Total percutaneous access for endovascular aortic aneurysm repair ("Preclose" technique)

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Objective: Percutaneous access during endovascular aneurysm repair has been difficult owing to the large size of the delivery catheters. This study reports a single-center experience of totally percutaneous access during endovascular abdominal and thoracic aortic repairs using the Preclose Proglide device (Abbott Vascular, Redwood City, Calif).

Methods: Between December 2004 and August 2006, 262 endovascular aortic aneurysm repairs were performed. Percutaneous access was used for the introduction of 12F to 24F sheaths (4.4-mm to 8.6-mm outer diameter). The technique involved deployment of two Proglide devices before insertion of the sheath ("Preclose" technique) with the sutures left extracorporeally for closure after conclusion of the procedure. A prospectively maintained endovascular database and medical records were retrospectively reviewed. Rates of technical success, failure modes, and the overall duration of the endovascular repair compared with a similar cohort using open femoral exposures were examined.

Results: A total of 559 Proglide devices were used to close 279 femoral arteries, and 175 (63%) required the insertion of 18F to 24F sheaths. There were 16 failures, mainly due to obesity, device malfunction, severe calcific disease, and faulty arterial punctures, for a technical success rate of 94.3%. The success rates for 12F to 16F size sheaths were significantly higher than for the larger 18F to 24F sheaths (99.0% vs 91.4%, P < .01). For both endovascular abdominal (EVAR) and thoracic (TEVAR) aortic repairs, the Preclose technique resulted in shorter overall procedure times compared with a similar cohort in which open femoral exposures were used (EVAR, 115 vs 128 min, P < .001; TEVAR, 80 vs 112, P = .019). Despite this reduction of procedure time, the savings on the cost of operating room time was negated by the cost of the Proglide devices ($295 per device).

Conclusions: Percutaneous access for endovascular aortic repair is safe and feasible using the Proglide device. Although the success rates are higher for smaller size sheaths, successful closures may be obtained for up to 24F sheaths. Percutaneous access may result in shorter overall procedure times and potentially lower operating room costs, but this appears to be offset by the cost of the closure devices. (J Vasc Surg 2007;45:1095-1101.)
The distribution of devices is given in Table I. Although there were some differences in the frequency of devices between the two groups, the proportion of EVAR and TEVAR cases ($P = .13$) was similar. A variety of anesthetic techniques were used, depending on patient comorbidities and operator preferences, but the distribution of techniques for the Preclose and surgical groups, respectively, were similar: general, 49% vs 55%; regional, 45% vs 44%; and local, 5% vs 1% ($P = .10$). The two cohorts were analyzed on a per groin basis. The Preclose group was further divided into a group consisting of smaller 12F to 16F sheaths and a group consisting of larger 18F to 24F sheaths, which are the typical profiles required for thoracic and abdominal endograft iliac limbs and main devices, respectively.

Perioperative outcomes, procedure times, and operating room usage costs (exclusive of any devices or disposables) were examined. Procedure time was defined as the period of time from either incision (surgical exposure) or skin puncture (Preclose technique) to final dressing application. At our institution, the usage cost of the operating room is (US) $3935 for the first 60 minutes (not prorated for shorter periods) and then $50/min thereafter.

Technical success (in-hospital or 30-day) of the Preclose technique was defined as closure of the arteriotomy without the need for additional local reconstruction such as endarterectomy, patch angioplasty, or interposition grafting. For both groups, access site–related complications such as seromas, infections, wound dehiscence requiring dressing changes, hematomas with or without transfusions, and prolongation of hospitalization were counted as failures of the therapy regardless of whether they required additional postoperative surgical or endovascular intervention. Moderate or large (>2 cm) asymptomatic or subclinical hematomas or seromas and arteriovenous fistulas were included as complications.

The first postoperative computed tomography (CT) scan was typically obtained at the 1-month follow-up visit. This and all subsequent CT scans always included the femoral vessels.

Statistical analyses were performed using the Student t test for continuous variables and the Fisher exact test for categoric variables. All aggregate values are given as mean ± standard deviation. Significance was achieved at $P < .05$. This study was approved by the Institutional Review Board.

