Author’s response to reviews

Title: St. Jude Medical Trifecta Aortic Valve: results from a prospective regional multicentre registry.

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Author’s response to reviews:

Dears Prof. Zamvar and Prof. Taggart,

Please find enclosed our revised manuscript entitled: “St. Jude Medical Trifecta Aortic Valve: results from a prospective regional multicentre registry”, for your reconsideration for possible publication in the Journal of Cardiothoracic Surgery.

We appreciated the encouraging and constructive comments by the Reviewer, which were very valuable in refining the afore-mentioned manuscript. We hope that we have now answered all questions, and that the manuscript has now been satisfactorily improved to be accepted for publication.

Please find below our itemized responses to yours and Reviewers’ comments. The response to the reviewer’s detailed comments is provided on the following pages. Comments by the reviewer are pasted in step-by-step.

Therefore, on behalf of my co-authors, I am submitting the enclosed revised manuscript for possible publication in the Journal of Cardiothoracic Surgery. It has not been submitted for publication nor has it been published in whole or in part elsewhere. I attest to the fact that all authors listed on the title page have read the manuscript, attest to the validity and legitimacy of the data and its interpretation, and agree to its submission to Journal of Cardiothoracic Surgery. I acknowledge that both I and the other authors have read the Instructions for Authors and agree with its contents.

Yours sincerely

Giovanni Mariscalco, M.D., Ph.D.

Reviewer #1:

1.1

“The life time for a second generation bioprosthesis is 10 to 15 years and to a 3rd generation bioprosthesis this time should be even greater. This period, greater to 6 months should be considered as a medium time evolution and not late evolution. This reason for this is well explained in the limitations, but even though I would consider best to name medium time evolution instead of a late one.”
Response and revision: We kindly thank the Reviewer for his/her important observations, and we totally agree with him/her. Therefore, we tried to emphasise the need for further studies that will assess the long-term results, confirming our early documented favourable data. In order to increase the clarity of our data presentation, we now delete the words “late outcome” (please “Results” section, “Early and medium-term clinical outcomes” section, page 6, line 17).

Reviewer #2:

2.1.

“I congratulate the authors for this interesting paper; however several issues must be addressed: 1 The sample is heterogeneous in some aspects which may compromise interpreting the results: surgical approach (full vs mini-sternotomy); 54.5% of concomitant procedures; different implantation techniques (supra vs infra-annular), reoperations (n=?, this data is missing) and remote follow-up;”

Response and revision: The observations of the Reviewer is interesting and certainly deserves further comments. We fully agree with the fact that the patient population enrolled in the present multicentre study is heterogeneous with reference to the surgical approach and implantation techniques. The present study was designed as a prospective multicentre registry with the aim to evaluate the use and outcome of this valve during the routine clinical and surgical activity in several participating hospitals. Our aim was to avoid strict inclusion and exclusion criteria in order to have a better insight into the usage of this valve in the everyday life. Although these variable have been previously demonstrated to minimally affect the durability of bioprosthesis in other larger series, we recognize the importance of the Reviewer’s comment, and we have now introduce his/her observations as “limitations” (please see page 10, lines 13-16). With reference with the variable “reoperations”, we apologize for the lack of clarity in our previous manuscript version. The redo cases were definitively not included in the present study. We have now clearly indicated the exclusion of reoperations in “Methods” section (please see “Patient selection” paragraph, page 4, line 6).

2.2.

“Considering that upon completion of 30 months (30th June 2013) the follow-up was closed, it is unlikely to have a maximum follow-up of 34 months (see Results, line 51).”

Response and revision: We apologize for this embarrassing type-setting error. The Reviewer is perfectly right: the maximum follow-up is 30 months. We have now corrected it (please see page 6, line 30).

2.3.
“It is written in the line 58 of Methods: " where the follow-up was not possible...". Based on this statement, authors must include in the results the number of patients who indeed had complete clinical and echocardiographic follow-up at 6 months and 1 year.”

