Author's response to reviews

Title: Initial experience with off-pump left ventricular assist device implantation in single center: retrospective analysis

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Author's response to reviews: see over
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Dear Editor in Chief:

We are pleased to submit a revised manuscript (MS # 4036301994490340) entitled “Initial experience with off-pump left ventricular assist device implantation in single center: retrospective analysis” to the *Journal of Cardiothoracic Surgery*. We have also addressed the reviewers’ concerns point-by-point below.

Reviewer 1:

We appreciate the reviewer’s opinion about the manuscript, but respectfully disagree with him that this submission does not offer new data. While the paper he refers to (Placement of long-term implantable ventricular assist devices without the use of cardiopulmonary bypass by Sun et. al) came from the same group at our institution, there are fundamental differences between the two.

The paper by Sun et al. only describes the surgical technique of off-pump LVAD placement as a method paper on how to perform the new technique, and it does not provide any clinical outcome, which is the ultimate goal for establishing any new technique, nor does it provide morbidity/mortality of patients undergoing OP-LVAD placement compared to LVAD implantation on CPB.

On the other hand, the message of our paper is twofold: 1.) Is OP-LVAD a feasible technique to learn and adopt? 2.) Are the clinical outcomes at 1 year comparable to current techniques of LVAD implantation on CPB? A determination of clinical outcomes will ultimately determine whether or not this technique becomes more accepted at other institutions.

Reviewer 2:

1. The data presented in the manuscript details implants that occurred between 2004 and 2007. Why haven’t more recent implants (3 additional years of experience 2008-2010) been included? Are the authors still using off pump techniques? Has the original technique been modified? If more recent data is available, this should be incorporated into the manuscript and results updated. If no further data is available, an explanation should be provided.

We appreciate the reviewer’s questions about the lack of inclusion of more recent implants; however, we decided to only present the data with the initial experience from 2004-2007. This technique has not been modified since the original publication by Dr. Sun, who was the only surgeon at our institution to perform this technique. Unfortunately, he is no longer with our institution. The initial study was performed during the aforementioned time period where he decided to perform off-pump LVAD
implantations on his first 29 consecutive patients, and it was our intention to focus on the
data from the initial learning experience with this new technique.

2. The authors, on pages 11 and 12 compare their bleeding rates to those of the
REMATCH and INTREPID trials, both of which included only large implantable
devices and are almost a decade old. Moreover, in this study, 15/27 devices are
the smaller 2nd generation continuous flow pumps. Hence, the comparison is
unfair. The authors should compare their continuous flow bleeding outcomes (for
those 15/27 pts) with those of contemporary series (HMII DT and BTT trials, both
published in NEJM).

While we agree with the reviewer that the most recent studies with contemporary devices
should be included, the studies in the NEJM by Slaughter et al. used stricter definitions of
bleeding: requiring > 2 units PRBCs in 24 hours. The decision was made to use
INTERMACS definitions for all causes of morbidity such as stroke, respiratory failure,
renal failure, infection, and bleeding (> 4 units PRBCs in 24 hours) for consistency with
the most current standardized definitions in the mechanical device support community.

On the other hand, the incidence of bleeding outcomes in Slaughter et al. is much higher
than ours, 29.6% vs. 81%, which is to be expected as they used stricter definitions of
bleeding outcomes to assess success of the technique. Perhaps their study will lead to a
change in the current definitions for future studies.

3. The authors spend a significant portion of the paper defining INTERMACS
criteria in the Methods section (page 5-6). This is unnecessary as these are
standardized definitions that can be referred to the INTERMACS database.
Similarly, the authors discuss in detail their surgical technique which was already
the subject of a previous well-written manuscript (J heart Lung Transplant 2008).
I recommend this section be shortened and referred to in the reference section.

We respectfully agree and accept the suggestion to remove the extensive definition of the
INTERMACS criteria as these are standardized definitions, and the revised paper has
been updated to reflect this change. Thank you for the suggestion.

4. The authors in the conclusion attribute the non-statistically significant
improvement in one year survival to the off-pump technique. This needs to be
softened up. Many events, changes in postoperative care, etc. can influence 1
year outcome.

We respectfully agree and accept the suggestion to include other variables that may affect
one year survival after off-pump LVAD implantation and have revised the paper to
reflect this change. Thank you for the suggestion.

5. Authors should include causes of death for all mortalities.
We appreciate the reviewer’s suggestion and the revised paper has been updated to reflect this change. Here are the causes of death in one year: sepsis with multi-organ failure (n = 6), coagulopathy with bowel necrosis (n = 1), and respiratory distress with right heart failure (n = 1). Thank you for the suggestion.

6. Authors describe results using 2 decimal points (27.95 days, std. dev 18.98, etc.) on page 10. Numbers should be rounded to whole figures.

We respectfully agree and accept the suggestion to present all figures using whole numbers and the revised paper has been updated to reflect this change. Thank you for the suggestion.

Thank you again for your consideration. Should you have any questions, please feel free to contact me at hamdy.elsayed-awad@osumc.edu or (614) 293-8487.

Sincerely,

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