Letter to the Editor

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A Prospective Meta-Analysis (PMA) Could Harmonize the Studies Focusing on Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)

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With the rapid development of novel surgical devices such as Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) and the eagerness of clinicians to use them, there is a risk that their usage in clinical practice exceeds the evidence-based principles required for their introduction. This might be truer in the fields, such as trauma surgery, where the patient population and the disease (injury) burden are very heterogeneous and time-sensitive, and thus not fitting for the more gold standard investigation methods. The studies that are currently being published considering the use of REBOA in clinical settings have significant limitations and raise concerns in terms of the risk of biases that might influence the gold-standard evidence-based synthesis. This paper elaborates on the merits of a Prospective Meta-Analysis (PMA) in reducing such biases.

Keywords: *Prospective Meta-Analysis; Resuscitative Endovascular Balloon Occlusion of the Aorta; Surgery; Trauma; Wounds; Injuries*

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DEAR EDITOR,

With the rapid development of novel surgical devices and the eagerness of clinicians to use them, there is a risk that their usage in clinical practice exceeds the evidence-based principles required for their introduction. This might be truer in fields such as trauma surgery, where the patient population and the disease (injury) burden are very heterogeneous and time-sensitive, and thus not fitting for the more gold standard investigation method where patients are randomized to a treatment. This has led to retrospective or prospective non-randomized analyses of different treatments in the trauma setting. However, new-generation statistical methods have given the opportunity to tackle this challenge by using these non-randomized data to gain high-quality evidence synthesis.

In a recent publication by Castellini and colleagues, the authors investigated the effectiveness of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in the management of major bleeding from torso injuries due to trauma by using a comprehensive systemic review and meta-analysis [1]. Exsanguinating hemorrhage is still the leading cause of preventable deaths after traumatic injury [2]. During the last decade, there has been a rapid development in REBOA devices and techniques as well as educational efforts for their use to get temporary hemorrhage control [3]. However, their role in clinical practice has been questioned and, to a large extent, compared to Resuscitative Thoracotomy (RT). The aforementioned study compares REBOA vs RT with/without REBOA, and REBOA vs non-REBOA. The results of the meta-analysis showed a significant decrease in mortality in the REBOA compared to RT subgroups, which was consistent with previous systematic reviews [4,5]. Nevertheless, as the

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authors do declare in their manuscript, there are several limitations with their investigation in terms of study design, participant selection bias, survival bias, and also heterogeneity and selection bias in reporting the results in the included studies in the meta-analysis.

To overcome these limitations, prospective collaborative methods with the use of Prospective Meta-Analysis (PMA) that has the capability of enhancing the breadth of evidence synthesis could be of value. In a PMA compared to a conventional retrospective meta-analysis, the studies are identified and evaluated to be eligible for inclusion before the results of these studies are released. To find the planned and ongoing studies, a systematic search in clinical trials and cohort registries and, subsequently, early contact with the investigators should be undertaken [6]. The cornerstone of a PMA is that the analysis strategies are determined before any results to the research question are known [7]. Therefore, a PMA has the capability of reducing the risk of publication bias and selective outcome reporting bias by agreeing on a standard set of core measures and time-point outcomes with the investigators in advance. In addition to its benefits in harmonizing the key outcomes, it has the capability of collecting studies with varied participants, selection criteria, and intervention design, which is the superiority of PMA over a multi-center study [8].

Apart from the conventional method of conducting a PMA (using the summary of results), it can also be designed in the context of a network meta-analysis or an individual patient data analysis. Through a network meta-analysis, instead of comparing two interventions with a narrow research question, the investigators can visualize and interpret all treatments for a given condition or disease, and all the possible comparisons between them, such as REBOA, partial REBOA, RT, and no-REBOA, can be included in the network meta-analysis to compare and assess their effectiveness. In a meta-analysis of individual patient data, instead of using summary data of each published paper, the raw data of each individual and participant can be collected and analyzed [9].

Although conducting a PMA could decrease several potential sources of bias, it may have some difficulties in terms of collaboration and forming a research network. Some investigators may not cooperate to contribute their data. A paradigm shift in moving from conventional retrospective systematic reviews and meta-analyses has its challenges since there is an innate tendency against changes in how individual physicians practice medicine, and also between healthcare systems. Here, the involvement of surgical societies or organizations is of great importance, as they could play a leading role.

In conclusion, the number of studies investigating the role of REBOA in trauma, especially in early hemorrhage control, is increasing. Most of these studies have limitations in their methodology that raise concerns for the conclusions drawn. Here we propose PMA as a new-generation statistical method. The role of leading surgical societies as stakeholders to increase collaboration for PMA is of importance. Although PMA is no magic wand to fix all the methodological limitations that arise in clinical studies where randomization is not feasible, it has the potential to harmonize the studies included in the meta-analysis to a greater extent.

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Ethics Statement

(1) All the authors mentioned in the manuscript have agreed to authorship, read and approved the manuscript, and given consent for submission and subsequent publication of the manuscript.
(2) The authors declare that they have read and abided by the JEVTM statement of ethical standards including rules of informed consent and ethical committee approval as stated in the article.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Author Contributions

MHT and SM developed the presented idea. MHT and RB prepared the first draft of the paper. All authors contributed to the final version of the manuscript.

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