ULTRASOUND GUIDED PERCUTANEOUS ENDOVASCULAR ANEURYSM REPAIR UNDER LOCAL ANAESTHESIA IS THE GOLDEN STANDARD

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Vatsa-aortan aneurysma korjataan nykyään yleensä suonensisäisellä tekniikalla. Jos potilaan aneurysman ja aortan anatomia eivät sovi suonensisäiselle toimenpiteelle, harkitaan avoleikkausta. Suonensisäisessä korjauksessa aneurysma eristetään verenkierron ulkopuolelle stenttiproteesin avulla, joka viedään aorttaan perkutaanisesti nivusvaltimoiden kautta. Endovaskulaarinen hoito edellyttää myös sitä, että valtimoissa ei ole merkittävää kalkkista ahtaumaa tai mutkaisuutta, joka estäisi stentin kulun aorttaan. Femoraalisuonten sulkulaitteiden käyttö suonensisäisten aneurysman korjausleikkauksissa vähentää komplikaatioiden ilmenemistä, vähentää aikaa hemostaasiin, sekä mahdollistaa aikaisemman potilaan mobilisaation toimenpiteen jälkeen.

Sulkulaitteiden asennukseen liittyy kuitenkin komplikaatioriskejä. Tavallisimmat komplikaatiot ovat vuoto, verenpurkauman kehittyminen, pseudoaneurysma ja suonen tukkiutuminen. Aikaisemmissa tutkimuksissa on todettu MANTA-sulkulaitteella olevan

pienempi komplikaatioriski verrattuna ProGlide-sulkulaitteeseen. Tämä tutkimus tehtiin kuitenkin aikana jolloin sulkulaitteita ei asennettu ultraääniohjatusti. Tämän retrospektiivisen tutkimuksen tarkoituksena oli selvittää, vaikuttaako ultraäänilaitteen käyttö ProGlide-sulkulaitteen komplikaatioriskiin. Tutkimuksen aineisto koostui 2.1.2017-9.2.2022 välisenä aikana kerättyyn aineistoon HUSpotilastietojärjestelmästä. Potilaiden tapahtumia seurattiin toimenpiteestä kotiutumiseen koko sairaalaolon ajan. Kaikissa toimenpiteissä oli käytössä ultraäänilaite sulkulaitteen asennusvaiheessa.

Lopullinen potilasaineisto koostui 637 potilaasta, joista 12 peruuntui sairastumisen vuoksi. Hoidettuja nivusia oli kokonaisuudessaan 1235, joista 1046 elektiivisiä, 129 stabiileja aneurysman ruptuuroita ja 60 epästabiileja aneurysman ruptuuroita. ProGlide-sulkulaitetta käytettiin elektiivisissä toimenpiteissä 973 kertaa, stabiileissa ruptuuroissa 119 kertaa ja epästabiileissa 32 kertaa. MANTA-sulkulaitetta käytettiin yhteensä 37 kertaa, Angioseal-sulkulaitetta 37 kertaa, suoraan avotoimenpiteeseen ilman sulkulaitteita päädyttiin 33 kertaa. ProGlide vaihdettiin toiseen sulkulaitteeseen 19 kertaa sekä konvertoitiin avoleikkaukseen 30 kertaa. Primaari päätetapahtuma on onnistunut sulkulaitteen käyttö ilman vaihtoa toiseen sulkulaitteeseen tai avoleikkaukseen. Sekundaari päätetapahtuma on femoraalisuonten jälkikorjausten määrä ja akuutin raajaiskemian tai infektion insidenssi toimenpiteen jälkeen. ProGlide-sulkulaittetta käytettiin ilman komplikaatioita elektiivisesti 936 kertaa (96,20%), stabiileissa RAAA-potilaissa 111 kertaa (93,28%), epästabiileissa RAAA-potilaissa 28 kertaa (87,50%).

Tutkimuksen päätelmänä on, että ProGlide sulkulaite on turvallinen ja tehokas väline nivuspunktioiden sulkemiseen aortan aneurysmien hoidossa silloin, kun punktion yhteydessä käytetään ultraääniohjausta. Lisäksi todettiin että instabiileilla aneurysmaruptuuroilla sukulaitetta ei aina voida asentaa ennen aortan sulkupallon asennusta.

