Author’s response to reviews

Title: Thrombus aspiration catheter improve the myocardial reperfusion of STEMI patients with high thrombus load during the emergency PCI operation

Authors:

Ping Li (lip0214802@sina.com)
Jiang-Wen Ruan (ruanjw0216345@sina.com)
Ming Liu (lium0214304@163.com)
Si-Yao Li (lisy012547@sina.com)
Zheng-Dong Wang (wangzd0213587@sina.com)
Wen-Chao Xie (xiewc024358@sina.com)

Version: 1 Date: 12 Aug 2019

Author’s response to reviews:

Reviewer reports:

Reviewer #1:

What antecedent drugs were used on these patients.

Reply: Patients with first diagnosis of STEMI and emergency PCI were included in this study. There was no standardized antecedent cardiovascular drug therapy in the past.

Were GP IIb/IIIa inhibitors used before or after aspiration?

Reply: GP IIb/IIIa inhibitors were used indiscriminately when coronary angiography was performed again after stent implantation and no reflux was found in the coronary artery of culprit.

Why is there such a long delay from symptom onset to hospitalization? This is many hours longer than most clinical trials, indicating perhaps a more mature thrombus less susceptible to complete aspiration.

Reply: There was no statistical difference in time of symptom onset to hospitalization between the two groups, even though it was relatively longer than other studies. Even if a more mature
thrombus was formed, we do not think it will affect the improvement of myocardial reperfusion by thrombus catheter aspiration.

Was the thrombus in any way quantified to justify the title of high thrombus burden?

Reply: We have revised the title as “Thrombus aspiration catheter improve the myocardial reperfusion of STEMI patients with high thrombus load during the emergency PCI operation”.

How was the sample size of 200 arrive at? Was there a primary endpoint and what were the assumptions in the trial?

Reply: Guangxi Yulin First People’s Hospital can radiate around 10 million people. The chest pain center was licensed in 2015. There were 1679 cases of PCI, of which 336 cases were emergency PCI in 2016. There were 2093 cases of emergency PCI, of which 402 cases were emergency PCI in 2017. After excluding emergency PCI that does not meet the criteria for admission, in order to ensure that the project can be completed within the time required and the results of the study are meaningful, the number of patients is designed to be about 200 conservative values.

Were these consecutive patients and did they need to have specific consent for randomization?

Reply: We numbered these patients continuously according to the time of admission. In their informed consent letters, we have clearly informed them what type of surgery to perform, and there is no need to give specific consent to randomized grouping.

What was the pre-PCI TIMI flow in this group of individuals?

Reply:

Comparison of TIMI blood flow in infarct-related artery before emergency PCI

<table>
<thead>
<tr>
<th>TIMI flow grades/ groups</th>
<th>A group (n=101)</th>
<th>B group (n=103)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIMI 0 level (n, %)</td>
<td>93 (92.1)</td>
<td>91 (88.3)</td>
<td>0.802</td>
</tr>
<tr>
<td>TIMI 1 level (n, %)</td>
<td>8 (7.9)</td>
<td>12 (11.7)</td>
<td></td>
</tr>
<tr>
<td>TIMI 2 level (n, %)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>TIMI 3 level (n, %)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
</tbody>
</table>
Note: PCI: percutaneous coronary intervention; TIMI: thrombolysis in myocardial infarction; A= Thrombus catheter aspiration, B= Balloon dilatation.

Note : This table is not recommended in the original manuscript.

What were the regional wall motion scores? Hard to detect an ejection fraction benefit with ejection fractions as high as these.

Reply : We don't have data on the regional wall motion scores for the time being. Although the LVEF of thrombus catheter aspiration group (group A) was higher than that of balloon dilatation group (group B), there was no statistical difference between the groups. Thus, we believe that the effect of thrombus catheter aspiration on myocardial remodeling is uncertain, which requires more in-depth study.

Secondly, what were the EKGs of these patients and what was the ST segment resolution?

Reply : ST segment resolution is not used as a detection index in this experiment, and there is no such data for the time being.

Was myocardial blush also assessed?

Reply : Our hospital has not yet carried out MBG testing, there is no such data for the time being.

Reviewer #2: This is an interesting study performed by Ping Li and colleagues. Nevertheless I believe that the focus of this manuscript better goes with a journal in the field of cardiology and not cardio-thoracic surgery. Therefore I would suggest to redirect the paper to another journal.

In my opinion the study and especially the value can be significantly improved by increasing the number of patients. Due to the "small" number the results are flaw and a meaningful conclusion cannot be drawn, although the topic is of great importance.

Reply : We appreciate your suggestions and concerns, and the sample size in future studies will be increased to make our results more meaningful.

Reviewer #3: Comments

In this study the authors have evaluated the safety and efficacy of thrombus aspiration catheter over conventional balloon dilatation in patient with STEMI with high thrombus load. The
authors have reported non-significant difference in echocardiographic outcomes and MACE between the groups. However, TIMI flow grade improved significantly without any incidence of stroke.

General comments

1. The whole manuscript needs grammatical correction and rephrasing of several sentences

Reply : We have revised the grammar of the whole manuscript.

2. The sample size appears inadequate and it requires a reasonable hypothesis based on previous studies to find the adequate number of patients in order to get adequate number of outcomes.

Reply : Guangxi Yulin First People's Hospital can radiate around 10 million people. The chest pain center was licensed in 2015. There were 1679 cases of PCI, of which 336 cases were emergency PCI in 2016. There were 2093 cases of emergency PCI, of which 402 cases were emergency PCI in 2017. After excluding emergency PCI that does not meet the criteria for admission, in order to ensure that the project can be completed within the time required and the results of the study are meaningful, the number of patients is designed to be about 200 conservative values.

3. In the current study, insufficient number of MACE does not provide statistically significant conclusive evidence.

Reply : The insufficient number of MACE may be related with the limited sample size. In addition, the sample size in future studies will be increased to make our results more meaningful.

4. There is no baseline echocardiographic data to compare with post PTCA echocardiographic variables. The change in LVEDD and EF after PTCA should have compared with baseline variables before PTCA in both the groups.

Reply : Because of the time limit of D2B, there was no routine cardiac ultrasonography before emergency PCI. Thus, there is no data of LVEDD and EF before PTCA.

Specific Comments

1. Title should be modified suitably

Reply : We have revised the title as “Thrombus aspiration catheter improve the myocardial reperfusion of STEMI patients with high thrombus load during the emergency PCI operation”.
2. Rephrase sentence in conclusion based on result.

Reply: We have revised the conclusion as “the application of thrombus aspiration catheter during the emergency PCI operation of STEMI patients with high thrombus load can better improve the myocardial reperfusion. There is no basis for increasing the stroke occurrence risk. However, it obviously fails to improve the recent prognosis and more studies need to explore its effect on myocardial remodeling and major adverse cardiovascular events”.

3. Introduction should be short and succinct.

Reply: We have revised the Introduction.

4. Write in detail about statistics, sample size calculation.

Reply: We have provided details of all the data.

5. Discussion should have been more focused.

Reply: We have revised the Discussion.