Indian Heart Journal 73 (2021) 129–131

Contents lists available at ScienceDirect

Indian Heart Journal

journal homepage: www.elsevier.com/locate/ihj

Short Communication

Mitral regurgitation following PASCAL mitral valve repair system: A single arm meta-analysis

Tikal Kansara [a, *], Ashish Kumar [b], Monil Majmundar [a], Craig Basman [c]

[a] Department of Internal Medicine, New York Medical College - Metropolitan Hospital Center, New York, NY, USA
[b] Department of Cardiovascular Research, Cleveland Clinic, Akron, OH, USA
[c] Department of Cardiology, Lenox Hill Hospital, New York, NY, USA

ARTICLE INFO

Article history:
Received 22 October 2020
Accepted 3 December 2020
Available online 7 December 2020

Keywords:
PASCAL mitral valve repair system
Mitral valve repair
Mitral regurgitation

ABSTRACT

Major consequences of untreated severe mitral regurgitation (MR) includes heart failure, ventricular remodeling and pulmonary hypertension leading to significant morbidity and mortality. MitraClip is the most widely used device for treatment of severe MR. To overcome some of the shortcomings of MitraClip, novel devices like PASCAL mitral valve repair system are developed. We performed a single arm meta-analysis for patients with severe mitral regurgitation (MR) undergoing PASCAL mitral valve repair system. The results showed that 93.8% patients had reduction in MR grade, with an average operative time of 88 min and an average increase of 86.33 m in 6-min walk test.

1. Short communication

Left untreated, severe mitral regurgitation (MR) leads to sequel including heart failure, left ventricular remodeling and pulmonary hypertension.[1] Despite the significant morbidity and mortality associated with untreated MR, there are a significant amount of patients not treated due to the perceived risk of surgery.[2] For the high-risk surgical patient, the only Food and Drug administration (FDA) approved transcatheter repair system, the Mitraclip (Abbott Vascular, Santa Clara, California, USA), reduces MR via a mechanism based off the Alfieri stitch. Because of its inherent limitations, several novel transcatheter devices are in development to overcome the shortcomings of MitraClip; the PASCAL mitral valve repair system (Edwards LiveScience, Irvine, California, USA) is among them. In contrast to previous generation MitraClip devices, PASCAL allows for independent leaflet capture, and contains a nitinol spacer in between the clasping arms to reduce tension on the leaflets. Additionally, the PASCAL device offers a more user-friendly method for steering. The first-in-man study was published in 2017. Till date, less than 200 patients have been reported to have undergone mitral valve repair using the PASCAL system.

Table 1
Baseline characteristics of patients undergoing PASCAL mitral valve repair system for treatment of grade III/IV mitral regurgitation.

Baseline Characteristics	
Age (years)	77.2 (184)
Female	74 (37.82%)
NYHA Class III/IV	143 (77.71%)
Comorbidities	
Hypertension	138/166 (80.72%)
Diabetes Mellitus	45/166 (27.12%)
Pulmonary Hypertension	8/62 (12.9%)
Aortic aneurysm	6/62 (10%)
Cardiomyopathy (ischemic/nonischemic)	63/93 (67.74%)
Previous MI	40/166 (24.10%)
Stroke/cerebrovascular event	50/134 (37.31%)
Aortic Valve Disease	23/62 (37.7%)
Pulmonary Valve Disease	17/62 (27.4%)
Tricuspid Valve Disease	35/62 (56.5%)
Coronary artery disease	48/103 (46.60%)
Peripheral vascular disease	6/93 (6.45%)
Heart Failure	36/62(58.1%)
Renal Disease	32/85 (37.64%)
Chronic lung disease	33/166 (19.90%)
History of cardiac surgery	21/72 (29.20%)
Euro Score II	8.03 (72)
Cadiac device (pacemaker/defibrillator)	25/122 (20.50%)
Atrial Fibrillation	124 (67.39%)
Medications	
Beta blockers	102/122 (83.61%)
ACE-I/ARBs	100/122 (81.97%)
Aldosterone antagonist	65/91 (71.43%)
Loop diuretics	111/122 (90.98%)
Lab Investigations	
eGFR	56.33 (161)

