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Percutaneous Treatment of Mitral Regurgitation with the PASCAL Device: A Full Grasp of the Pathology?

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The management of mitral regurgitation (MR) has dramatically changed during the last decade. Imaging progress, a better comprehension of MR physiopathology and a growing therapeutic armamentarium widely contributed to this game changing. Thus, numerous approaches have been proposed for transcatheter mitral valve repair (TMVR) of symptomatic and severe MR. Tailored to the anatomy and the underlying mechanism, those techniques, reproducing surgical approaches, offer an effective treatment for inoperable or high surgical-risk patients. The percutaneous toolbox now encompasses mitral valve (MV) replacement, annuloplasty and last, but definitively not least, leaflets approximation.

Despite very promising preliminary reports, the spread of percutaneous MV prosthesis and annuloplasty (either direct or indirect) is still limited, because of technical and anatomical considerations, with a high screen failure rate. Moreover, none of these devices have been evaluated in the setting of a randomized trial yet.

Conversely, the leaflets approximation is by far the most widespread TMVR strategy. Mimicking the surgical approach with suture to create a double orifice, the Mitraclip[®] system (Abbot Vascular, Santa Clara, CA, USA) was the first “new kid on the block”. Since its first implantation in 2003, more than 100,000 procedures have been performed to date. The feasibility, safety and long-term efficacy of this approach is well established based on very large registries (1) and randomized trials (2-4).

The PASCAL repair system (Edwards Lifesciences, Irvine, CA, USA) is a promising competitor (5). This three-catheters (guide, steerable and implant)-based system is designed for an optimized maneuverability. Most of all, the device itself, thanks to its specific design (a 10-mm central spacer, two 25-mm width spring-loaded paddles and two 10-mm length clasps) offers

interesting features that can potentially make it an essential tool for MR corrections: the spacer, intended to fill the regurgitant orifice, is supposed to reduce the residual MR whereas the clasp/paddle pair improves load distribution and reduces stress on the leaflets. Also, the possibility of independent leaflet capture, allowing a theoretical high-quality leaflets grabbing, can be useful in challenging situations like strong leaflet restriction or large coaptation gap. Last, the PASCAL system can be elongated, allowing a narrow profile, thus a lower risk of entanglement in the mitral sub-valvular apparatus.

The promising short-term results of the multicenter, prospective, single-arm CLASP study (6) led to CE Mark approval for the treatment of both primary and secondary MR with the PASCAL system. To date, more than 1,500 patients have been treated with this device, mostly in Europe.

As there can be a world of differences between an industry-sponsored study including carefully selected patients and “real-world” reports, publications of large registries were eagerly expected. In this issue of *JACC: Cardiovascular Interventions*, Mauri et al. report the German experience on 309 patients with severe and symptomatic MR (primary 33%; secondary 52%; mixed 16%) who were treated in 10 highly experienced centers. The results are encouraging with a technical success of 96% and importantly, among the 308 patients discharged alive, a residual $MR \leq 2$ in 93.5% with a mean trans mitral gradient of 3.3 ± 1.5 mmHg. Of note, 73% of patients received only one device, mean procedure time was 96 ± 47 minutes, and independent grasping was applied in 48% of patients. At 30 days, the MVARC device success was 81.9%, with a significant improvement in patients’ symptoms, since 72% of patients were in NYHA \leq class 2 (vs 14% before the index procedure)(7).

Authors should be congratulated for this so-far largest data set, which are a supplemental proof that the PASCAL device is henceforth a full-fledged of the MR percutaneous correction (figure 1). However, this report raises some questions:

- The reporting centers are TMVR-high volume ones, with an extensive experience with the MitraClip system. Thus, the reproducibility of those results by lower-volume centers is questionable. Moreover, evaluating the learning curve of the PASCAL technique in such a setting is therefore at best challenging if not heavily biased. Indeed, thanks to their previous experience of TMVR, the authors, even in their initial experience with the PASCAL, had already overcome challenging steps like trans-septal puncture and comprehensive assessment of the MV. Therefore, a potential head-to-head comparison of the initial experiences of those two techniques would be irrelevant.
- The ongoing CLAPS II F and D trials (NCT03706833) both aim at demonstrating that the PASCAL device is non-inferior to the MitraClip device with respect to the proportion of patients with major adverse events (at 30 days), MR severity reduction (at 6 months) and recurrent heart failure hospitalizations and all-cause mortality (at 2 years) in patients with severe (3+/4+) and symptomatic functional (CLASPS II F) and degenerative (CLASPS II D) MR. Pending those results, operators have to choose between two efficient devices, mainly according to anatomic criteria. At the beginning of the MitraClip experience, anatomic suitability was assessed according to the EVEREST criteria. Owing to the operators experience and substantial technical improvements of the new generations of the MitraClip, EVEREST criteria are no longer used to evaluate the feasibility of the procedure, yet still predict its outcomes. In an appropriate way, Mauri et al. reported hereby relevant anatomical suitability criteria for MitraClip therapy. Worthy of note, in

the present report, some centers initially restricted the PASCAL device for non-complex anatomy, whereas others treated patients deemed unsuitable for a MitraClip. The appropriate patient selection for each device is the next challenge for TMVR experts. This clarification will be all-the-more tough that both devices constantly evolve: the FDA-approved 4th generation of MitraClip now encompasses four clip sizes and offers independently controlled grippers, while a new smaller CE-marked version of the PASCAL (PASCAL Ace) was recently launched.

- The herein reported single leaflet device attachment (SLDA) rate was 2.3%. As a reminder, this rate with the MitraClip was 1 % (125 out of 12334 patients) in the TVT registry, ranging from 1.3% in the beginner (1-18 procedures) to 0.8 % in the well-experienced (>52 procedures) centers (1). At this step, evaluating the significance of this observation would be premature, but one should keep it in mind as future larger registries will tell us if there is a “price to pay” for the theoretically reduced leaflets ‘stress induced by the PASCAL device.

This large real-life report demonstrates the feasibility and the efficacy of the PASCAL device as a TMVR approach but also raises new challenges to be addressed for a full mastery of the percutaneous MR management. What technique offers the best grasp for the toughest anatomies, such as annular or leaflet calcification, very restrictive or short posterior leaflet, small valve area, large coaptation gap or Barlow disease?

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FIGURE LEGEND

Figure 1: Summary of the PASCAL program

Accepted manuscript



CE mark (mitral valve): 2019
Worldwide experience: 1500



	CLASP study ⁶ (n=62)	Mauri V et al. ⁷ (n=309)
Baseline NYHA class III or IV	51.6%	86%
Post procedural residual MR $\leq 2+$	98%	93.5%
Single Leaflet Device Attachment	1.6%	2.3%
CLASP clinical success	86.9%	86.9%
30-days MAE rate	6.5%	4.1%
30-days NYHA class I or II	85%	72%

Next step: CLASP II F and D trials
(evaluation of the non-inferiority to MitraClip)

