# Users' Guide to the Urological Literature

## How to Use an Article About Therapy

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**Purpose:** Most surgical interventions have inherent benefits and associated risks. Before implementing a new therapy we should ascertain the benefits and risks of the therapy and assure ourselves that the resources consumed in the intervention will not be exorbitant.

**Materials and Methods:** We suggest a 3-step approach to using an article from the urological literature to guide patient care. We recommend asking whether the study can provide valid results, reviewing the results and considering how the results can be applied to patient care.

**Results:** Key methodological characteristics that have an impact on the validity of a surgical trial include randomization, allocation concealment, stratification, blinding, completeness of followup and intent to treat analysis. To the extent that the quality is poor inferences from this study are weakened. However, if its quality is acceptable, one must determine the range within which the true treatment effect lies (95% CI). One must then consider whether this result can be generalized to a patient and whether the investigators have provided information about all clinically important outcomes. It is then necessary to compare the relative benefits of the intervention with its risks. If one perceives that the benefits outweigh the risks, the intervention may be of use to the patient.

**Conclusions:** Given the time constraints of busy urological practices and training programs, applying this analysis to every relevant article would be challenging. However, the basics of this process are essentially what we all do hundreds of times each week when treating patients. Making this process explicit with guidelines to assess the strength of the available evidence will serve to improve patient care. It will also allow us to defend therapeutic interventions based on available evidence and not on anecdote.

*Key Words: evidence-based medicine; databases, bibliographic; information storage and retrieval; urology; PubMed*

Urologists are constantly faced with clinical scenarios that require additional evidence to support decision making on a daily basis. EBCP has been defined as the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."[1] The quality of evidence depends on the design of the study and its methodological quality, which should be carefully scrutinized before applying it to patient care.

Scales et al introduced the first article of the Users' Guide to the Urological Literature by elaborating on the principles of EBCP and the hierarchy of evidence concept.[2] In a subsequent review article Krupski et al outlined effective and time efficient approaches to searching the urological literature for the best available evidence.[3] We focus on the critical appraisal of surgical trials that relate to therapy and/or prevention. A clinical scenario relating to the treatment of stress urinary incontinence is used as a practical exercise to illustrate the use of this framework as it applies to the urological literature. Review and discussion of the overall quality of the contemporary incontinence literature or of clinical concerns with the treatment of stress urinary incontinence are beyond the scope of this article and not its focus.

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### CLINICAL SCENARIO

You are in the office seeing the last patient of the day, an overall healthy and sexually active 57-year-old white female who was referred to you for assessment and treatment of urinary incontinence. Her chief complaints are leakage with coughing, sneezing and lifting her grandchildren. Medical history is notable only for 3 uncomplicated vaginal deliveries. She has not undergone any prior incontinence or prolapse surgeries. Physical examination demonstrates a well estrogenized vaginal mucosa, urethral hypermobility, defined as greater than a 30-degree deflection on a cotton swab test, and no evidence of pelvic organ prolapse. Urodynamic evaluation demonstrates no significant detrusor hyperactivity, and normal bladder compliance and capacity as well as normal pressure normal flow voiding without post-void residual urine. Stress urinary incontinence is demonstrated by a Valsalva stress test with a leak point pressure of 83 cm $H_2O$.

The patient has been compliant with a dedicated program of pelvic floor muscle exercises for more than 1 year but has experienced only minimal improvement and still requires protective pads. She wishes to explore more definitive options in the form of surgery. You counsel her that she would likely benefit from an anti-incontinence procedure such as TVT® and review the potential benefits and risks of this procedure with her. She seems happy with the plan but mentions that her best friend underwent Burch colposus-



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pension at the same time as abdominal hysterectomy and has been dry. She also mentions that the surgeon of her friend said that the Burch procedure remains the gold standard procedure for urinary incontinence. She asks whether she should undergo the same procedure.

You indicate to her that the mid urethral polypropylene sling has become the most popular procedure for stress urinary incontinence in the United States and you believe that it is as good as Burch colposuspension, while less invasive. You promise to investigate any available comparisons of the 2 options and discuss them with her upon a return visit. She is agreeable to this plan and schedules a followup consultation with you in 1 week.

