Editorial Commentary

Prophylactic Use of Biologic Mesh in Ileal Conduit (PUBMIC trial)

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Parastomal hernia (PSH) may occur in up to 30% of all patients undergoing radical cystectomy with ileal conduit (IC) (1). PSH repair is a challenging surgery with 50% recurrence rates (2). In an attempt to reduce PSH formation, a plethora of strategies have been proposed, including a prophylactic mesh placement at the time of stoma construction (3).

The only randomized controlled trial in this field, conducted by Liedberg *et al.*, demonstrated that prophylactic synthetic mesh placement significantly reduced the incidence of clinical PSH at two years post-surgery (11% *vs.* 23%) (4). Moreover, prophylactic synthetic mesh placement continued to provide protection against clinical PSH beyond two years post-surgery, indicating sustained long-term benefits. Yet, no improvement in the rate of radiological PSH was observed. Based on these findings, the authors concluded that prophylactic synthetic mesh implantation during urinary diversion with IC decreases the risk of PSH without increasing the risk of short- or long-term complications related to the mesh.

It should be highlighted that a major limitation of this study was that clinicians assessing PSH during follow-up were not blinded to the treatment allocation and, thus, rather subjective. The latter might have introduced a systematic bias in the collection and interpretation of the findings since patients with prophylactic mesh placement could be presumed to be less likely to have developed a clinical hernia during follow-up (5-7). Indeed, high-quality studies from colorectal surgery define hernia recurrence as a composite measure based on clinical examination, blinded radiological imaging (abdominal computed tomography and/or ultrasonography), and patient-reported outcomes (8). Incorporating clinical assessment, radiological findings, and patient-reported outcomes could offer a more comprehensive evaluation of hernias in future relevant urological trials.

Despite the innovative findings by Liedberg *et al.*, prophylactic mesh placement during IC has not made its way into clinical practice. Moreover, its use is not currently addressed in the European or American guidelines for muscle-invasive bladder cancer (9,10). Additionally, the positive findings of the first randomized controlled trial in this field were not endorsed by high-volume centers specializing in the surgical management of bladder cancer (11,12). Indeed, also in our tertiary referral center for bladder cancer, we avoid using prophylactic mesh placement during IC (13). Similarly, placement of a mesh to prevent PSH is not currently recommended for colostomies (14). Nevertheless, it seems that the surgical technique, and not the prophylactic mesh placement, is the main driver for optimal outcomes after stoma construction (15).

The PUBMIC study, the second randomized controlled trial on strategies for PSH prevention after IC, addresses the safety and efficacy of prophylactic biologic mesh placement (16). Still, its findings necessitate critical analysis. Radiological and clinical PSH rates did not significantly differ between patients receiving prophylactic biologic mesh and those who received a standard IC without mesh

placement up to two years after surgery. Similarly, the surgical interventions for hernia repair were similar between the two groups. Overall, no mesh-related complications were reported. It should be noted that, although Liedberg *et al.* focused exclusively on open surgeries, in the PUBMIC trial, 50% of the included patients underwent robotic radical cystectomy, which enhances the generalizability of the study and reflects modern real-world clinical practices. Still, no subgroup analyses focusing on the surgical approach or on patients at higher risk of PSH were performed.

Compared to the earlier study by Liedberg *et al.*, the PUBMIC trial used a biologic mesh and not a synthetic mesh. In both studies, prophylactic mesh placement was associated with longer operative time. High-volume, high-quality studies from colorectal surgery suggest that synthetic mesh is superior to biologic mesh in patients with ventral hernia, in terms of two-year hernia recurrence risk. Nevertheless, both types of mesh present similar short- and long-term safety profiles (17). Still, it should be stressed that the price of a biological mesh is more than 200 times higher than that of a synthetic mesh (18).

Even though the prophylactic placement of a mesh at the time of IC construction may not protect against PSH development within two years following surgery, one strategy to maximize its value might be to target patients at increased risk of PSH development (19). Patients with higher body mass index, chronic obstructive pulmonary disease, prior abdominopelvic radiation, previous abdominal surgeries, or locally advanced disease may profit from prophylactic mesh placement. In particular, obese patients or patients with chronic obstructive pulmonary disease experience increased intraabdominal pressure, making them particularly prone to hernia formation (20). Additionally, patients with prior radiation therapy or compromised fascial integrity due to previous surgeries, as well as those undergoing extensive resection due to locally advanced disease, may benefit from mesh reinforcement to mitigate structural weaknesses (21,22). It seems that a personalized risk assessment is mandatory to identify those who might benefit the most from this intervention. Therefore, future studies should prioritize investigating these specific patient populations. Still, given that Liedberg *et al.* showed an improvement only in clinical PSH development and that the PUBMIC trial showed no benefit from prophylactic mesh placement within two years following surgery, only patients with longer life expectancy after surgery should be selected for prophylactic mesh placement.

The PUBMIC trial has significantly contributed to the ongoing debate, demonstrating that prophylactic mesh placement at the time of IC construction does not appear to prevent PSH development within the first two years after surgery. Notably, the trial utilized the FlexHD structural biological mesh, which is absorbable. This characteristic raises the possibility that patients receiving a biological mesh may still develop PSH in the longer term (23). Consequently, further research is essential to investigate the long-term efficacy of prophylactic mesh placement. However, conducting such studies presents substantial challenges due to the large sample sizes required. The high mortality rate associated with radical cystectomy further complicates this, as it leads to a progressive reduction in the number of at-risk patients who remain available for long-term analyses (24).

Taken together, the PUBMIC trial represents a significant contribution to the role of prophylactic mesh placement. While its findings do not support its routine use in all patients undergoing radical cystectomy with IC, they emphasize the importance of patient-specific strategies and long-term outcome monitoring. Overall, the feasibility and safety of prophylactic mesh placement, as demonstrated in this trial, lay the groundwork for its selective application in some high-risk cases. Thus, future studies should focus solely on patients at high risk for developing PSH after radical cystectomy with IC.

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Footnote

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