
We appreciate the comments from Kalampokis and colleagues on our study [1] and we share their conclusion. We believe that well-designed clinical trials are needed to obtain high levels of evidence for the surgical treatment of prostate cancer. For other treatments, high levels of evidence have been acquired via clinical trials not directly analysing the main treatments, resulting in high degrees of recommendation that have been interpreted in a confused way by clinicians [2].

We recognize the difficulty in achieving a good design for clinical trials in the radical prostatectomy (RP) setting. First, the endpoint measured in a clinical trial must be well defined and accurately objectifiable. Moreover, if the evaluable treatment is a surgical step, as posterior reconstruction of the rhabdosphincter (PRR) is, the rest of the surgical procedure must be the same, which is difficult to achieve even if it is always performed by the same surgeon. The distribution of patients must of course be randomised, but the surgeon should not be conditioned by this randomisation at the beginning of the overall surgery. Therefore, the randomisation should only be communicated to the surgeon at the start of the procedural step being investigated. Obviously, the patient and the clinicians who perform follow-up should be blinded to the procedure.

In this particular trial, the outcome measure of urinary continence recovery is hard to evaluate and has important methodological aspects to consider. In a post hoc analysis of our clinical trial, we assessed some of the questionnaires commonly used to assess urinary continence recovery and observed that the only strict measure of urinary continence is based on question 3 of the abbreviated version of the Expanded Prostate Cancer Index Composite (EPIC-26) questionnaire [3]. Our evaluation based on use of no pads was the only measure of urinary continence recovery that was related to PRR (manuscript accepted for publication in Actas Urológicas Españolas). This instrument for measuring urinary continence after RP is the only one related to patient quality of life in the post-RP setting [4]. An uncontrolled confounder in the evaluation of urinary continence in men after RP is de novo—and often transient—development of overactive bladder [5], which can contaminate the results and may sometimes be caused by residual urinary tract infections or the impact of reabsorption of suture material. Finally, we note that the effectiveness of PRR can probably be attributed to the different positioning of the urethrovaginal junction and lengthening of the posterior urethra [6].

Conflicts of interest: The authors have nothing to disclose.

References


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