(*continued on next page*)

* Corresponding author. Department of Internal Medicine, Metropolitan Hospital Center, 1901 First Avenue, Room 704, New York, NY, 10029, USA.
E-mail address: tikal_kansara@yahoo.co.in (T. Kansara).

https://doi.org/10.1016/j.ihj.2020.12.003

Table 1 (*continued*)

Baseline Characteristics	
proBNP	2825 (91)
BNP	535 (82)
MR Etiology	
Functional	83/184 (45.11%)
Degenerative	73/184 (39.70%)
Mixed	27/184 (14.67%)
Outcome	
Time of implantation	88 min
Severe bleeding	4/134 (3%)
30 days mortality (all cause)	9/166 (5.42%)
Myocardial Infarction	0
NYHA Class I	34/108 (31.48%)
NYHA Class II	77/126 (61.11%)
Mean increase in 6 min walk distance	88.33 m

We searched PubMed, EMBASE, Web of Science and Google Scholar for original articles of patients undergoing PASCAL mitral valve repair system through September 1st, 2020. Search queries included "PASCAL mitral" and "mitral valve repair system". We performed a single arm meta-analysis of included studies reporting mitral regurgitation grades at follow-up operated with PASCAL mitral valve repair system. Inverse variance method with empirical Bayes estimator of Tau2 was used to pool proportions.

In total, 5 studies were included, comprising 184 patients.[1–5] Baseline characteristics are presented in Table 1. The average age was 77.2 years, 62.2% of patients were males. 82% patients had hypertension, 27% had diabetes mellitus and 67.6% patients had atrial fibrillation. 45.3% patients had functional MR, 34.04% patients

