Letter to the Editor

Response to "Not All Grams per Deciliter of Hemoglobin Are Equal"

We appreciate the reader's commentary as well as the thought-provoking discussion inspired by REAL-PE.[1] We certainly agree that there are different types of bleeding and that procedural blood loss represents a single category of bleeding. That being said, the bleeding risks associated with large-bore thrombectomy in anticoagulated patients extend beyond procedural blood removal and include (but are not limited to) access site and catheter-associated traumatic bleeding. All bleeding types are captured in this analysis. Furthermore, we defined and presented bleeding risk within 7 days of the procedures by multiple metrics in REAL-PE, including clinically meaningful metrics such as hemoglobin decrease by >5 g/dL and requirement for blood transfusion. The association of requirement for blood transfusion with increased mortality (and morbidity) has been well documented in multiple patient categories including those at highest risk of pulmonary embolism as well as in patients following both vascular and cardiac procedures.[2-5] Regardless of etiology, bleeding to this degree certainly portends a serious adverse outcome.

We appreciate that ultrasound-assisted catheter-directed thrombolysis (USCDT) and mechanical thrombectomy are very different procedures. This is one of the many reasons we advanced the work of REAL-PE to evaluate utilization of these diverse therapies in a robust real-world population. We will respectfully challenge the comments referring to bleeding "during USCDT" representing bleeding "under thrombolytic therapy." Contemporary USCDT with low doses of administered thrombolytic represent a distinct therapy compared with traditional, full-dose systemic thrombolytic treatments. We need to better characterize these bleeding risks because they are distinct. REAL-PE helps advance that work.

With regard to risk stratification, more work is in process. Multivariable regression was performed in REAL-PE to allow identification of unique associations of therapies with major bleeding risk without the data elimination that can occur from incompletely matched pairs required by other strategies. As our tools advance, so too will our ability to further elucidate these comparisons. Even the strengths of the Truveta platform utilized in REAL-PE and our ability to harness them will continue to improve with time. We look forward to this work as well as to implementation of real-time big data analytic techniques similar to those used in REAL-PE to monitor safety and efficacy of strategies in diverse fields of clinical care including and beyond the treatment of pulmonary embolism.

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Peer review statement

Associate Editor Sahil A. Parikh had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Editor in Chief Alexandra J. Lansky.

Declaration of competing interest

Peter Monteleone is an advisory board member for Abbott, Boston Scientific, Medtronic, and RapidAI; is a consultant for Abbott, Penumbra, Boston Scientific, and Medtronic; and reports speaker honoraria from Boston Scientific and Medtronic. Daniella Kadian-Dodov receives honoraria for participation in educational conferences from Abbott, Boston Scientific, Women As One, and Medscape and receives research support from Philips for work unrelated to this manuscript. Sahil A. Parikh is an advisory board member for Abbott, Boston Scientific, Medtronic, Philips, and Cordis; has conducted research for Abbott, Boston Scientific (data and safety monitoring board), Shockwave Medical, Surmodics, TriReme, Veryan Medical, Acotec, Concept Medical, and MedAlliance; is a consultant for Abiomed, Canon, Inari, Penumbra, and Terumo; and holds equity in Encompass Vascular, Advanced Nano Therapies, and Efemoral.

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