## THE LITERATURE SEARCH

Having recently read the article by Krupski et al on how to search the urological literature effectively,[3] you decide to apply this newly acquired knowledge by performing a literature search. Remembering the PICOT framework, which stands for type of patient (P), intervention (I) of interest, comparison (C) intervention, outcome (O) of interest and type of trial (T), you formulate the focused clinical question that you would like to answer: "In a female patient with stress urinary incontinence (P), does a TVT (I) compared with a Burch colposuspension (C) improve the stress urinary incontinence symptoms (O) when investigated in a randomized controlled trial (T)?"

Ideally you would hope to find a systematic review of several high quality studies of this topic or an evidence-based synopsis. Therefore, you direct your first search to the evidence-based reviews function in OVID™, which is available to you through your local institution, and use the individual search terms colposuspension, tension-free vaginal tape and urinary incontinence. After they are combined this query returns 30 abstracts (date of access May 03, 2008), of which one represents an abstract from the Cochrane Central Register of Controlled Trials with the title, Prospective multicenter randomized trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence.[4] This study appears to address exactly the question that you are investigating. While recognizing that this search strategy is insufficient to identify all available evidence in this field, you decide to retrieve this article and review it carefully.

## STUDY SUMMARY

The study by Ward and Hilton represents a multicenter, randomized, controlled trial that was performed at university hospitals and district general hospitals in the United Kingdom and Eire to compare TVT with colposuspension as primary treatment for stress incontinence.[4] The study enrolled 344 female patients with stress incontinence between May 1998 and August 1999, of whom 175 and 169 were randomized to TVT and colposuspension, respectively. The primary end point of the study was cure of stress incontinence, defined as a negative 1-hour pad test and a negative stress test on urodynamic evaluation 6 months after surgery. The investigators found no statistically significant differences between cure rates in the TVT and colposuspension groups (115 of 175 patients or 66% vs 97 of 169 or 57%, respectively). Bladder injury was more common in the TVT group, whereas other outcome measures, such as operating room time, hospital stay, time to return to normal activity and time to spontaneous micturition, favored the TVT group. The investigators concluded that the TVT procedure shows promise for urodynamic stress incontinence because of comparable success rates and overall decreased perioperative morbidity.

## HOW TO USE AN ARTICLE ABOUT A SURGICAL THERAPY

Before implementing a new therapy you should ascertain its benefits and risks, and ensure that there is enough evidence to support the decision to embark on the new therapy. Ideally EBCP as it relates to therapy should be based not only on a single study, but on several high quality randomized trials with similar findings that have been summarized in a systematic review and meta-analysis. The critical appraisal of review articles will be the subject of a future contribution to this series. Meanwhile, systematic reviews and meta-analyses remain relatively rare in the urological literature, often forcing us to rely on individual studies, as in this case.

We outline a 3-step approach to critically appraise an article about surgical therapy (see Appendix). 1) You should assess whether the study is valid. In other words, do the results of the study represent an unbiased estimate of the treatment effect, ie can you believe the results? 2) You must review the results. 3) You should assess whether the results are applicable to your patient.

### Are the Results Valid?

***1) Did the 2 groups begin the study with a similar prognosis? a) Did the investigators consider the surgical learning curve?*** When critically appraising surgical trials, unlike drug trials, it is of paramount importance to pay attention to differential expertise bias.[5–7] Bias is defined as "any trend in the collection, analysis, interpretation, publication or review of data that can lead to conclusions that are systematically different from the truth."[8] Differential expertise bias stems from the fact that most surgeons favor 1 approach (because they are more experienced or comfortable with it) over another to treat a certain problem. The magnitude of bias that differential expertise can introduce into the study depends on 3 considerations, including 1) whether the number of participating surgeons with expertise in the 2 procedures is equal in the 2 groups, 2) how steep the learning curve of the new procedure is and 3) whether the comparison group is undergoing a new technique that is technically challenging. In this situation the results of the trial might be biased toward the less technically challenging procedure.

In the trial by Ward and Hilton no detailed information was provided about the training, experience or minimum number of procedures a surgeon must have completed to be eligible for this study.[4] Colposuspension, which represented an established procedure at the time of trial accrual (May 1998 to August 1999), was performed according to the standard technique at each institution. On the other hand, all surgeons underwent "training in the TVT procedure in a recognized center."[4] However, this training was not standardized and the assessment of surgical competence was left to individual surgeon judgment. Of note, TVT was a new procedure at the time of study initiation and it had only been first described 2 years previously by Ulmsten et al.[9] There-