Experience using a single ProGlide percutaneous closure device for vascular closure after transcatheter aortic valve replacement: case series

Experiencia con el uso de un solo dispositivo de cierre percutáneo ProGlide para el cierre vascular luego del reemplazo percutáneo de válvula aórtica: serie de casos

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ABSTRACT

Introduction. Transcatheter aortic valve replacement (TAVR) is currently the treatment of choice for patients with high or prohibitive surgical risk who need an aortic valve intervention. The minimally invasive approach has demonstrated several benefits; in this scenario, percutaneous closure devices have proven to be safe and effective in comparison with surgical cut-down for vascular access.
Initialy two ProGlide devices were used for each puncture site. This study presents our experience using only one closure system for each patient.
Materials and methods. This is a retrospective observational study to evaluate the results of using a single ProGlide device for main vascular access closure in 50 patients undergoing TAVR.
Results. We included in our study 50 consecutive patients of whom 42% (21) were men. The median age was 80.5 years, and the median EuroScore and STS scores were of 7 and 14 points respectively. Success rate of closure of the main vascular access with the ProGlide system was 96% (48 patients). Failure of closure with the device was observed in 2 patients, however none of them required surgical intervention. The median compression time was 4 minutes.
Conclusion. In our experience, the use of a single ProGlide Device for closure of the main access undergoing TAVI was safe and effective.

Keywords: TAVR, vascular access, ProGlide

RESUMEN

Introducción. El reemplazo valvular aórtico percutáneo (TAVI) es actualmente la terapéutica de elección para aquellos pacientes de elevado o prohibitivo riesgo quirúrgico que necesitan intervención de su válvula aórtica. El abordaje minimalista demostró ventajas, en ese aspecto los dispositivos de cierre percutáneo han demostrado ser seguros, eficaces y beneficiosos en comparación con la disección quirúrgica del sitio de punción. Inicialmente se utilizaban dos dispositivos ProGlide por sitio de punción, en el presente trabajo demostramos nuestra experiencia utilizando un solo dispositivo por paciente.
Materiales y métodos. Estudio observacional descriptivo de series de casos para evaluar los resultados obtenidos al utilizar un solo dispositivo ProGlide para el cierre vascular en 50 pacientes consecutivos de elevado riesgo quirúrgico sometidos a reemplazo valvular aórtico percutáneo.
Resultados. De los 50 pacientes, 42% (21) eran hombres y el resto mujeres, la mediana de edad fue de 80,5 años, con una mediana para STS y EuroSCORE de 14 y 7 puntos, respectivamente. La tasa de éxito del cierre satisfactorio del acceso principal con el dispositivo único ProGlide fue del 96% (48 pacientes). Se observó falla del dispositivo en 2 pacientes, ninguno de los cuales requirió intervención quirúrgica. La mediana de tiempo de compresión fue de 4 minutos.
Conclusiones. En nuestra experiencia, el uso de un solo dispositivo ProGlide para cierre de acceso principal sometido a TAVI resultó seguro y eficaz.

Palabras clave: TAVI, acceso vascular, ProGlide.

Revista Argentina de Cardioangiología Intervencionista 2023;14(3):110-113. https://doi.org/10.30567/RACI/202303/0110-0113

INTRODUCTION

Percutaneous transcatheter aortic valve replacement (TAVR) has turned into the preferred option for patients who have a serious commitment of the aortic valve and a high or prohibitive surgical risk. Results have improved significantly due to advances in devices, techniques and operators´ skills since its first implant in humans in 2002[1].

The implanting technique has evolved towards one which is less complex and invasive for the patient, showing that by avoiding the surgical access has a positive impact on the results.

Within the percutaneous closure devices, the Perclose ProGlide system of Abbott Vascular is the one most used in our surroundings.It is a gadget mediated by pre-tied polypropylene monofilament suture[2]. The afore mentioned device has shown advantages as regards time of hemostasis, mobilization and discharge of patient, with a low percentage of related complications[3-5].

However, the vascular complications in the access site are still an important problem and this system in particular requires a learning curve. That's why its usage has not been generalized yet.

In the first trials which compared the use of ProGlide with the surgical dissection of the access site, two devices of percutaneous closure mediated by suture to seal high caliber devices (5-21 Fr).

Even so, there is little information available which compares the use of one or two closure devices per access site.

To use a unique device has remarkable advantages, like a procedure with less steps, a shorter duration, less stenosis in the femoral artery and a cost reduction, which would be translated into a greater use of these devices.

Having into account the context mentioned, the purpose of this study is to show the results obtained when using a unique ProGlide device in patients who underwent a percutaneous aortic valve replacement.

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No conflicts of interest whatsoever.

Received: 05/09/2023 | Accepted: 14/09/2023

TABLE 1. Demographic variables of the studied population.

