Reviewer’s report

Title: Application of Regent Mechanical Valve in Patients with Small Aortic Annulus: 3-year Follow-up

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Reviewer: Ralf Guenzinger

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The authors describe in their study the results and the clinical and echocardiographic follow-up of 40 patients who underwent aortic valve replacement with a size 17 (n=18) or a size 19 (n=22) St. Jude Medical Regent mechanical prosthesis.

- study population is quite young (mean age 47.2±5.8 years), LV function is moderate impaired (about 45%)
- body surface area is 1.61±0.26 m2 (patients with small physical constitution)

Major Compulsory Revisions

Some facts are not conclusive in the presented study:

1. The reason for aortic valve replacement is not clear. Therefore the authors should include a table with preoperative patient characteristics (e.g. kind of aortic valve pathology ...).

For example, mean pressure gradients across the aortic valve determined by echocardiography are approximately 45 mmHg preoperatively, which seems to indicate aortic valve stenosis whereas left ventricular mass index (LVMI) is approximately 117 g/m2, which is not a left ventricular hypertrophy and therefore argues against aortic valve stenosis. Moreover, why should there be a left ventricular mass regression in case of normal LV wall diameters (117 => 80)?

2. In the conclusion the authors stated: „for selected patients with small aortic annulus...“

In the Material and Methods section it is not stated by the authors what their selection criteria were. Is it a prospective or a retrospective analysis? What are the exclusion and inclusion criteria?

Are these 40 patients all patients with small annuli during the enrolment period (01-2008 – 04-2011) and all received a 17 or 19 SJM Regent valve or where there any patients with small annuli received other procedures (i.e. aortic root enlargement, stentless valve, Ross- or Konno- operation).

This has to be mentioned in the manuscript!
3. In the Results section it is stated that “All patients underwent echocardiography examination preoperatively and at one year post-operation”. In the Discussion section the authors state: “by a mean 3-year follow-up, the heart function of all patients (LVEF and LVFS) improved...“ although the authors have only one-year echo data. Therefore they can only talk about 1-year data with regard to LV-function and present only clinical data for 3 years. Follow-up of the patients has to be consistent through the whole manuscript.

4. What kind of mattress sutures were used? Evertting or non-evertting? This is also important when talking about valve positioning and should be mentioned in the manuscript.

Moreover, the St. Jude Medical Regent valve is not a complete supra-annular valve because parts of the sewing cuff remain intraannular.

5. In the discussion section the authors write about patient-prosthesis-mismatch (PPM). In their manuscript the incidence of PPM is only 10% in the size 17 group and 0% in the size 19 group and therefore unbelievable low despite of the low BSA (1.61±0.26 m²) which is comparable or higher. In the manuscript of Sezai et al (2010) the incidence of PPM for the SJM Regent valve of size 17 ranges from 18-84% (4 different studies).


Minor Essential Revisions

1. In the Reference list there is a mistake that should be corrected: reference 2 and 12 are the same!!! Moreover the reference list should be more up to date! The newest reference is from 2007 (5 years old!!!)!!!

2. In case of young patients as in the case of this study, exercise gradients were desirable, because young patients have a more active life and with more exercise the small valve could be a limiting factor.

3. Table 1 shows the operative characteristics. In most of the patients (88 and 87%) concomitant procedures were performed. Mean aortic cross clamp-times (45 and 51 minutes) are unbelievable low and does not match with the published literature for these patients and with my personal experience for this kind of patients and this kind of pathology (AV- and MV-surgery => 45 minutes???) This fact should be readdressed by the authors.

In my opinion the manuscript does not receive a high enough priority for publication in the Journal of Cardiothoracic Surgery especially because there are several studies existing in the literature (see below) dealing with this subject and
their presentation is better elaborated. The Reviewer does not expect that revision will sufficiently increase the priority and therefore cannot consider a revised version of this paper. Maybe the authors can make a new submission of the data with more patients, a longer FU, and better elaborated methods (e.g. stress echo).


**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests