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Editorial

Vascular closure devices: the jury is still out

Dispositivos de cierre vascular: el debate sigue abierto

Juan M. Ruiz-Nodar,[a,b,*] and Javier Pineda Rocamora[a]

[a] *Unidad de Hemodinámica, Servicio de Cardiología, Hospital General Universitario Dr. Balmis, Instituto de Investigación Sanitaria y Biomédica de Alicante (ISABIAL), Alicante, Spain*
[b] *Departamento de Medicina Clínica, Universidad Miguel Hernández, Alicante, Spain*

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Transcatheter aortic valve implantation (TAVI) is an established treatment for elderly patients with severe symptomatic aortic stenosis. Currently, most procedures are performed through transfemoral transcatheter aortic valve implantation (TF-TAVI) under conscious sedation via vascular access with safe and effective closure.[1] Nonetheless, large-bore transcatheter arterial accesses are inherently associated with a higher risk of vascular and hemorrhagic complications.[2]

The use of vascular closure devices (VCDs) in endovascular procedures has grown exponentially. Their emergence has reduced time to hemostasis, facilitated early ambulation and discharge, and reduced hospitalization costs.[2-4]

However, failed VCDs are not an uncommon finding (1%-8%), and vascular and hemorrhagic complications—most commonly found at the access site—can sometimes determine procedural success or failure.[5,6] Vascular complications significantly contribute to clinical outcomes in the short- and long-term, including length of stay, rehospitalizations, need for blood transfusions, and all-cause mortality.[2,4] Therefore, successful arterial access and closure is critical in TAVI.[2,7,8]

CURRENT DEVICES

The most widely used VCDs for large-bore arteriotomy closure are the suture-mediated closure system, Perclose ProGlide system (Abbott Vascular, United States), and the most recent plug-based MANTA vascular closure device (Teleflex/Essential Medical, United States).

The failure mechanisms associated with the Perclose ProGlide device include suture-related malfunction, unsuccessful deployment, and incomplete vessel wall apposition. Potential errors associated with the MANTA device include failed deployment, intraluminal or subcutaneous deployment, collagen detachment, delivery handle-related arterial occlusion, and incomplete handle apposition.[5,6,8]

The first feasibility studies ever conducted on the MANTA device showed promising safety and efficacy. Afterwards, several registries have presented their findings that compare favorably with suture techniques.[8-11]

Two recent randomized clinical trials have compared the 2 techniques. The MASH trial included 210 patients and found no differences in its primary endpoint: puncture site-related major and minor complications (10% with the MANTA vs 4% with the ProGlide; $P = .16$).[6] In contrast, in the CHOICE-CLOSURE trial of 516 patients, the MANTA device was associated with a higher rate of puncture site-related major and minor vascular complications (19.4% vs 12% with ProGlide; $P = .029$), and a similar incidence of puncture-site bleeding (11.6% vs 7.4%; $P = .133$).[12]

In an article published in *REC: Interventional Cardiology*, Martinho et al.[13] present an interesting single-center observational study on the largest real-world experience with the MANTA device. The aim of the study was to evaluate the safety and efficacy profile of the device in a consecutive unselected cohort of patients referred for TF-TAVI. The registry included 245 patients from March 2020 through February 2022. The participants' median age was 81 years, 52.7% were women, and the median EuroSCORE II was 3.15%. The 30-day TF-TAVI puncture site-related vascular complications were studied according to the Valve Academic Research Consortium (VARC) criteria. Regarding the primary outcome measure of the study—efficacy according to the VARC-3 criteria—successful puncture-site closure was achieved in 92.2% of participants. There were no major vascular or hemorrhagic complications, and only 8.6% experienced minor vascular complications according to the VARC-3 criteria (secondary safety outcome measure). The main predictors of device failure were a minimum femoral artery diameter and, consequently, a higher sheath-to-femoral artery diameter ratio, and the presence of more tortuous and calcified arterial accesses.[13]

Compared with the most recent clinical trials, the study by Martinho et al.[13] found rates of device failure that were lower than those in the MASH trial (7.8% vs 20%), but higher than those reported by the CHOICE-CLOSURE trial (4.7%). According to the authors, some of these differences may be attributed to the varying and inconsistent definitions of device failure across the studies.[6,12]

According to researchers, the study limitations include its single-center retrospective design, the absence of comparisons with other closure devices, and the lack of postoperative ultrasound scans for some of the participants (which were mandatory in the CHOICE-CLOSURE trial, potentially contributing to a higher detection rate of access site-related complications).[12] We should also

*** Corresponding author.**
E-mail address: ruiz_jmi@gva.es (J.M. Ruiz-Nodar).
@RuizNodarJM

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mention that the registry included only patients considered eligible for closure with the MANTA device and excluded those with "unsuitable" anatomies.

To date, the available information, which includes numerous observational studies, 2 current randomized controlled trials, and more than 1 meta-analysis, suggests that vascular and hemorrhagic complications associated with collagen-based VCDs are quite similar to those of suture-based devices. No significant differences in the VCD failure rate have been reported, with identical 30-day all-cause mortality rates in the 2 groups.

CONCLUSIONS

The gradual reduction in the rate of vascular complications is the result of better preoperative assessment and technological support. Meticulous preoperative planning, with multidetector computed tomography for iliofemoral arterial axis study and ultrasound-guided access, should allow for an optimal approach to the access site and avoidance of incorrect cannulations.

Undoubtedly, cannulation of severely calcified arteries is associated with worse outcomes because of the difficulty involved in attaching the suture systems, and the higher risk of poor plug device apposition. Conversely, puncture sites without wall calcification should consistently yield better results, regardless of the type of VCD used.

Finally, regardless of the system used, angiographic or ultrasound confirmation after closure is always necessary to identify undetected VCD failures, vascular occlusions, or subcutaneous deployments, and expedite the implementation of corrective measures.[5,13]

In the search for the ideal VCD, several criteria have been proposed: successful deployment with immediate hemostasis in ≥ 98% of procedures, reduction of device-related major vascular complications to ≤ 1%, versatility to adapt to challenging anatomies, universal applicability with minimal exclusions, user-friendliness, easy access to the arterial site after closure, and the potential for early ambulation.[5] Such a perfect closure device, however, is still far from being a reality, which is why VCD innovation must continue to minimize vascular complications and achieve such goals.

A less well studied yet undoubtedly pivotal variable to achieve favorable outcomes with any VCD is the operator's experience, which is key to guaranteeing closure success and reducing VCD-related complications. However, measuring, quantifying, and analyzing this variable across different studies is a daunting task. Thus, although the perfect device may never become a reality, there will always be experienced operators who prefer certain types of VCDs.

With the current results, the decision to choose one VCD over another should be based on the patient's anatomy and basically on the operator's preferences and experience. An important consideration is that, to date, the MANTA device is more expensive than ProGlide, which, added to the substantially larger number of patients treated with TAVI, could pose a major obstacle to its selection in preference to suture-based systems.

In the meantime, we should consider innovations and technological advancements in the field of VCDs as welcome news for the interventional community. Soon, these advancements will likely position TF-TAVI as the technique of choice for most patients with symptomatic aortic stenosis.

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CONFLICTS OF INTEREST

None declared.

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