Variables	Total cohort (50patients)
Age (years old), median [IQR]	80.5[80.0-82.0]
Body mass index, median [IQR]	24.0[24.0-25.0]
Genre (M), % [CI95%]	42.0%[28.2-56.8%]
Arterial hypertension, % [CI95%]	90.0%[78.2-96.7%]
Diabetes mellitus, % [CI95%]	58.0%[43.2-71.8%]
Smoking, % [CI95%]	56.0%[41.3-70.0%]
Dyslipidemia, % [CI95%]	42.0%[28.2-56.8%]
Peripheral vascular disease, % [CI95%]	32.0%[19.5-46.7%]
COPD, % [CI95%]	62.0%[47.2-75.3%]
STS score, median[IQR]	14.5[12.0-16.0]
EuroSCORE, median [IQR]	7.00[6.00-7.00]

IQR: Interquartile range COPD: chronic obstructive pulmonary disease.

TABLE 2. Variables related to the procedure.

Femoral access,%	100%
Radial access,% [CI95%]	76.0%[61.8-86.9%]
Hematocrit pre-procedure, median [IQR]	41.0[40.0-43.0]
Hematocrit post-procedure, median [IQR]	38.0[37.0-40.0]
Hematocrit fall, median [IQR]	3.00[3.00-4.00]
Tp, median [IQR]	96.0[93.0-98.0]
Kptt, median [IQR]	33.0[31.0-33.0]
Introducerused, % [CI95%]	
14 Fr	40.0%[26.4-54.8%]
18 Fr	60.0%[45.2-73.6%]
Use of ultrasound, % [CI95%]	68.0%[57.5-83.8%]
Use of radioscopy, % [CI95%]	32.0%[19.5-46.7%]
Transfusions, %	0%
Vascularcomplication	2.00%[0.05-10.6%]
Compressiontime(minutes), median [IQR]	4.00[3.00-5.00]
Heparinsingledose, %	100%
Protaminesingledose, %	100%

IQR:Interquartilerange

MATERIALS AND METHODS

Design and scope of study

An observational and descriptive study of series of cases was carried out in order to assess the results obtained when using a single ProGlide device for the vascular closure in patients submitted to the percutaneous aortic valve replacement by the same interventional team. This team previously fulfilled a learning curve of a minimum of 10 devices per operator in two high complexity centers of the Área Metropolitana de Buenos Aires (AMBA). Data were compiled retrospectively and they were analyzed in order to determine the efficiency and safety in the usage of a single device of percutaneous closure.

Participants

50 consecutive patients were included with symptomatic severe aortic stenosis who were submitted to percutaneous aortic valve replacement between July 2022 and July 2023. Those patients who had severe calcification of the femoral artery in the anterior face in the puncture site were considered ineligible to take part. No patient was excluded. Interventions were performed under sedation and regional anesthesia.

Suture technique

In order to achieve the hemostasis in the access site, the Perclose ProGlide device was used in all the patients. Before the procedure, all the access sites were assessed through multislice angiotomography to determine the puncture site and the presence or absence of vascular disease. If more than the 50% of the common femoral artery, chosen as primary access site, showed calcification, it was considered as positive-for vascular disease.

The ProGlide device placement technique (**Figure 1**) consisted of the eco guided or guided puncture through the administration of contrast from the homolateral external iliac artery, followed by the colocation of a 7 Fr introducer in the common femoral artery and a sodium heparin bolus at the rate of 100 Ul per kg of patient´s weight. At the end of the procedure, after the last angiographic control, all the patients were administered an ampoule of EV protamine in slow infusion. A J 0.035 guide was inserted through the access site, the femoral introducer was taken out and the ProGlide device was inserted on the guide until pulsatile blood flow was obtained through the outlet port. After that, step 1 was activated and the device was pulled 45 degrees upwards. While keeping a moderate tension, steps 2 and 3 were carried out and the thread was cut in its distal position. Finally, step 4 took place and, when taking out the device, the 0.035 guide was introduced again through the device entrance port.

Variables

The demographic variables studied were: age, body mass index, genre, arterial hypertension, diabetes mellitus, smoking, dyslipidemia, peripheral vascular disease, COPD, STS score and EuroSCORE. Besides, the variables related to the procedure included: usage of femoral access or radial access, hematocrit pre-procedure, hematocrit post-procedure, hematocrit fall, Tp, Kptt, used introducer (14 Fr, 18 Fr), use of ultrasound and radioscopy, transfusion requests, presence or absence of vascular complications and compression required time (expressed in minutes).

Analysis of data

The categorical variables are expressed in proportional terms, together with their corresponding 95% confidence intervals (CI 95%). On the other hand, the quantitative variables are submitted as average and standard deviation (SD) or as median and interquartile range (IQR), depending on its distribution. Shapiro-Wilk test was used to determine the distribution of quantitative variables and software R[6]was used to analyze data.

RESULTS

Fifty consecutive patients who were submitted to TAVR were included. The demographic characteristics of the population studied are shown on **Table 1**. The average age was 80.5 years [IQR: 80-82]. The arterial hypertension prevalence was 90% [CI95%: 78.20-96.7%],the diabetes mellitus was 58% [CI95%: 43.2-71.8%], 32%[CI95%: 19.5-46.7%] of the patients had peripheral vascular disease and 62% [CI95%: 47.2-75.3%] had chronical obstructive pulmonary disease. Risk scores showed an average of 14 [IQR: 12-16] and 7 [IQR: 6-7] for STS and EuroSCORE, respectively.