Response and revision: We apologize for the unclarity of the sentence. We refer to the deceased patients (n= 1 at 6 month, and 16 at 1 year), in which echocardiographic examinations could not be obviously performed. Causes of death were collected and obtained by telephone interviews of family members and/or confirmed or clarified by the general practitioners. We have now slightly changed the sentence (please see pages 4 and 5, lines 27 and 1, respectively).

2.4.

“There is a missing word in "Hemodynamic results" (line 40)"

Response and revision: We apologize for this error. Corrected.

2.5.

“The range of logistic EuroScore in table 1 differs from that written in the "Results" (line 13).”

Response and revision: The reviewer is correct in underlying the difference between the two ways to report the data. Again, we apologize for the unclarity in reporting this data (range/Results vs interquartile range/Table). We have now change the text in the paper according to the table report, in order to avoid any misunderstanding to the readers (please see page 6, line 7)

2.6.

“In table 2, probably due to a typing error, itens of the column of variables are not corresponding to the data of the column of implants."

Response and revision: Again, the reviewer is accurate and right. We apologize for this error, and we have now corrected the typing error and aligned the data to the corresponding variables (please see revised Table 2).

2.7.

“In table 4, the number of patients who had an Echo done in the four different time frames is missing.”

Response and revision: We apologize for this lack of data, which have now been inserted (please see revised Table 4).
2.8.

“Figures must be self-explanatory, therefore the number of patients under follow-up has to appear in the figure 1.”

Response and revision: We have now added the requested data.

Reviewer #3:

3.1.

“Dear authors. Some comments and suggestions to try to help your nice paper.-Logistic Eurscore- it’ known this score was not developed for valve surgery and overestimates in about 3 times the mortality. The best score would be STS or EuroScore II or scores specific for valve surgery.”

Response and revision: We totally agree with the Reviewer, but unfortunately the dataset was created including the additive EuroScore, and we are not able to provide the EuroScore II nor the STS.

3.2.

“Patient population is old (average age 75 years). The older the patient more is valve durability. As the follow up period is short it would be nice to see what happens to these valves in a younger population where the durability is supposed to be lower. What is the usual lower age limit to indicate a biological prosthesis in your centers? How many patients received a mechanical valve at the same period? Another interesting data would be how many TAVIs were implanted at these institutions during the study period?”

Response and revision: We thank the Reviewer for his/her valuable observations. Bioprosthesis implantation was decided on the basis of the cut-off 65 years according to the international guidelines, unless specifically requested by the patient. Unfortunately, we are not able to provided the precise data on number of implanted mechanical valves or performed TAVI during the study period at each centers.

3.3

“30 months mean follow up is a relatively short period to evaluate valve durability, even in this relatively old population.”

Response and revision: The reviewer’s comment is adequate and we agree with it. We tried to emphasise the need for further studies that will assess the long-term results, confirming our early documented favorable data. In order to increase the clarity of our data presentation, we decided
to avoid the use of the words “Late outcome” and to highlight the point that our results are related to the early and mid-term outcome. Please also see point #1.1.

3.4.

“What was the anticoagulation/antiplatelet treatment regime and for how long in the PO period?”

Response and revision: Generally, patients with bioprostheses were managed with anticoagulation therapy for the first 3 months, and aspirin thereafter.

3.5.

“5 endocarditis occurred during follow up. How many of this patients were operated for native valve endocarditis?”

Response and revision: We thank the Reviewer for his/her relevant question. None of these patients affected by endocarditis were originally operated on for native valve endocarditis (please see page 7, lines 2 and 3).

3.6.

“The authors recognized the study limitations such as the small sample size, lack of control group with other bioprostheses and relatively short follow up period. The hemodynamic performance of this valve was quite good as shown in other studies.”

Response and revision: We thank the Reviewer for his/her positive comments.