**Perclose Proglide.** This is a 6F suture-mediated closure device that is inserted over a 0.035-inch guidewire and designed to close arteriotomies after 5F to 7F sheaths. A single 3-0 polypropylene suture is deployed with a full-thickness vertically oriented bite of the artery using a pair of nitinol needles. The two strands of a preformed slipknot are color-coded to indicate the tying strand and the locking strand. The arteriotomy is closed by pulling on the tying strand, pushing down the preformed slipknot using the accompanying knot pusher, and locking the knot by retracting on the locking strand. The guidewire is removed during the deployment of the sutures but is replaced before removal of the device to maintain access to the artery. The list price for each device is (US) $295.

**Surgical exposure technique.** The common femoral artery was exposed using a 4-cm to 6-cm transverse oblique incision made just below the inguinal ligament. The incision was continued down through the subcutaneous tissues to the level of the femoral sheath, where the dissection was oriented longitudinally directly anterior to the femoral artery. Approximately 2 to 3 cm of the artery was circumferentially exposed. The artery was punctured using an 18-gauge needle through a separate stab incision placed 3 to 4 cm inferior to the incision to allow a shallower angle of entry into the artery and the incision to collapse during the procedure. The arteriotomy was closed with 5-0 polypropylene suture using standard techniques. Adjunctive endarterectomies, with or without patch angioplasties, were performed as necessary.

In cases of proximal iliac occlusive disease or severe arterial scarring from prior closure devices or multiple femoral catheterizations, we preferentially use serial dilators (Coons dilator, Cook, Inc, Bloomington, Ind) to “Dotter” the stenoses or enlarge the femoral arteriotomy. We also liberally use these dilators to gauge the size and quality of the access vessel before attempting insertion with the endograft delivery catheter.

### Table I. Distribution of abdominal and thoracic endovascular devices between Preclose and surgical exposure groups

<table>
<thead>
<tr>
<th>Device</th>
<th>Preclose</th>
<th>Surgical</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVAR Zenith*</td>
<td>81</td>
<td>63</td>
<td>.58</td>
</tr>
<tr>
<td>Excluder†</td>
<td>28</td>
<td>42</td>
<td>.01</td>
</tr>
<tr>
<td>AneuRx‡</td>
<td>2</td>
<td>3</td>
<td>.38</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>0</td>
<td>.25</td>
</tr>
<tr>
<td>TEVAR TAG†</td>
<td>67</td>
<td>27</td>
<td>.0001</td>
</tr>
<tr>
<td>Talent‡</td>
<td>1</td>
<td>11</td>
<td>.002</td>
</tr>
<tr>
<td>TX2*</td>
<td>1</td>
<td>8</td>
<td>.01</td>
</tr>
<tr>
<td>Total cases</td>
<td>183</td>
<td>154</td>
<td></td>
</tr>
</tbody>
</table>

*Cook, Bloomington, Ind.
†W. L. Gore & Associates, Flagstaff, Ariz.
‡Medtronic, Minneapolis, Minn.

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In cases of proximal iliac occlusive disease or severe arterial scarring from prior closure devices or multiple femoral catheterizations, we preferentially use serial dilators (Coons dilator, Cook, Inc, Bloomington, Ind) to “Dotter” the stenoses or enlarge the femoral arteriotomy. We also liberally use these dilators to gauge the size and quality of the access vessel before attempting insertion with the endograft delivery catheter.
Preclose technique. The common femoral artery was accessed percutaneously using a micropuncture kit consisting of 21-gauge needle with a 0.018-inch guidewire and 3F introducer (Galt Medical Corp, Garland, Tex). Care was taken to puncture the common femoral artery along its anterior aspect at least 1 cm proximal to the origin of the profunda femoris artery. This was always confirmed with a small manual injection of contrast using an ipsilateral oblique projection of the image intensifier.

A 0.035-inch guidewire was inserted into the aorta and the puncture site dilated with a 7F sheath. A Proglide device was advanced over the guidewire, rotated medially approximately 30°, and deployed, but the strands were left out extracorporeally and tagged with a small clamp. Guidewire access was maintained, and a second Proglide device was inserted, rotated laterally 30°, and deployed. After this device was removed, hemostasis was maintained by reinserting the 7F sheath. This procedure was repeated for the contralateral side for EVAR (unilateral for TEVAR). The access site was serially dilated (Coons dilator), over a stiff guidewire and after systemic heparinization, to match the outer diameter of the device introducer sheath or delivery catheter to facilitate its entry.

