%.[15] A few factors have been proposed for device failure, but the actual parameters predicting failure remain largely unknown. This study was conducted to determine additional factors and to re-examine the currently known factors predisposing to ProGlide® device failure when it is used for the closure of large hole arteriotomies. The study also aimed to determine the predictive cut off values of the different factors predisposing to device failure.

MATERIALS AND METHODS

This retrospective study included 458 patients in whom the ProGlide® vascular closure device was deployed to close large hole arteriotomies (16—26 Fr sheaths) between March 2012 and September 2017. There was no use of ultra low profile devices, and, therefore, the study included only those cases which were repaired using ProGlide® vascular closure device for 16—26 Fr sheaths. The percutaneous approach was used to repair abdominal aortic aneurysm (AAA), thoracic aortic aneurysm (TAA), type B aortic dissection (TBAD), and for trans-catheter aortic valve implantation (TAVI). Patients who had a CFA diameter less than6 mm, calcification in the anterior surface of CFA, or who could not afford to self pay for the ProGlide® device were not treated with it. Of note, the ProGlide® device is not reimbursed in Taiwan. The smallest sheath used was 16 Fr, and the CFA diameter had to be greater than 6 mm to accommodate these large sheaths. Therefore patients with a vessel size <6 mm were excluded.

Vascular access was obtained through the anterior aspect of the CFA (best entry point) under ultrasound guidance. The depth of the puncture site from the skin to the anterior surface of the CFA was determined using a contrast enhanced computed tomography (CT) scan, performed prior to the operation. In obese individuals, the exact calculation of the depth of the puncture site was determined from the inguinal skin to the anterior surface of CFA. The CFA was routinely measured 10—15 mm above the femoral bifurcation, and this point was considered the standard reference point. All the punctures were performed under ultrasound guidance; the puncture site was the same (i.e. 10—15 mm above the femoral bifurcation), and it was not difficult to precisely locate this under ultrasound guidance. The diameter of the CFA was determined using a CT scan performed prior to the procedure. The degree of calcification was assessed by measuring the percentage of calcification circumferentially using a non-contrast enhanced CT scan. This assessment was also based on the standard reference point on the CFA. Two ProGlide® devices were routinely deployed in each femoral artery before insertion of a large sheath (>16 Fr). A third device was used if the arteriotomy could not be closed after closure of the two pre-loaded devices. All the procedures were standardised.

All the operators had similar training backgrounds, and there was a high consensus on treatment policy through routine meetings. They were all experienced in using vascular closure devices under ultrasound guidance and performed all the procedures. Two cardiovascular surgeons and a radiologist performed the image reading, including characteristics and all the measurements of the CFA. If inter-observer differences were ≥10%, the measurements were repeated; if the inter-observer differences were ≤10%, the average measurement was considered as final.

The use of warfarin or novel oral anticoagulant (NOAC) prior to surgery was routinely discontinued and low molecular weight heparin was prescribed if a therapeutic anticoagulant substitute was needed clinically. However, patients were continued on dual or mono-antiplatelet therapy.

A retrospective chart review was performed to record all underlying diseases; operative procedure details; and post-operative outcomes, including body mass index, the presence of comorbidities, sheath size, ProGlide® failure, etc.

The primary outcome evaluated was ProGlide® failure in large hole arteriotomies >16 Fr. Failure was defined as (1) inability to achieve CFA closure; (2) successful repair but development of acute lower limb ischaemia and haemodynamic compromise; or (3) delayed pseudoaneurysm formation during the follow up period requiring open repair.

The study design and methods were approved by the Institutional Review Board.

Patients who underwent repair of AAA, TAA, and TBAD were evaluated with a post-operative contrast CT scan at three, six, and 12 months and subsequently every year. All the patients in the study were regularly followed up for more than one year. However, patients who underwent TAVI did not receive a routine post-operative contrast CT scan or femoral artery Duplex scan follow up, since it was not considered necessary.