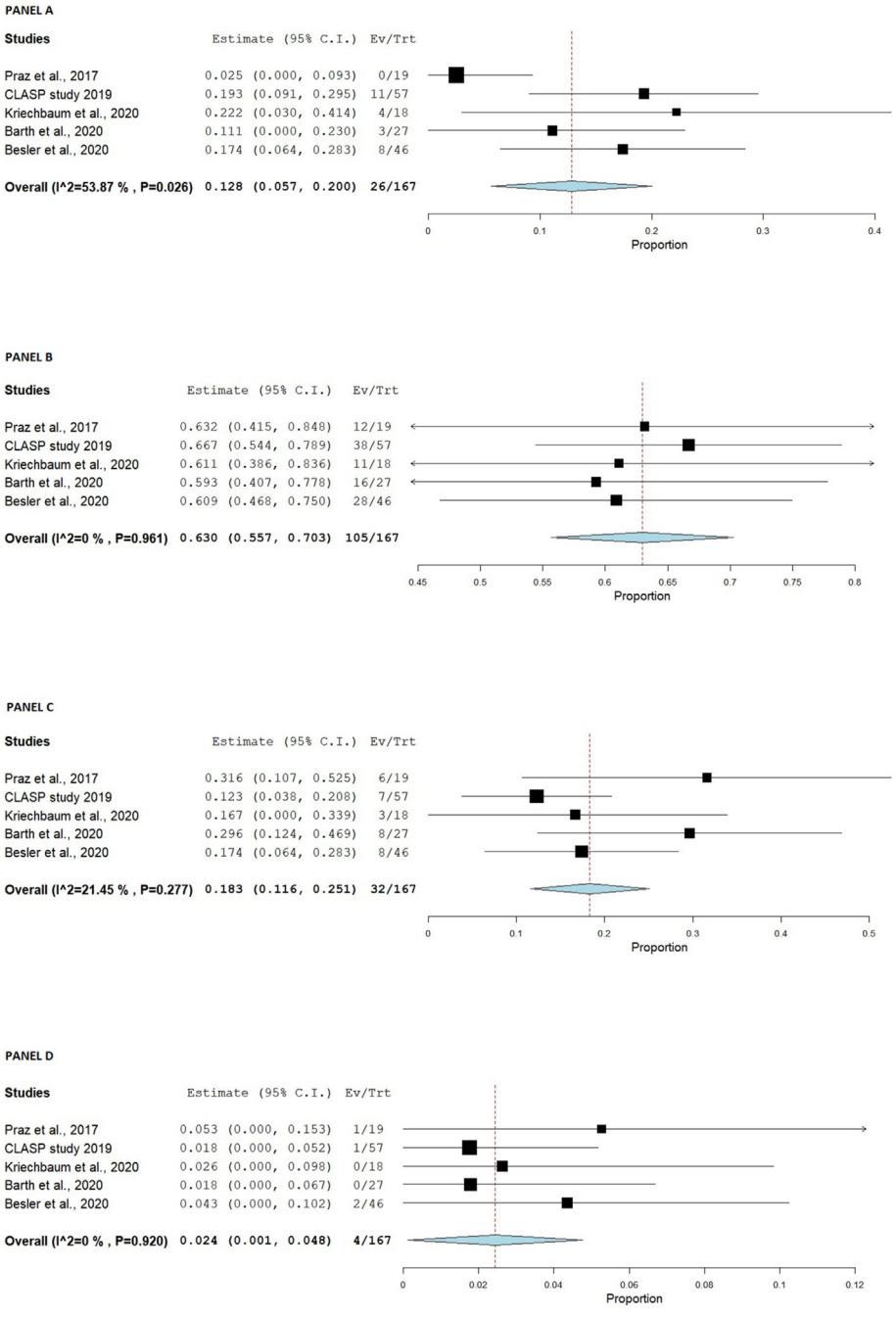

Fig. 1. Forest plots: PANEL A: MR grade 0**; PANEL B:** MR grade 1**; PANEL C:** MR grade 2**; PANEL D:** MR grade 3.

had degenerative MR and 20.7% patients had mixed etiology. All patients had grade III, or IV MR. 3 studies had 30 days follow-up, one study had 5 months follow up and one study had only post-procedural outcomes available. The average time for device implantation was 88 min. Mean increase in 6-min walk test on follow up was 86.33 m. 12.8% (CI 5.7%–20%; I2 = 54%) of patients at follow up had grade 0 MR, 63% (CI 55.7%–70.3%; I2 = 0%) patients had grade I MR, 18% (CI 11.6%–25.1%; I2 = 21%) had grade II MR, and 2.4% (CI 0.1 %–4.8%; I2 = 0%) patients had a grade III MR (Fig. 1). With respect to adverse outcome 4/134 (3%) of the patients had severe bleeding and 30 days all-cause mortality was seen in 9/166 (5.42%) of the patients.

In conclusion, PASCAL mitral valve repair system leads to reduction in MR grade and improved 6-min walk test distance without any adverse outcomes.

Source of research support or funding

None.

Declaration of competing interest

The authors declare they have no conflict of interest.

References

1. Lim DS, Kar S, Spargias K, et al. Transcatheter valve repair for patients with mitral regurgitation: 30-day results of the CLASP study. *JACC Cardiovasc Interv*. 2019;12(14):1369–1378. https://doi.org/10.1016/j.jcin.2019.04.034.
2. Kriechbaum SD, Boeder NF, Gaede L, et al. Mitral valve leaflet repair with the new PASCAL system: early real-world data from a German multicentre experience. *Clin Res Cardiol*. 2020;109(5):549–559. https://doi.org/10.1007/s00392-019-01538-3.
3. Barth S, Hautmann MB, Arvaniti E, et al. Mid-term hemodynamic and functional results after transcatheter mitral valve leaflet repair with the new PASCAL device. *Clin Res Cardiol*. 2020. https://doi.org/10.1007/s00392-020-01733-7.
4. Praz F, Spargias K, Chrissoheris M, et al. Compassionate use of the PASCAL transcatheter mitral valve repair system for patients with severe mitral regurgitation: a multicentre, prospective, observational, first-in-man study. *Lancet*. 2017;390(10096):773–780. https://doi.org/10.1016/S0140-6736(17)31600-8.
5. Besler C, Noack T, von Roeder M, et al. Transcatheter edge-to-edge mitral valve repair with the PASCAL System: early results from a real-world series. *EuroIntervention*. 2020. https://doi.org/10.4244/EIJ-D-20-00216.