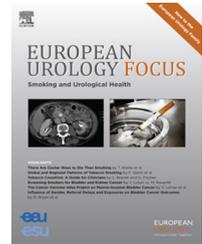


available at www.sciencedirect.com
journal homepage: www.europeanurology.com/eufocus



Grey Zone

Grey Zone: Urinary Incontinence

Andrea Tubaro^{a,*}, Arjun K. Nambiar^b,
Members of the EAU Guidelines Urinary Incontinence Panel

^a Department of Urology, La Sapienza University, Sant'Andrea Hospital, Rome, Italy; ^b Freeman Hospital, Newcastle-upon-Tyne Hospitals NHS Trust, UK

In an ideal world, clinical guidelines would be based on outcomes from standardised reviews and meta-analyses of high-quality randomised clinical trials. Urinary incontinence (UI) is an area in which high-quality evidence is not always available or forthcoming. Rather than blame ourselves for not providing the missing evidence, we need to explore the reasons for the gap before we try to implement a solution. For recommendation in a guideline, diagnostic and therapeutic strategies generally should have proven clinical utility, involving availability, feasibility, effectiveness, and cost issues.

The problems with UI stem from it being both a symptom and a sign. Subjective (patient-reported) and objective (clinician-elicited) measures of UI can be used to both diagnose the condition and evaluate the outcome, with contradictory results sometimes reported when patient and surgeon opinions are compared. The very definition of UI can be a matter of debate: how often and how much does a patient have to leak to be deemed incontinent?

Another problem we have is with diagnostic tests; these are used not only for diagnosing UI but also for measuring other parameters of lower urinary tract function. The diagnostic accuracy and prognostic utility of these tests can vary significantly depending on the dysfunction being measured. We know, for example, that voiding diaries can help in measuring the frequency of UI episodes, but we have little proof that this is a useful prognostic tool. Pad tests may quantify the amount of leakage an individual experiences on a given day, but is this representative of their daily experience? Is there any correlation between increasing pad weight and treatment outcomes? Evaluating the clinical utility of diagnostic tests is difficult, especially for conditions

that do not have a clearly defined and measurable diagnostic threshold such as UI. As an example, some would argue that urodynamic evaluation via cystometrography is the gold standard test for lower urinary tract function, but using it as a diagnostic tool for UI is confounded by the possible coexistence of other conditions or phenomena such as detrusor hypocontractility or overactivity, increased bladder sensitivity, low bladder compliance, and outlet obstruction. This is before we even begin to consider the individual variability in urodynamic findings in the same individual at different time points.

Another clouded issue is outcome parameters for treatments for UI. Patient- and surgeon-reported outcomes may differ: patients may be objectively “dry” (by some definition) but may develop side effects such as pain, constipation, or dyspareunia that negate any positive effects of treatment. Conversely, a patient who is markedly debilitated by incontinence and unable to leave home may report an operation as astoundingly successful despite still experiencing leakage of small amounts a few times a week. The problem is the variable relationship between quality of life (QoL) and objective outcome measures. UI is largely about QoL, and treatments should be aimed at improving QoL for individual patients, although we still need objective outcome measures to understand whether treatments provide the effect they are intended to deliver. A similar improvement in QoL can be achieved with different balances of efficacy and side effects, which is why counselling and establishing shared goals is such an important aspect of UI management.

When looking into the different outcome parameters that have been used in functional urology, regulatory

* Corresponding author. Department of Urology, La Sapienza University, Sant'Andrea Hospital, Via di Grottarossa, 1035, Rome 00189, Italy. Tel. +39 06 3377 7712; Fax: +39 06 3377 5059. E-mail address: andrea.tubaro@mac.com (A. Tubaro).

agencies are increasingly focused on patient-reported outcomes (PROs) because these are considered to be more relevant to patients compared to other objective measures such as pad tests and voiding diaries. We all agree on the importance of PROs in clinical research, but these are outcome measures that will vary significantly according to how patient expectations are managed, and as a result can be a potential source of bias in a clinical trial setting.

Our understanding of the pathophysiology of UI remains unclear, and different treatments were developed to address the various possible pathophysiological mechanisms. We expect certain treatments to work in certain subsets of patients, but we are still unable to accurately identify responders upfront. Some of the recommendations in the EAU guidelines are currently based on expert opinion and they may remain so for some time. Having said that, we can certainly design better trials to address some of the grey areas in UI. We need to improve the external validity of randomised trials by targeting the different patient populations that we deal with in our practice, including children, the frail elderly, and men with storage dysfunction. We do not know whether prophylactic anti-incontinence surgery makes sense at the time of prolapse surgery. We do not know whether measuring urethral sphincter function helps in selecting patients for different surgical techniques for stress UI. The list goes on. A perusal of the guideline will highlight these areas and we have tried to be as objective as possible in our assessment of the available evidence.

One possible solution is the organisation of patient registries. A registry for patients with urgency UI could help in evaluating the effectiveness of different interventions in

the real world. A registry on surgery for male post-prostatectomy stress UI could shed some light on the outcome of male slings and artificial sphincter surgery in this patient population. Registries have their own drawbacks, but for real-world assessment of interventions they can be invaluable. Randomised trials often exclude large subsets of the population, but these large subsets are still going to come through our doors in need of help. We need to know whether our scientifically studied treatments with their statistically significant outcomes will help the human being on the receiving end, irrespective of the “exclusion criteria”.

Another issue to address is quality measures for UI treatment, as there needs to be a consensus around the metrics to be used. Perhaps the retreatment rate is the single parameter that, despite its limitations, would be available in most countries and centres to measure the “effectiveness” of an intervention. The caveat is that in the world of functional urology, intervention includes everything from counselling to surgery. There is no surgery without counselling, and the relative weight of the two interventions on patient QoL is hard to discern.

Functional urology, and particularly UI, remains an exciting and challenging field of research. The level of complexity is one of the things that drew us into the field, and is undoubtedly what will keep us busy in the coming years.

Conflicts of interest: Andrea Tubaro has received consultancy fees from Allergan, Astellas, and AMS/Boston Scientific, and investigator fees from Ipsen. Arjun K. Nambiar has nothing to disclose.