Statistical analysis plan

The data collected were entered in Microsoft Excel (2016, Microsoft Corp., Redmond, WA, USA) and analysed using R software version 3.4.3. Continuous data were presented as mean and standard deviation. Categorical data were presented as count and percentage. A receiver operating characteristic (ROC) curve analysis was performed to determine the cut off point of BMI, the depth of the skin puncture site, sheath size, and CFA diameter for ProGlide® failure. The chi-square test and Fisher exact test were used to find associations between categorical variables and device failure. Associations between pre-operative variables and device failure were examined using the chi-square test. Pre-operative variables that were associated with device failure were considered in the multivariable logistic regression analysis. A p value $< .05$ was considered to be statistically significant.

RESULTS

The majority of the patients were male ($n = 346$, 75.5%). Forty-five patients were on low molecular weight heparin, and 60 patients were on dual antiplatelet therapy; the rest of the patients were on mono-antiplatelet therapy. Groin scars were observed in 36 patients (26 patients had a previous femoral cut down procedure due to extracorporeal membranous oxygenation insertion; 10 patients had previous TAA stent grafting via femoral cut down procedure). The baseline characteristics of the study participants are presented in Table 1.

Overall, 602 CFA access sites were used in 458 patients. Of the 602 access sites, 471 (78.2%) were calcification free, 11 (1.8%) had 51—75% circumferential calcification, 39 (6.5%) had 26—50% circumferential calcification, and 81 (13.5%) had 1—25% circumferential calcification. In our series, the CFA diameter was 8.0 ± 0.5 mm, the depth of the puncture site from the skin to the anterior surface of the CFA was 27.4 ± 6.6 mm, and the sheath size was 19.3 ± 2.4 Fr (Table 2). A GORE Dryseal sheath (W.L. GORE & Associates, Flagstaff, AZ, USA) was used in 402 of the 602 access sites; Medtronic Sentrant sheath (Medtronic Cardiovascular, Santa Rosa, CA, USA) in 102; and for the others, direct device insertion (such as stent graft from Cook) was used without any specific large sheath. Three hundred and eighty access sites were used for AAA repair, 109 for TAVI, 68 for thoracic endovascular aortic repair (TEVAR) for TBAD, and 45 for TAA repair. Two ProGlide devices (mean sheath size 18.8 ± 1.9 Fr) were used in 531 access sites (88.2% of cases), while three devices (mean sheath size 23 ± 1.6 Fr) were used in 71 access sites (11.8% of cases). The ProGlide success rate was higher for the 18 Fr sheath size than sheath sizes ≥19 Fr (Fig. 1).

The primary outcome of ProGlide® failure was observed in 46 of the 602 access sites (7.6% of the cases) (Fig. 2). The median follow up time was 25 (2—67) months. In 44 access sites, failure to close the arteriotomy led to bleeding and required prompt open repair; in two access sites, acute limb ischaemia (thrombosis) developed after closure of arteriotomy and required urgent open repair.

Baseline characteristics such as BMI and PAD (Table 3) were significantly associated with device failure ($p < .001$, for all). Among patients with PAD, device failure was observed in 61.5% of patients who underwent AAA repair ($p < .001$ for rate of failure vs. success) and in 75% of patients who underwent TAVI ($p = .003$ for rate of failure vs. success). Among patients on low molecular weight heparin, the incidence of device failure was 9.8% ($p = .198$ for rate of failure vs. success).

Table 1. Baseline characteristics of 458 patients in whom 602 common femoral artery endovascular access sites (16-26 French) were closed by ProGlide®