ULTRASOUND GUIDED PERCUTANEOUS ENDOVASCULAR ANEURYSM REPAIR UNDER LOCAL ANAESTHESIA IS THE GOLDEN STANDARD

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ABSTRACT

Introduction: Introduction of percutaneous closure devices has been a major step for lower invasiveness in EVAR, and made it possible to perform percutaneous endovascular aneurysm repair (PEVAR), without the need to open the groins. The aim of this study was to evaluate the success of using percutaneous technique in all EVARs, including ruptured aneurysms and to distinguish possible risk factors for failure. Material and methods: All patients who underwent EVAR due to either unruptured or ruptured abdominal aortic aneurysm during 2017-2021 were extracted from our prospectively maintained Husvasc-registy. Case records of the patients were reviewed retrospectively and details of the closure devices used to close the arterial access as well as the success for the closure were evaluated. Since 4/2011, all EVARs at our institution have been performed percutaneously using ultrasound guided puncture and insertion of closure device.

Results: Alltogether 1235 groins were treated; 1124 (91%) with Proglide™ and 111 (9%) with either primary open surgery (3%), Angioseal™ (3%) or Manta™ (3%). In the Proglide™ group, 973 patients were treated electively; 119 with stable RAAA and 58 with unstable RAAA. In the elective group; 936 (96%) were treated without complications. In the stable RAAA group, 111 (93%) patients had no complications, whereas 28/32 (88%) of the instable RAAA patients were complication-free. Altogether, 1075 patients (96%) were treated with Proglide without complications.

In conclusion, Proglide™ is safe and effective in both elective and emergency aortic repair, when used under ultrasound guidance.

INTRODUCTION

Endovascular aneurysm repair has replaced open surgery as the first option for patients with large abdominal aortic aneurysm. After the introduction of this procedure 1991 by Juan Parodi (Parodi et al 1991), the development in the technique and devices has been substantial. One major step for even lower invasiveness has been introduction of percutaneous closure devices. Vascular closure devices were introduced mid 1990's to decrease vascular complications, reduce the time to do hemostasis with manual compression and allow earlier mobilization of the patient after the procedure. These early devices were for smaller size introducers (Patel et al 2010). Preclosure technique was introduced in 1999 and it allowed closure of the artery using bigger sheets (Haas et al 1999). This development made it possible to perform percutaneous endovascular aneurysm repair (PEVAR), without the need to open the groins. In our institution, PEVAR was introduced in 2011 and ever since all EVAR procedures are done without surgical CFA exposure, using Proglide closure devices. The aim of this study was to evaluate restrospectively the success of our strategy using percutaneous technique in all EVARs, including ruptured aneurysms and to distinguish possible risk factors for failure.

METHODS

All patients who underwent EVAR due to either unruptured or ruptured abdominal aortic aneurysm during 2017-2021 were extracted from our prospectively maintained Husvasc-registy. Case records of the patients were reviewed retrospectively and details of the closure devices used to close the arterial access as well as the success for the closure were evaluated.

We use routinely ultrasound to gain common femoral artery (CFA) access. All procedures are done in local anaesthesia. After the puncture, a 5 fr sheet is introduced to the artery to dilate the arteriotomy before introducing the closure device to the artery. We use 2 Perclose Proglide™ devices per CFA access site routinielly in EVARs. In the end of the procedure, we tighten the Proglide sutures. The first tightening is done while the guidewire is still in place in order to check hemostasis and in case of remarkable bleeding at this phase, we either compress the access site or use Manta™ devise

according to preference of the operator. In some unstable rupture cases without time to introduce Proglide sutures, Manta closure device have been used to close the arteriotomy. These patients are not included in this study but the number of such cases are reported in the Figure 1. Technical success is defined as no secondary procedures due to bleeding or occlusion of the artery. All failures to close the arteriotomy were recorded, as well as procedures due to bleeding or pseudoaneurysms. In some patients, conversion to open surgery was needed and these were naturally also counted as failures. Primary outcome measure is successful percutaneous closure of the access site without need of other percutaneous devices or groin opening. Secondary outcome measures are the rate of late common femoral artery repairs and the incidence of acute limb ischemia and infection after the procedure. This study was approved by the Institutional Review Board of Abdominal center.

RESULTS

Alltogether 1235 groins were treated; 1124 (91%) with Proglide™ and 111 (9%) with either primary open surgery (37, 3%), Angioseal™ (37, 3%) or Manta™ (37, 3%). In the Proglide™ group, 973 patients were treated electively; 119 with stable RAAA and 58 with unstable RAAA. In the elective group; 936 (96%) were treated without complications. 17 patients were converted to other device, and 20 patients to open repair. In the stable RAAA group, 111 (93%) patients had no complications, whereas 28/32 (88%) of the instable RAAA patients were complication-free. Together 1075 patients (95,6%) were treated with Proglide without complications.