Most introducer sheaths and delivery catheters have a step-off or a “lip” at the interface between the dilator and the outer sheath. We were concerned that this step-off could catch on the subcutaneous tissue or, even worse, on the Perclose suture. The leading edge of most sheaths is purposely tapered to minimize this step-off. This edge could get frayed during its passage through the subcutaneous tissue and cause further arterial injury. We believed that predilating the tract could potentially minimize this risk. The cost of the dilator set is (US) $170.44.

After conclusion of the endovascular repair, the introducer sheath was slowly removed while manual compression was applied to the groin. Stiff 0.035-inch guidewire access was maintained, and the preformed knots of the two sutures were cinched down over the guidewire. Manual pressure was released from the groin. After verification of adequate hemostasis, the guidewire was reinserted and manual pressure was reapplied to the groin. A third Proglide device was deployed before removal of the guidewire in select cases if there was persistent pulsatile bleeding after the second suture was cinched down.

Surgical conversion was indicated if this third device failed to resolve the bleeding. In these cases, a 12F dilator was reinserted over the guidewire to plug the arteriotomy, and the artery was repaired surgically. It was critical to the safety of this technique that guidewire access be maintained until adequacy of hemostasis could be verified. Distal perfusion was confirmed with continuous-wave Doppler imaging, and anticoagulation was fully reversed to restore the activated clotting time to <150 seconds. Compression was maintained for 5 to 10 minutes and the patient kept at bedrest for 4 to 6 hours.

Fig 1. Distribution of sheath sizes in the Preclose (striped) and surgical (solid) cohort. There were significantly higher proportions of 16F sheaths in the Preclose group (*P = .03) and 18F sheaths in the surgical group (#P < .001).

RESULTS

Preclose technique group. Between December 2004 and August 2006, 262 endovascular aortoiliac repairs were performed (137 EVAR, 118 TEVAR, 7 iliac). Of the 381 femoral arteries accessed for insertion of 12F to 24F sheaths, 279 (73.2%) were managed with 559 Proglide devices using the Preclose technique in 183 patients (105 EVAR, 71 TEVAR, 7 iliac). Four femoral arteries (1.4%) required only one device, 270 (96.8%) were closed with two devices, and five arteries (1.8%) required a third device. The four femoral arteries that used only one device all involved 12F sheaths and occurred early in our experience. Although all four cases were successful, two devices were routinely used for all subsequent cases. The distribution of sheath sizes is given in Fig 1. Large size sheaths (≥18F) comprised >63% (175/279) of the sheaths in the Preclose cohort.

The overall technical success rate of the Preclose technique was 94.3% (263/279 femoral arteries). There were 16 complications (ie, failures) requiring open repair of 13 femoral arteries and emergency placement of a covered stent in two arteries for severe retroperitoneal hemorrhage. One case of necrotizing arteritis with a mycotic pseudoaneurysm presented on postoperative day 27 that required a common femoral artery replacement with autogenous femoral vein (Table II). Between the subsets of smaller and larger size sheaths, the technique was significantly more successful in the former group at 99% (103/104) vs 91.4% (160/175, P < .01; Fig 2). There were no other hematomas, pseudoaneurysms, or other access-related complications that required additional surgical or endovascular interventions. All cause mortality was 2.2% (4/183), but access-related mortality was 0%.

Surgical exposure group. Between October 2003 and August 2006, 154 consecutive endovascular aortic repairs (108 EVAR and 46 TEVAR) that only involved femoral introduction of the devices were identified (total of
among the 258 femoral exposures). Cases during this period that involved alternative access, such as iliac or aortic sites, were excluded. The distribution of sheath sizes among the 258 surgical femoral exposures was largely similar to the Preclose group except where noted (Fig 1). A total of 16 intraoperative and early postoperative complications resulted in a technical success rate of 93.8% (242/258; \(P = .86\), compared with Preclose technique). The 16 complications consisted of 10 endarterectomies with patch angioplasties, 3 wound infections, 2 infected seromas requiring incision and drainage, and 1 severe arteritis that required débridement and replacement of the common femoral artery with an autogenous femoral vein. All cause mortality was 1.3% (2/154; \(P = .69\), compared with Preclose technique) with 0% access-related mortality (Table III).