100% of the cases had femoral access with main access site, whereas 76% [CI95%: 61.8-86.9%] had radial access as secondary access. There were 24% of patients with secondary contralateral femoral access.

Expandable balloon valves with their 14 Fr introducer were

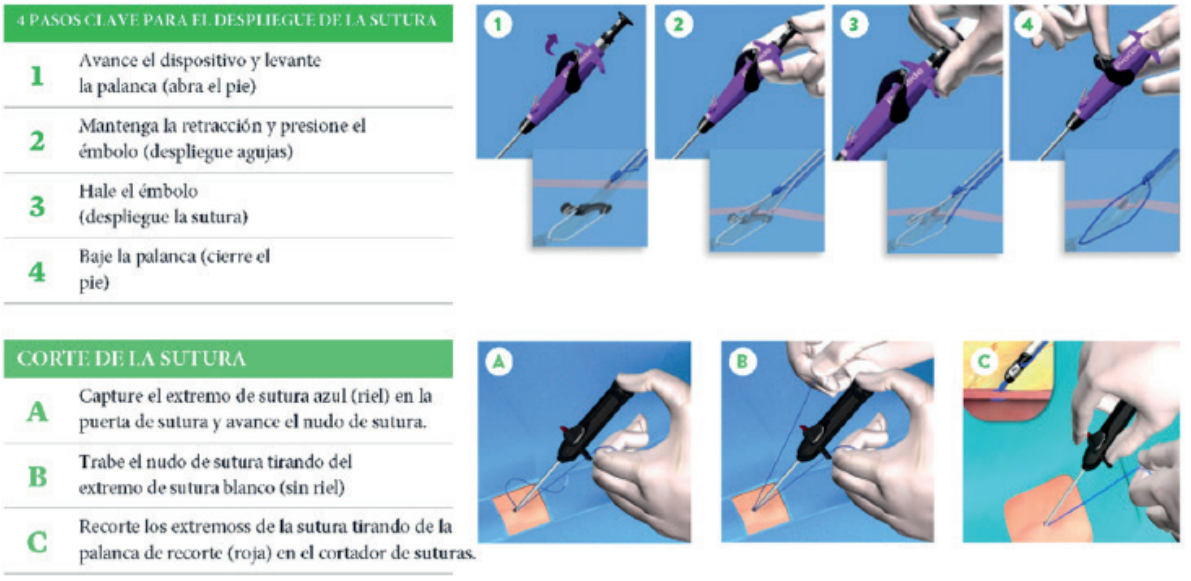

Figure 1. *ProGlide device placement technique.*

used in 40% [CI95%:26.4%-54.8%] of the patients, and self-expandable valves with their corresponding 18 Fr delivery system were used in the rest of the cases.

The secondary puncture site, either femoral or radial, was carried out according to anatomy and by direct puncture in all the cases, whereas for the primary puncture site eco-guided puncture was carried out in 68.0% [CI 95%: 57.5-83.8%] of the cases. In those patients were ultrasound guide was not used the puncture was made through the angiographic guide, with a contrast injection from the site of the secondary puncture, being this one radial or femoral contralateral by crossover (**Table 2**).

The success rate of satisfactory closure of the main access with the single ProGlide device was of 96%. A device failure was observed in only two patients; in both cases the failure mechanism was the non-intentional cut of the main thread in step 2. Manual compression was used for 20 minutes in one case and 25 minutes in the second case achieving the hemostasis of the access site. In none of the cases surgery was required.

The average for the compression time was 4 minutes [IQR: 3-5], with afall of hematocrit of 3 percentage points [IQR:3-4], and in no case transfusions were needed.

DISCUSSION

This study describes the experience of a working team with the use of a single percutaneous closure ProGlide device in patients undergoing percutaneous aortic valve replacement with two kinds of percutaneous valves. The most relevant result was to register a 96% success in the use of a single device by patient, similar to the previously exposed with the use of double ProGlide by access[3,4] which had comparable results in terms of safety and feasibility (success of up to 93.9%)[5].

We believe the success of this technique consists in the accurate choice of access, trying to avoid calcified plaques in the anterior face of the artery and overall an accurate puncture guided by imaging, which allows the entrance of the guide by the center of the anterior face of the artery, which results in a more symmetrical and effective closure of the vessel [7,8].

Using a single device simplifies the procedure by reducing the necessary steps and time in the cath-lab. On the other hand, it allows to optimize economic resources and thus to expand its use, which has as a main goal to reduce hospitalization days, infection incidence at the surgical site and promote early mobilization.

CONCLUSIONS

Based on our experience, we have proven that the exclusive use of a percutaneous closure ProGlide device by each patient is as safe as effective for the closure of the main access site in patients undergoing percutaneous aortic valve replacement, independently if balloon or self-expandable valves are used. Future research is needed in order to have further conclusions on this topic.

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