Parameter	Overall ($n = 458$)	AAA ($n = 236$)	TAA ($n = 45$)	TAVI ($n = 109$)	TBAD ($n = 68$)
Age - y	70.5 ± 12.2	71.9 ± 8.2	68.5 ± 8.4	79.4 ± 5.6	52.5 ± 14.7
BMI - kg/m^2	25.0 ± 3.2	25.1 ± 3.0	24.7 ± 3.5	25.0 ± 3.1	24.8 ± 3.7
Drinking[a]	46 (10)	18 (7.6)	8 (17.8)	9 (8.3)	11 (16.2)
Smoking[b]	256 (55.9)	125 (52.7)	25 (55.6)	64 (58.7)	42 (61.8)
Hypertension	271 (59.2)	144 (60.8)	24 (53.3)	54 (49.5)	49 (72.1)
Diabetes mellitus	278 (60.7)	156 (65.8)	26 (57.8)	71 (65.1)	25 (36.8)
Hyperlipidaemia	172 (37.6)	83 (35)	19 (42.2)	54 (49.5)	16 (23.5)
Carotid stenosis >70%	129 (28.2)	76 (32.1)	11 (24.4)	35 (32.1)	7 (10.3)
COPD	114 (24.9)	57 (24.1)	14 (31.1)	30 (27.5)	13 (19.1)
History of CVA	94 (20.5)	54 (22.8)	10 (22.2)	21 (19.3)	9 (13.2)
CAD	202 (44.1)	105 (44.3)	19 (42.2)	56 (51.4)	22 (32.4)
Haemodialysis	136 (29.7)	72 (30.4)	11 (24.4)	36 (33.0)	17 (25.0)
Gastroduodenal ulcer	68 (14.8)	38 (16)	5 (11.1)	18 (16.5)	7 (10.3)
PAD[c]	97 (21.2)	51 (21.5)	13 (28.9)	27 (24.8)	6 (8.8)
Groin scar	36 (7.9)	10 (4.2)	0 (0)	14 (12.8)	12 (17.6)

Data are presented as mean ± standard deviation or as absolute number (%). AAA = abdominal aortic aneurysm; TAA = thoracic aortic aneurysm; TBAD = type B aortic dissection; TAVI = trans catheter aortic valve implantation; BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular accident; CAD = coronary artery disease; PAD = peripheral arterial disease.

[a] Drinking was defined as > 100 mL of alcohol consumption per day.

[b] Smoking was defined as > 10 cigarettes per day.

[c] Includes patients with symptomatic or asymptomatic disease.

Table 2. Characteristics of 602 common femoral artery endovascular access sites analysed

	Overall, $n = 602$	AAA, $n = 380$	TAA, $n = 45$	TAVI, $n = 109$	TBAD, $n = 68$
CFA diameter – mm	8.0 ± 0.5	8.0 ± 0.5	8.0 ± 0.5	8.1 ± 0.6	8.0 ± 0.5
Skin to CFA distance – mm	27.4 ± 6.6	27.4 ± 6.6	27.7 ± 7.9	27.8 ± 5.7	26.8 ± 7.3
Sheath size – French	19.3 ± 2.4	18.4 ± 1.3	24.1 ± 0.9	18.2 ± 1.1	23.0 ± 1.4

Data are presented as mean ± standard deviation. CFA = common femoral artery; AAA = abdominal aortic aneurysm; TAA = thoracic aortic aneurysm; TBAD = type B aortic dissection; TAVI = trans catheter aortic valve implantation.

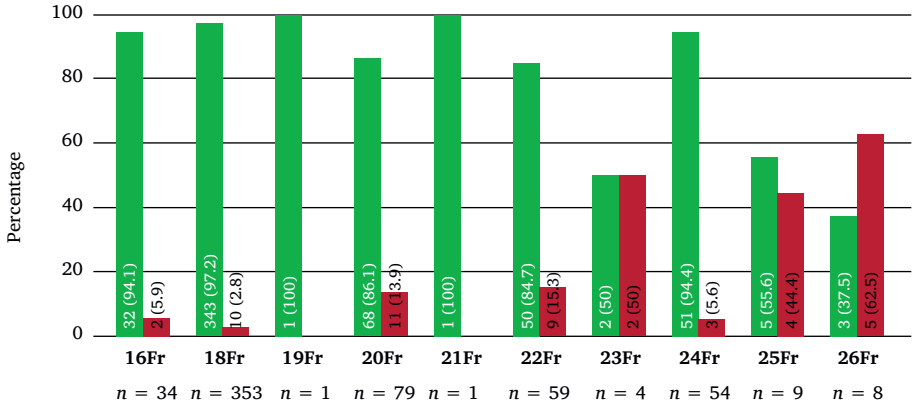

Figure 1. Success (green)/failure (red) rates of 602 ProGlide® endovascular access closure attempts by sheath size. Fr = French.