Procedure durations and operating room costs. The mean duration of the procedure was compared between a consecutive series subset of the 149 patients in the Preclose cohort that only involved percutaneous transfemoral accesses (101 EVAR, 48 TEVAR) and the surgical exposure group. For both types of procedure, the Preclose technique resulted in a shorter mean procedure time than surgical exposure (Table III). This translated into a lower operating room usage cost. However, when the weighted average cost of the closure device per groin ($591.06) was included, the EVAR Preclose group was more expensive than the surgical group, and the TEVAR Preclose group maintained a slight cost advantage.

DISCUSSION

Percutaneous access during endovascular aortic repairs has been difficult because of the large sizes of the delivery systems. Avoidance of surgical femoral exposure may result in shorter procedure time, fewer wound complications, and increased patient comfort. The practical size limit of achieving hemostasis with manual compression alone is likely 12F (sheath), although this has never been formally studied. Among the various percutaneous arterial closure devices, suture-mediated devices offer the purported advantages of a permanent suture, the least amount of intravascular and extravascular foreign material, and similarity with conventional arterial repair.

In this study, we retrospectively examined the safety and effectiveness of percutaneous closure of femoral arteries after introduction of 12F to 24F sheaths using a suture-mediated closure device. Although the successful closure was slightly higher for 12F to 16F sheaths, the overall rate of technical success was >94% in a consecutive series of nearly 300 femoral arteries. Furthermore, almost all of the complications occurred intraoperatively and were amenable to treatment with surgical or endovascular methods, and there was no access-related mortality.

Several authors have previously described the Preclose technique of percutaneous femoral closure after large sheath access.\(^1\)\(^-\)\(^7\) The entire reported experience, however, has solely involved the use of the Perclose Prostar XL device, the technical success rates have varied widely from 62% to 100%, and similar with the current study, closures of smaller sheaths (<18F) were better than larger ones (Table IV). In contrast with the Proglide device used in the current study, the Prostar XL:

\(1\) has a larger profile (10F vs 6F) that requires more extensive subcutaneous dissection for the sutures to accommodate the 24F collar of the device and allow the sutures to seat properly,
Table III. Comparison between subsets of Preclose and surgical exposure groups

<table>
<thead>
<tr>
<th>Technique</th>
<th>EVAR</th>
<th>TEVAR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preclose</td>
<td>Surgical</td>
</tr>
<tr>
<td>Patients (n)</td>
<td>101</td>
<td>108</td>
</tr>
<tr>
<td>Femoral arteries (n)</td>
<td>173</td>
<td>212</td>
</tr>
<tr>
<td>Age (years)</td>
<td>71 ± 8</td>
<td>72 ± 9</td>
</tr>
<tr>
<td>Male:Female</td>
<td>91:10</td>
<td>98:10</td>
</tr>
<tr>
<td>EIA (mm)</td>
<td>8.8 ± 1.3</td>
<td>8.8 ± 1.5</td>
</tr>
<tr>
<td>Complication (%)</td>
<td>11 (11)</td>
<td>10 (9.2)</td>
</tr>
<tr>
<td>Mortality (%)</td>
<td>1 (1.0)</td>
<td>2 (1.9)</td>
</tr>
<tr>
<td>Procedure time§</td>
<td>115 ± 45</td>
<td>128 ± 31</td>
</tr>
<tr>
<td>OR cost</td>
<td>$6697 ± $2240</td>
<td>$7351 ± $1557</td>
</tr>
<tr>
<td>OR cost + Proglide§</td>
<td>$7881</td>
<td>$7351</td>
</tr>
</tbody>
</table>

EVAR, Endovascular repair; TEVAR, thoracic endovascular repair; EIA, external iliac artery diameter; OR, operating room.
*Access-related failure/complication only.
†All-cause mortality.
‡Duration in minutes of endovascular procedure.
§Mean only.

