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Platinum Opinion

Prostate Biopsy: Hyperbole and Misrepresentation Versus Scientific Evidence and Equipoise

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The European Association of Urology (EAU) and the American Urological Association (AUA) guidelines regarding the superior prostate biopsy approach are in conflict. The recently updated AUA guidelines state that clinicians may use either the transrectal (TR-Bx) or the transperineal (TP-Bx) route when performing prostate biopsy (conditional recommendation; evidence level: grade C) [1]. The AUA guidelines provide the level of available evidence next to the recommendation. By contrast, the EAU guidelines state that the TR-Bx approach should be abandoned and replaced with TP-Bx owing to the lower risk of infectious complications (strength rating: strong) [2]. The EAU guidelines provide an explanatory footnote that the grade of evidence used to formulate the recommendation is of low certainty, with limited confidence in the estimated effect of TP-Bx in reducing infectious complications.

It is interesting that despite recognizing that the evidence available is of low quality, the two guideline panels came to different conclusions. Perhaps more interesting is the manner in which these guidelines are presented to and consumed by clinicians. The absence of high-quality evidence has left a void that is increasingly occupied by opinions, debates, and point-counterpoint debate among experts. Many a debate has taken place in our specialty (active surveillance vs treatment of prostate cancer, partial vs radical nephrectomy, robotic vs open surgery), but few contemporary issues can elicit as visceral a reaction as that observed during discussions comparing TR-Bx and TP-Bx.

It is virtually impossible to escape the repeated proclamations in various fora, including peer-reviewed journals, medical news reports, and social media outlets, that TP-Bx is the superior technique. Often, selected TP-Bx studies with minimal infectious complications are contrasted with

selected TR-Bx studies with the highest infection rates. This hyperbolic approach to describing existing data has manufactured an ecosystem in which the purported “virtually zero” risk of infection after TP-Bx is viewed as the truth. It is one thing to engage in spirited banter by describing TR-Bx as a dirty or transfecal procedure in order to make a point, but it is an entirely unnecessary and willful distortion of the evidence to refer to TR-Bx as unethical or medical malpractice. Given that TR-Bx is used by the vast majority of the urological community worldwide, such discourse is not only libelous to fellow professionals but also creates an environment of confusion and distrust for patients. In reality, there is wide variation (within and across regions) in the rates of infectious complications reported for both TR-Bx and TP-Bx. It is unclear how the proponents reconcile the European reports of higher infectious complication rates after TP-Bx with antibiotic prophylaxis (eg, 3.2% in the meta-analysis used in EAU guidelines and 4.3% in a multicenter study) and the lower rate of infections after TR-Bx (1.1% of men biopsied in the Göteborg-2 trial) [3–5].

The professional organizations that develop guidelines are clearly not responsible for how their constituents (urologists and the public) consume or misrepresent the guidelines. However, clear, unambiguous, and evidence-based messaging can reduce the risk of misunderstanding or misrepresentation. Although the quality of evidence and rationale for the strength ratings are rightfully disclosed in the footnotes, most readers probably do not read past the top-line recommendations. The EAU guidelines explicitly state that TR-Bx should be abandoned and give a strong rating for TP-Bx, but they also give a strong rating for TR-Bx with iodine rectal preparation, and the workflow diagram includes a criterion on whether TP-Bx is “feasible”. This

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suggests that the strong recommendation favoring TP-Bx by the EAU panel is somewhat conditional, and not as categorical as has been promoted.

It is worth mentioning that RCTs used in the meta-analysis that forms the basis for the EAU guidelines were quite variable (in prophylaxis, technique, and definitions) and none was conducted to assess differences in infectious complications between the two procedures. Furthermore, the UK population study referenced in the guidelines to support TP-Bx also demonstrated significant trade-offs, such as high rates of urinary complications and hospital admissions, that are not discussed in the EAU guidelines [6]. This selective use of supportive data and omission of clinically relevant countervailing information may raise concerns about a balanced approach during the review process. Readers should be aware of the panel's acknowledgment that the strong rating favoring TP-Bx is not necessarily based on strong evidence, but is rather based on the panel's overall judgment regarding the clinical implications of infectious complications.

The AUA guidelines do not reference the three main studies used to formulate the EAU guideline recommendation favoring TP-Bx. They refer to the multiple ongoing RCTs on TR-Bx versus TP-Bx (from Europe and the USA) and suggest waiting for the results to provide necessary comparative effectiveness data [7–10]. By contrast, the EAU guidelines do not mention any ongoing RCTs on this topic. It is curious that the EAU guidelines panel has chosen to await the results of RCTs before making recommendations about antibiotic prophylaxis for TP-Bx, but the guidelines neither mention any ongoing RCT nor acknowledge the need for trials comparing TR-Bx and TP-Bx.

Perhaps the trend towards TP-Bx has permeated clinical practice in some regions to such an extent that the EAU guidelines panel has lost equipoise, and any data, even of low certainty, would have garnered a strong recommendation for TP-Bx. Let us hope that this is not the case, and that the door is still open for the guidelines, which are

promoted as living documents, to incorporate stronger evidence as it becomes available. Whether one believes in the superiority of one biopsy procedure over the other, high-quality evidence demonstrating comparative effectiveness must remain the final arbiter. It is only then that we can transition from belief-based practice to evidence-based practice.

Conflicts of interest: The author has nothing to disclose.

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