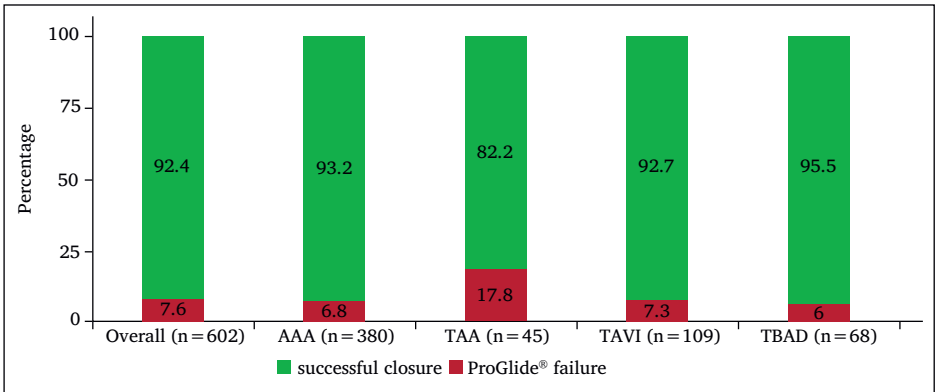

Figure 2. Incidence of ProGlide® failure. AAA = abdominal aortic aneurysm; TAA = thoracic aortic aneurysm; TAVI = transcatheter aortic valve implantation; TBAD = type B aortic dissection.

Procedural aspects such as the depth of the puncture site and sheath size were significantly associated with device failure ($p < 001$, for all). The incidence of failure was analysed based on the ProGlide® instructions for use (IFU) and a higher incidence of failure was noted with the use of >21 Fr sheath size than the ≤21 Fr sheath size (17.2% vs. 4.9%; $p < .001$; Table 4). There was no association between CFA diameter anddevice failure ($p = .077$).

The predictive cut off points of different variables (BMI, depth of puncture site, sheath size, and diameter of CFA) for ProGlide® failure were obtained using a ROC curve. A BMI ≥28.7 kg/m^2 (area under curve [AUC] 0.863), depth of skin puncture site ≥ 33 mm (AUC 0.900), and use of sheath size ≥ 19 Fr (AUC 0.717) were found to be significantly associated with device failure ($p < .001$, for all; Fig. 3). In the final model, device failure was significantly associated with sheath size, the depth of the puncture site from the skin to the anterior surface of the CFA, and the presence of calcification ($p < .001$ for all) (Table 5).

A subgroup analysis was performed in each operative group to determine factors predisposing to ProGlide® failure. The AAA group usually required one or two 18 Fr

Table 3. Comparison of patient associated baseline characteristics between successful ProGlide® access closure and ProGlide® failure

	Successful closure (n = 556)	ProGlide® failure (n = 46)	p*
Female	129 (23.2)	15 (32.6)	.15
Male	427 (76.8)	31 (67.4)	
Drinking	53 (9.5)	5 (10.9)	.79
Smoking	304 (54.7)	23 (50)	.54
Hypertension	336 (60.4)	29 (63)	.75
Diabetes mellitus	335 (60.3)	27 (58.7)	.87
Hyperlipidaemia	205 (36.9)	13 (28.3)	.26
COPD	131 (23.6)	11 (23.9)	.99
Coronary artery disease	246 (44.2)	20 (43.5)	.99
Haemodialysis	164 (29.5)	14 (30.4)	.86
Peripheral artery disease[a]	107 (19.2)	26 (56.5)	<.001
Groin scar	39 (7)	4 (8.7)	.56

Data are presented as absolute numbers (%). COPD = chronic obstructive pulmonary disease.
*Chi-square test and Fisher exact test were used to find associations between categorical variables and ProGlide® failure; $p < .05$ was considered statistically significant.
[a] Includes patients with symptomatic or asymptomatic disease.

