

Author reply

Re: Letter - Conflicting evidence and methodologic concerns in recent meta-analyses of tranexamic acid in radical cystectomy

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We thank our colleagues for their thoughtful and constructive comments regarding our recently published systematic review and meta-analysis on tranexamic acid (TXA) use during radical cystectomy. Their letter raises important points and contributes meaningfully to the discussion of a topic for which high-quality evidence remains limited.

As acknowledged in our manuscript, the main limitations of this review include the heterogeneity of the analyzed population, the scarcity of randomized controlled trials, and the variability in TXA infusion protocols and outcome definitions across studies. These limitations are inherent to the currently available literature and should be taken into account when interpreting the pooled estimates.

We agree that thromboembolic outcomes deserve particularly cautious interpretation, especially because event risk may accumulate over time. In the present meta-analysis, these outcomes were not treated as a single uniform endpoint; rather, they were grouped according to the definitions and followup frameworks reported in the original studies and analyzed as distinct postoperative thromboembolic outcomes. Given the limited evidence available in the setting of radical cystectomy, we considered preservation of the original study-level definitions methodologically preferable to imposing an artificial harmonization that could itself introduce misclassification. Nevertheless, we fully

agree that this approach may contribute to clinical heterogeneity, even in the setting of low statistical heterogeneity, and that the pooled estimate should therefore be interpreted as a comparative safety signal rather than as a precise estimate of absolute risk at a single standardized time point.

We also thank the authors for identifying the discrepancy in Figure 5 regarding the total number of patients in the placebo arm of the Ahmed et al study. As correctly noted, the total number in that specific forest plot should be 468 rather than 438. We repeated the analysis using the corrected value. Importantly, this adjustment did not change the overall interpretation of the result. The original pooled estimate for perioperative blood transfusion was OR 0.56 (95% CI 0.32–0.97), whereas the corrected analysis yielded OR 0.58 (95% CI 0.35–0.95), thus maintaining the same direction and significance of the association, still favoring TXA for this endpoint. We are grateful for the opportunity to clarify this point.

We agree with our colleagues that the available evidence remains fragile; however, our study was designed precisely to synthesize the best currently available data in a field where robust randomized evidence is still scarce. In our view, the main message of this review remains unchanged: TXA should not be considered an innocuous intervention in the context of radical cystectomy. Its use may still be appropriate in selected patients and under careful clinical judgment, but the current evidence does not support its uncritical or routine protocolized use in this setting.

We hope that ongoing and future well-designed randomized studies, adequately powered for both efficacy and safety outcomes, will provide the clarity needed to better define the role of TXA during radical cystectomy.

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