Table IV. Review of previously reported experience on percutaneous closures of access sites after endovascular repair (all using the Prostar XL)

<table>
<thead>
<tr>
<th>First author</th>
<th>Date</th>
<th>Vessels (N)</th>
<th>Sheath (F)</th>
<th>Success rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haas§</td>
<td>1999</td>
<td>13</td>
<td>16, 22</td>
<td>100%</td>
</tr>
<tr>
<td>Torsello7</td>
<td>2000</td>
<td>29</td>
<td>16, 22, 24</td>
<td>Overall, 62%</td>
</tr>
<tr>
<td>Kennedy6</td>
<td>2001</td>
<td>15</td>
<td>16</td>
<td>80%</td>
</tr>
<tr>
<td>Teh4</td>
<td>2002</td>
<td>82</td>
<td>16-20, 22</td>
<td>85%</td>
</tr>
<tr>
<td>Howell3</td>
<td>2003</td>
<td>148</td>
<td>16</td>
<td>94%</td>
</tr>
<tr>
<td>Kennedy6</td>
<td>2004</td>
<td>15</td>
<td>16</td>
<td>80%</td>
</tr>
<tr>
<td>Torsello7</td>
<td>2005</td>
<td>27</td>
<td>14-24</td>
<td>87%</td>
</tr>
<tr>
<td>Morasch5</td>
<td>2006</td>
<td>94</td>
<td>12, 18</td>
<td>81%</td>
</tr>
</tbody>
</table>

The only advantage that the Prostar XL technique offers over the Proglide is that it typically requires only one device per femoral artery because there are already two sutures oriented in a cross-pattern and, therefore, there is a cost benefit ($425 per device vs $590 for 2 Proglide devices, a difference of $165).

2. has a more cumbersome deployment mechanism that relies on accurate placement of four needles for its two sutures vs two needles with one suture,
3. uses a braided suture (vs monofilament) with increased potential for infections and occasional failure of the slip knots to slide down, and
4. relies on the operator to tie the proper slipknot after removal of the large sheaths.

Admittedly, all of these relative disadvantages can be overcome with proper technique and sufficient experience. The only advantage that the Prostar XL technique offers over the Proglide is that it typically requires only one device per femoral artery because there are already two sutures oriented in a cross-pattern and, therefore, there is a cost benefit ($425 per device vs $590 for 2 Proglide devices, a difference of $165).

Although review of the time points at which each of the complications occurred did not demonstrate a clear learning curve, the cases serve to illustrate a few key points about their management and the apparent risk factors for technical failure. Proper initial femoral puncture (ie, anterior aspect of the mid-common femoral artery) is critical. In the case of a suprainguinal puncture of the external iliac artery, the inguinal ligament can impede complete laying-down of the slipknot and the access site is too high for manual compression, leading to uncontrolled hemorrhage. This occurred in two cases. In both, this was not immediately recognized from the small amount of bleeding at the puncture site and the guidewire was removed. In both of these instances, the proximal superficial femoral artery was rapidly exposed through a medial longitudinal incision, guidewire access was re-established, and a short covered Viabahn stent (W. L. Gore & Associates, Flagstaff, Ariz) was deployed.

These cases notwithstanding, the ability to maintain guidewire access from the beginning to the end of the closure allows management of most hemorrhagic complications by reinsertion of a sheath or large dilator, restoration of hemostasis, and un hurried surgical repair of the arteriotomy. In contrast with a suprainguinal puncture, a low femoral puncture (ie, superficial femoral artery) can result in a flow-limiting dissection with limb ischemia due to the small size of the entry vessel.

Any anatomic configuration that necessitates a significant amount of pushing or torqueing of the sheath or delivery catheter can increase the risk of failure of the Preclose technique. This occurs most commonly in patients with small or diseased iliac arteries, or severe iliac tortuosity, or both. The increased pressure and torque applied to the sheath may extend the size of the arteriotomy made by the sheath profile alone. Furthermore, it may also cause the Proglide sutures to actually pull out of the vessel altogether or reduce their purchase such that they are insufficient to reposition the arteriotomy.

We believe that the ability to completely reverse the anticoagulation is important to the technique. Similar to open surgery, formation of clot is essential for hemostasis. Two patients were coagulopathic despite infusions of plasma, platelets, and protamine. There was persistent bleeding and the artery repaired surgically. Direct examina-
tion of the vessel showed the two Proglide sutures deployed correctly and sutures securely tied, but pulsatile bleeding between the sutures and needle holes. We now consider coagulopathy a contraindication to this technique.