Table 4. Instruction for use (IFU) of the ProGlide® device and incidence of device failure

	Within IFU (≤ 21 French)		Outside IFU (> 21 French)		p*
	Access sites	ProGlide® success	Access sites	ProGlide® success	
Overall (n = 602)	468 (77.7)	445 (95.1)	134 (22.3)	111 (82.8)	<.001
AAA (n = 380)	358 (94.2)	341 (95.3)	22 (5.8)	13 (59.1)	<0.001
TAA (n = 45)	0 (0)	0 (0)	45 (100)	37 (82.2)	–
TAVI (n = 109)	107 (98.2)	101 (94.4)	2 (1.8)	0 (0)	.005
TBAD (n = 68)	3 (4.4)	3 (100)	65 (95.6)	61 (93.8)	.999

Data are presented as absolute numbers (%). No. of access sites within and outside IFU is used as the denominator to derive the percentage of ProGlide® success. P value – comparison of success rates between two groups. AAA = abdominal aortic aneurysm; TAA = thoracic aortic aneurysm; TAVI = transcatheter aortic valve implantation; TBAD = type B aortic dissection.
* Chi-square test and Fisher Exact test were used to find associations between the type of operation and ProGlide® failure; $p < .05$ was considered statistically significant.

sheaths in the CFA; the TAA and TBAD groups required one 20–26 Fr sheath in the CFA, based on the size of the thoracic endoprosthesis; and the TAVI group required one 16 or 18 Fr sheath in the CFA. There was no significant association between the incidence of device failure and the operative procedure performed in the subgroup analysis.

Post-operative follow up imaging (CT or duplex scan) was performed in 400 patients (544 access sites, of which 132 required ≥ 21 Fr sheath in the CFA). There was no evidence of pseudoaneurysm or stenosis in the CFA of any of these patients. Only 51 patients who underwent a TAVI were followed up with a post-operative CT or duplex scan for other medical reasons, and a retrospective review showed no evidence of femoral pseudoaneurysm formation.

DISCUSSION

The main findings from this retrospective study are that a sheath size ≥19 Fr, a BMI ≥28.7 kg/m^2, and depth of skin puncture site ≥33 mm are associated with an increased risk of peri-procedural failure of the Perclose ProGlide® technique when used for the percutaneous closure of large bore femoral arteriotomies.

According to the evidence, procedural failure can be attributed to several factors, including sheath size, CFA diameter, sheath to femoral artery ratio, obesity, the presence of calcification, inappropriate puncture of the femoral artery, inexperience of the operator, groin scar, and bifurcations of the femoral artery above the inguinal ligament.[1,11,15–19]

In the study, a sheath size ≥19 Fr was a significant predictor of ProGlide® failure. Similar to this study, other researchers have reported an association between increased sheath size and closure failure. In a meta-analysis by Georgiadis et al.,[17] increased sheath size (≥20 Fr) was associated with the primary failure of the percutaneous endovascular approach, necessitating conversion to a femoral cut down. The association between large sheath size and procedural failure was also reported in a retrospective study by Lee et al.[20] in which the technical success rate was lower in the larger (18–24 Fr) vs. smaller (12–16 Fr) sheath size subsets (91.4% vs. 99%; $p < .01$). Hu et al.[12]