DISCUSSION

To the authors' knowledge, this is the largest analyzed series on Proglide preclosure devices in endovascular aortic repair. It demonstrates effectiveness and safety of the device in both elective and emergency settings.

A total of 1235 common femoral arteries were punctured, of which 15% in emergency aortic repair. The use of preclosure devices was similar in the elective and stable RAAA groups, while they were used much less often in unstable patients. This, naturally, is explained by the urgency to achieve hemodynamic stability by placing an occlusion

balloon in the descending thoracic aorta. After stabilization, preclosure devices could typically be deployed when puncturing the other side, and the first access was closed surgically or with other closure devices.

Overall, access site closure could be achieved in about 95% of cases, and complication rates were low. Patients are usually discharged on the first postoperative day, and later admissions for access site complications are very rare. Minor complications were more common: occasionally, use of multiple devices is required, as calcification plaques prohibit the needles to join thru the plaque. Furthermore, minor oozing from the puncture site is common, but can most often be managed by 5-10 minutes manual compression. Postoperative hematomas are common, but do not require intervention.

This study is limited by its retrospective nature. This is most significant in evaluation of minor complications such as required manual compression, size of the hematoma, access site pain, and healing of the dermal incision, as these are not systematically included in patient records. On the other hand, major complications of large bore arterial holes tend to require emergency intervention, and the authors are confident that all major bleeds and infections are captured in the data.

Access preclosure techniques in local anaesthesia have been a major step forward in minimally invasive aortic and cardiac surgery, and the technique has been applied in numerous different clinical and anatomical settings (Del Prete A et al 2020, Moriyama N et al 2019 1, Moriyama et al 2019 2, Dahlbacka S et al 2020.). The Proglide device by Abbott has been a workhorse in EVAR procedures at our institution for the last decade. The learning curve for Proglide has been established as quite steep (ref). The percutaneous technique is further augmented by using ultrasound for puncture. Ultrasound guided puncture is beneficial as it allows for accurate selection of the puncture site, and leads to higher technical success rate for the closure devices (Del Prete A et al 2020, Moriyama et al 2019 2).

In conclusion, Proglide™ device is safe and effective in both elective and emergency aortic repair. In unstable patients, use of closure devices should not delay the hemodynamic stabilization of the patient by percutaneous aortic occlusion balloon.

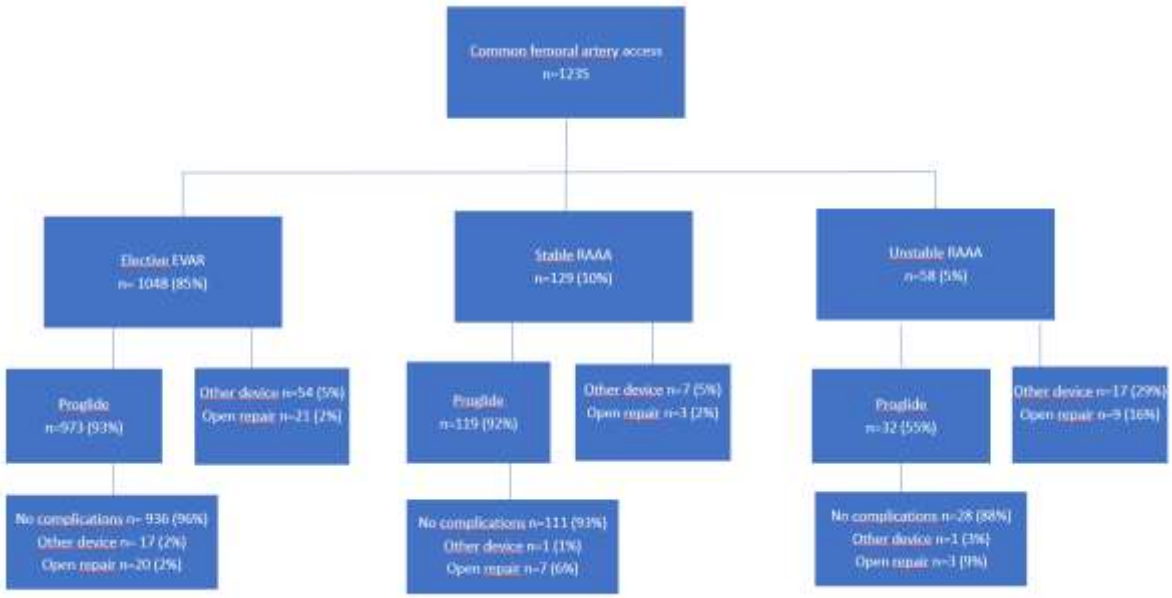

Figure 1. Flow chart of the patients.

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