Author's response to reviews

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

Authors:

Dong Zhao (zhao.dong@zs-hospital.sh.cn)
Chunsheng Wang (wang.chunsheng@zs-hospital.sh.cn)
Tao Hong (hong.tao@zs-hospital.sh.cn)
Cuizhen Pan (pan.cuizhen@zs-hospital.sh.cn)
Changfa Guo (guo.changfa@zs-hospital.sh.cn)

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Author's response to reviews: see over
Dear editor,

Thank you very much for your work about our manuscript submitted to your respectable journal. The precious comments from you and the reviewers help improve the quality of our research. We have checked the manuscript and revised it according to your comments (The changes in revised manuscript were marked in red). Please refer to the following.

**Reviewer #1**

**Comment:** This paper can be accepted after some revisions.

**Reply:** Thank you very much for your comments.

**Comment:** How did the author choose the patients to use this small Regent valve, especially a 17mm valve?

In our present study, only patients with both small aortic annulus and BSA (1.51 to 1.77m²) underwent the Regent valve replacement. From the information of St Jude Company, the 17mm Regent valve is suitable for patient with BSA <1.7 m². So a 17mm Regent valve almost fits most patients’ require. If they have bigger BSA, we might choose other procedure such as root enlargement.

**Comment:** There are many spelling and grammar errors in the manuscript, need careful revision.

We have invited a native English speaker to revise the paper. The manuscript was revised throughout for typos and grammar.

**Reviewer #2**

**Comment:** This paper can be accepted with Minor Essential Revisions

Thank you very much.

**Comment:** In the paper, the patients’ BSA is around 1.51 to 1.77m2, if the author meet with a patient with small annulus and bigger BSA, for example, 1.95 m2, what will the authors do?

From the information of St Jude Company, the 17mm Regent valve is suitable for patient with
BSA <1.7 m², and 19mm Regent valve is suitable for patient with BSA<1.9 m². In our study, the patients’ BSA is around 1.51 to 1.77m². A 17mm Regent valve may satisfy most patients. If we have a patient of BSA 1.95 with small aortic annulus, we might do a root enlargement procedure.

**Comment:** A 17 mm valve is really difficult for doctors to choose, what is the reason that the authors choose this valve?

Because our patients had small BSA, we used the 17mm Regent valve.

**Comment:** There are many spelling errors in the manuscript, please revise

We have invited a native English speaker to revise the paper. The manuscript was revised throughout for typos and grammar.

**Reviewer #3**

**Comment:** This paper can be accepted with Minor Essential Revisions

Thank you very much.

**Comment:** In this paper, the authors applied 17 or 19mm valve in the operation, for us, it is always difficult to make the mind to use a 17mm valve, what is the rationale for the authors?

From the information of St Jude Company, the 17mm Regent valve is suitable for patient with BSA <1.7 m2, and 19mm Regent valve is suitable for patient with BSA<1.9 m2. In our study, the patients’ BSA is around 1.51 to 1.77m2. A 19 mm Regent valve satisfied all patients, and a 17mm Regent valve may satisfy most patients. Hence, in the operation, if the measure of aortic annulus was less than 19mm, we used a 17mm regent valve.

**Comment:** Describe more clearly the two patients of PPM after implantation of 17mm valve.

Revised in the manuscript

**Comment:** Many spelling and grammar errors found in the manuscript.

We have invited a native English speaker to revise the paper. The manuscript was revised throughout for typos and grammar.
Major Comment: 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)?

Thank you very much for your good suggestion. We added a new table ‘Table 1. aortic valve characteristics’ in the manuscript. In our study, our cases included aortic stenosis (congenital), aortic stenosis (degenerative), aortic insufficiency(rheumatic), aortic stenosis and insufficiency(rheumatic), and SBE. In both groups, more than 60% were rheumatic valvular diseases, which is different from the data in western countries. That is why we have a approximately 45 mmHg mean pressure gradients preoperatively and LVMI of 117 g/m2. At one year after operation, we observed the diameter of left ventricle decreased, leading to mass regression.

Major Comment: 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!

Our study was a retrospective study. In the period (01-2008 – 04-2011), 1946 AVR procedures with mechanical prostheses were performed in our hospital. A 17-mm or a 19-mm SJM Regent was implanted in 54 (2.8%) patients. Of those 54 patients, 14 patients were excluded because of the big aortic annulus (>19 mm in diameter). And
then do the follow-up and analysis. We added it to the manuscript. In the manuscript, “for selected patients”, I was going to mean with low BSA. I have modified the sentence.

**Major Comment:** 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.

Actually, we have one year follow-up data as well as a mean-3-year-follow-up data. But I did not use 3-year data because we think it was not comparable, for example, we could not compare the data at 4-year-follow-up to the data at one-year-follow-up. We have revised the manuscript as required.

**Major Comment** What kind of mattress sutures were used? Everting 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.

Thank you very much for the suggestion. We have revised the manuscript as suggested. We used non-evertting mattress sutures.

**Major Comment** 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).

According to the information of St Jude Company, the 17mm Regent valve is suitable for patient with BSA <1.7 m2, and 19mm Regent valve is suitable for patient with BSA<1.9 m2. In our study, as the reviewer mentioned, the BSA of the two groups was 1.61±0.26 m2. Actually, the BSA in 17mm group was 1.53±0.12 m2. That is main reason for our low PPM rate (10% in the size 17 group and 0% in the size 19 group). Another reason may be related to the aortic valve pathology. If the patients have severe aortic valve stenosis, they may have subannulus hypertrophy, which may result in high aortic transvalvular pressure gradient. Besides, in the papers of Minardi G, et al. and Sezai A, et al., the incidence of PPM was 10.5% (2/19) and 10.3%, similar to our study. We added those to discussion part.

Minor Comment 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!!!)!!!
I have revised the manuscript and add some present papers.

Minor comment. 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.
Yes, that is good suggestion. We will pay more attention to our future work.

Minor comment. 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.
We contribute the low clamp-time firstly to our valve pathology. Actually, when we performed a valve replacement in a patient with severe aortic stenosis (for example, degenerative case), aortic valve replacement alone may need 50 minutes. However, if it is a rheumatic one or SBE, 20 to 30 minutes was enough for aortic valve replacement. A mitral valve replacement also took around 25 minutes. Tricuspid valve repair normally did not use any clamp-time. For concomitant CABG, normally
one graft concerning the young age of the patients. Note that rheumatic heart disease +SBE took around 70% of all cases. Secondly, we are experienced group. Yearly, we have more than 1500 cases of valve replacement.