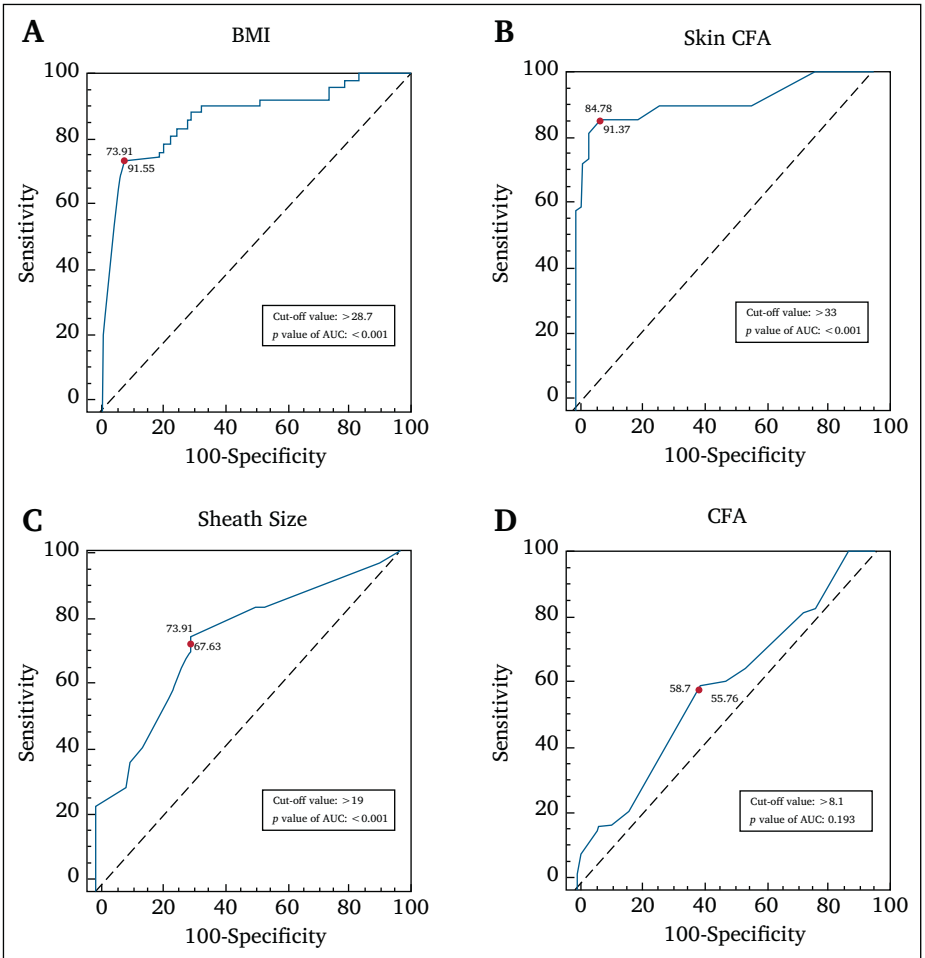

Figure 3. Receiver operating characteristic (ROC) curves for different variables predicting ProGlide® failure. (A) ROC for BMI. (B) ROC for depth of skin puncture site. (C) ROC for sheath size. (D) ROC for diameter of CFA. AUC = area under the curve; BMI = body mass index; CFA = common femoral artery.

Table 5. Logistic regression analysis of associations between classified variables and device failure

	p value	OR (95% CI)
Calcification (>50%)	1 < .001	13.36 (3.5-51.3)
Skin to CFA, mm	1 < .001	1.53 (1.3-1.8)
Sheath size, Fr	1 < .001	1.58 (1.2-2.0)

Associations between pre-operative variables and device failure were examined using the chi-square test. Pre-operative variables that were associated with device failure were considered in the multivariable logistic regression analysis. A p value < .05 was considered as statistically significant. OR = odds ratio; CI = confidence interval; CFA = common femoral artery; Fr = French.

also reported that a sheath size >20 Fr is an independent predictor of ProGlide® related complications. In contrast, a study by Bechara et al.[21] found no statistically significant association between sheath size (p < .17) and closure failure, but noted a reduction in the number of failure events with time (p < .007). The ProGlide® device is approved for the closure of arterial punctures of 5—21 Fr sheath size; the maximum diameter being 26 Fr.[14] However, cases were included in which the device was used to close large hole arteriotomies of 16—26 Fr sheath size. The licensed threshold of the ProGlide® device and real world practice might vary at certain times. In this study, it was found that a cut off value of ≥19 Fr and a sheath size of ≥19 Fr had a sensitivity of 73.91% and a specificity of 67.63% to predict ProGlide® failure. Further studies are required to confirm this association.