Severe calcifications, groin scarring, and obesity can also lead to technical complications (Fig 3). Groin scarring from prior catheterizations and, ironically, from previously placed percutaneous closure devices or surgery can cause misdeployment of the Proglide sutures due to the inability of the needles to penetrate through the arterial wall or the overlying scar tissue. This increased resistance can lead to the separation of the suture from the back end of the needle. Although obesity as a single measure is not necessarily a risk factor, as it relates to the depth of the subcutaneous tissue at the groin, it can negatively affect the ability to properly insert the Proglide device into the artery.

To summarize, we would consider contraindications to the procedure to be:

1. obesity, but of more importance a thick pannus in the groin vs generalized overweight state or truncal obesity not involving the groins,
2. severely scarred groin from multiple prior catheterizations or surgical procedures because the Proglide needles may not penetrate through the scar,
3. high (suprainguinal ligament) femoral bifurcation because hemorrhage cannot be easily controlled with manual compression,
4. need for frequent introducer sheath removals and insertions,
5. proximal iliac occlusive disease,
6. small iliofemoral arteries relative to the profile of the device being inserted, and
7. anterior or near circumferential calcific disease.

It was encouraging that there were so few infectious complications in the Preclose group. We attribute this to the sterile technique and environment of the operating room. Indeed, the only such complication in our series involved a polytrauma victim with a thoracic aortic transection that was repaired with a stent graft. The emergency conditions and a potentially unrecognized break in sterile technique may have contributed to the Perclose infection and resultant mycotic femoral pseudoaneurysm. As with any procedure involving implantable endovascular devices, the highest level of aseptic technique is critical to avoid limb and life-threatening infectious complications.

The main limitation of this study is its retrospective design and its inherent selection bias. The criteria for deciding who undergoes surgical exposures or the Preclose technique were not standardized. Arguably, the surgical group may have been anatomically disadvantaged owing to many of the same factors that made the Preclose technique unsuitable, such as obesity, scarring, and severe atherosclerotic disease as mentioned. Conversely, the only way we can truly eliminate this would be through a prospective, randomized study, which may be ultimately required before the merits of this technique can be scientifically validated.

The economics of percutaneous access for EVAR and TEVAR deserve mention. Measuring only the time-based “usage” cost of the operating room is artificial and not reflective of all the fiscal complexities that enter into the in-hospital cost of this expensive therapy. It seemed appropriate, however, because operating room time was the only potential cost end point affected for EVAR, with the obvious exception of the device cost itself. We purposely did not consider the cost of the Coons dilators, which being part of the Preclose technique, should be factored into the overall device cost. Conversely, this would not have materially altered the final conclusions of the cost analysis, which was that the Preclose technique was not necessarily cost-effective.
Currently, percutaneous closures are not reimbursed, regardless of what setting or device. The only justification from the hospital’s standpoint involves some aggregate qualitative and quantitative measures of time-savings, fixed-resource utilization, and patient satisfaction. From a physician’s standpoint, surgical femoral exposure (Current Procedural Terminology code 34812) during endovascular procedures is reimbursed at $373.82 (2006 Medicare Fee Schedule for Florida, Locality 1) per groin. This means a loss of nearly $750 per patient for EVAR. Unfortunately, this discrepancy may have implications in the current setting of declining physician reimbursement.

CONCLUSION

This study represents, to our knowledge, the largest series of percutaneous endovascular aortic repairs using the Preclose technique and the first using the Proglide device. The results indicate that the technique is a safe and effective method of percutaneous arteriotomy closure after introduction of large sheaths in a select group of patients, with a higher technical success rate than historically reported with the Prostar XL device.

The technique is well tolerated by patients, with almost no postoperative discomfort typical of a groin incision and rapid return to normal activities. Although to date we have not had any late ischemic events due to secondary development of occlusive disease at the site of Perclose deployment, long term outcomes of femoral arteries closed with this technique remains unknown at this time and clinical vigilance is warranted.

AUTHOR CONTRIBUTIONS

Conception and design: WL
Analysis and interpretation: WL, MB
Data collection: WL, MB
Writing the article: WL, TH
Critical revision of the article: WL, PN, TH
Final approval of the article: WL, MB, PN, TH
Statistical analysis: WL
Obtained funding: Not applicable
Overall responsibility: WL

REFERENCES