This study noted a significant association between a BMI ≥28.7 kg/m^2 and ProGlide® failure. However, literature evidence on the association between BMI and closure failure has been contrasting. In the study by Hu et al.,[12] a BMI >30 kg/m^2 (p = .021) was an independent predictor of ProGlide® related complications. However, a study by Bechara et al.[21] found no statistically significant association (p < .86) between BMI (mean 18—42.5 kg/m^2) and closure failure. Similarly, the study by Zakko et al.[22] demonstrated that obesity (BMI ≥ 30 kg/m^2) is not a contraindication to the percutaneous approach using the ProGlide® closure device. In the study by Zakko et al., patients with a lower BMI had reduced vessel depth and inner vessel diameter,

factors that are associated with failure of the percutaneous approach, especially when larger sheath sizes are used.[22]

In the current study, a depth of skin puncture site ≥33 mm was also a significant predictor of ProGlide® failure. These findings are similar to those reported by Hu et al., in whose study, a CFA depth >4 cm was an independent predictor ($p = .001$) of closure failure.[12] Although the mean BMI of subjects included in the study was 25.0 ± 3.2 kg/m^2, the association between ProGlide® failure and increased BMI and depth of skin puncture site could be attributed to the presence of thick subcutaneous tissue in the groin. The presence of thick subcutaneous tissue at the site of puncture may hinder the smooth advancement of the knot towards the arterial wound and may also result in a slackening of the knots.

In the current series, no significant association was found between the use of anti-coagulants/antiplatelets and ProGlide® device failure. In line with these findings, a study by Kong[23] reported a 100% success rate with ProGlide® device among patients on anticoagulants or dual antiplatelet therapy.

For scarred groin, evidence supports the factor to be significantly associated with high device failure and increased incidences of late repairs and other complications.[17–19] Failure is attributed to needle deflection in such cases.[18,19] However, in this series a groin scar was not associated with device failure ($p = .56$).

The use of bailout strategies has been suggested in cases of vascular closure device failure. According to a study by Patel et al.,[24] the use of an Angio-Seal device is safe and effective for augmenting the pre-close technique in patients undergoing percutaneous endovascular aneurysm repair. In the current study, a third ProGlide® device was inserted when the arteriotomy could not be closed with two. All the operators in the series had performed at least 100 cases of vascular closure using the ProGlide® device, ruling out the possibility of operator inexperience. Patients were carefully selected for ProGlide® device use, based on local data and data from other publications. Patients who were considered to be at high risk of device failure were treated through a surgical cut-down approach.

Recently, new plug based devices, such as the Manta (Essential Medical, Inc., Malvern, PA, USA) and the PerQ-Seal vascular closure device (Vivasure Medical Ltd., Galway, Eire), have been designed for closure of large bore arteriotomies up to 24 Fr.[25,26] In the current series, there were no ultra low or lower profile devices (i.e. sheath size smaller than 16 Fr) available for endovascular aortic aneurysm repair (EVAR). The devices available in the series for thoracic repairs included GORE TAG, Conformable GORE TAG (CTAG) device (W. L. Gore & Associates, Flagstaff, AZ, USA), Valiant Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, CA, USA), and Zenith TX2 (Cook Incorporated, Bloomington, IN, USA). Although ultra low and low profile devices were unavailable in this series, it is speculated that further studies are necessary to assess whether a reduced device profile, as low as 14 Fr, adds a different bearing to the results. Moreover, further studies are essential to assess whether the factors associated with ProGlide® failure in this study are also associated with failure of the new devices designed for closure of large bore arteriotomies.

The study has limitations. The first limitation is its retrospective design. Second, although post-operative imaging (CT or duplex scan) performed in 400 patients revealed no pseudoaneurysm or other vascular complications, not all the patients could be evaluated through post-operative imaging for late complications, due to the retrospective nature of the study. Third, the number of TBAD and TAA repairs performed was relatively low, and thus a comparison between different procedures could not be undertaken. In view of these limitations, a large, prospective, well conducted registry study is required to further confirm the results of this study.

CONCLUSION

This study demonstrated a significant association between ProGlide® failure and factors such as BMI, the presence of CFA calcification, the presence of PAD, the depth of the skin puncture site, and sheath size. Therefore, careful patient and sheath selection, as well as the adoption of an appropriate operational procedure, is crucial to reducing ProGlide® failure. Furthermore, the increased incidence of failure observed with ≥21 Fr vs. 16–21 Fr sheath size indicates that using the ProGlide® device outside the IFU may not be warranted. Although a cut off of ≥19 Fr, which is less than the previously published cut off level of 21 Fr, was a predictor of ProGlide® device failure in this study, further studies are required to confirm this.

CONFLICT OF INTEREST

None.

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