2007 Guideline for the Management of Ureteral Calculi

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INTRODUCTION

The American Urological Association Nephrolithiasis Clinical Guideline Panel was established in 1991. Since that time, the Panel has developed three guidelines on the management of nephrolithiasis, the most recent being a 2005 update of the original 1994 *Report on the Management of Staghorn Calculi*.[1] The European Association of Urology began their nephrolithiasis guideline project in 2000, yielding the publication of *Guidelines on Urolithiasis,* with updates in 2001 and 2006.[2] While both documents provide useful recommendations on the management of ureteral calculi, changes in shock-wave lithotripsy technology, endoscope design, intracorporeal lithotripsy techniques, and laparoscopic expertise have burgeoned over the past five to ten years.

Under the sage leadership of the late Dr. Joseph W. Segura, the AUA Practice Guidelines Committee suggested to both the AUA and the EAU that they join efforts in developing the first set of internationally endorsed guidelines focusing on the changes introduced in ureteral stone management over the last decade. We therefore dedicate this report to the memory of Dr. Joseph W. Segura whose vision, integrity, and perseverance led to the establishment of the first international guideline project.

This joint EAU/AUA Nephrolithiasis Guideline Panel (hereinafter the Panel) performed a systematic review of the English language literature published since 1997 and a comprehensively analyzed outcomes data from the identified studies.

Based on their findings, the Panel concluded that when removal becomes necessary, SWL and ureteroscopy remain the two primary treatment modalities for the management of symptomatic ureteral calculi. Other treatments were reviewed, including medical expulsive therapy to facilitate spontaneous stone passage, percutaneous antegrade ureteroscopy, and laparoscopic and open surgical ureterolithotomy. In concurrence with the previously published guidelines of both organizations, open stone surgery is still considered a secondary treatment option. Blind basketing of ureteral calculi is not recommended. In addition, the Panel was able to provide some guidance regarding the management of pediatric patients with ureteral calculi. The Panel recognizes that some of the treatment modalities or procedures recommended in this document require access to modern equipment or presupposes a level of training and expertise not available to practitioners in many clinical centers. Those situations may require physicians and patients to resort to treatment alternatives.

This article will be published simultaneously in *European Urology* and *The Journal of Urology®*. The Panel believes that future collaboration between the EAU and the AUA will serve to establish other internationally approved guidelines, offering physician and patient guidance worldwide.

METHODOLOGY

The Panel initially discussed the scope of the guideline and the methodology, which would be similar to that used in developing the previous AUA guideline. All treatments commonly employed in the United States and/or Europe were included in this report except for those that were explicitly excluded in the previous guideline or newer treatments for which insufficient literature existed. In the analysis, patient data were stratified by age (adult versus child), stone size, stone location, and stone composition. Later, however, the data were found to be insufficient to allow analysis by composition. The outcomes deemed by the Panel to be of particular interest to the patient included the following: stone-free rate, number of procedures performed, stone-passage rate or probability of spontaneous passage, and complications of treatment. The Panel did not examine economic effects, including treatment costs.

Outcomes were stratified by stone location (proximal, mid, and distal ureter) and by stone size (dichotomized as $\leq$10 mm and $>$10 mm for surgical interventions, and $\leq$5 mm and $>$5 mm for medical interventions and observation where possible; exceptions were made when data were re-

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ported, for example as <10 mm and ≥10 mm). The mid ureter is the part of the ureter that overlies the bony pelvis, i.e., the position of the ureter that corresponds to the sacroiliac joint; the proximal ureter is above and the distal ureter is below. Treatments were divided into three broad groups:

1. Observation and medical therapy
2. Shock-wave lithotripsy and ureteroscopy
3. Open surgery, laparoscopic stone removal, or percutaneous antegrade ureteroscopy.

The review of the evidence began with a literature search and data extraction. Articles were selected from a database of papers derived from MEDLINE® searches dealing with all forms of urinary tract stones. This database was maintained by a Panel chair. The abstract of each paper was independently reviewed by an American and a European Panel member, and articles were selected for data extraction if any panel member felt it might have useful data. Additional articles were suggested by Panel members or found as references in review articles. In total, 348 citations entered the extraction process. An American and a European Panel member each independently extracted data from each article onto a standardized form. The team members reconciled the extractions, and the data were entered into a Microsoft Access® (Microsoft, Redmond, WA) database. The Panel scrutinized the entries, reconciled the inconsistencies in recording, corrected the extraction errors, and excluded some articles from further analysis for the following reasons:

1. The article was included in the previous guideline.
2. The article did not provide usable data on the outcomes of interest.
3. Results for patients with ureteral stones could not be separated from results for those with renal stones.
4. The treatments used were not current or were not the focus of the analysis.
5. The article was a review article of data reported elsewhere.
6. The article dealt only with salvage therapy.

A total of 244 of the 348 articles initially selected had extractable data. Articles excluded from evidence combination remained candidates for discussion in the text of the guideline.

The goal was to generate outcomes tables comparing estimates of outcomes across treatment modalities. To generate an outcomes table, estimates of the probabilities and/or magnitudes of the outcomes are required for each intervention. Ideally, these are derived from a synthesis or combination of the evidence. Such a combination can be performed in a variety of ways depending on the nature and quality of the evidence. For this report, the Panel elected to use the Confidence Profile Method,[3] which provides methods for analyzing data from studies that are not randomized controlled trials. The Fast*Pro computer software[4] was used in the analysis. This program provides posterior distributions from meta-analyses from which the median can be used as a best estimate, and the central 95% of the distribution serves as a confidence interval. Statistical significance at the $p < 0.05$ level (two-tailed) was inferred when zero was not included in the CI.

Because of the paucity of controlled trials found on literature review, however, the outcome for each intervention was estimated by combining single arms from various clinical series. These clinical series frequently had very different outcomes, likely due to a combination of site-to-site variations in patient populations, in the performance of the intervention, in the skill of those performing the intervention, and different methods of determining stone-free status. Given these differences, a random-effects, or hierarchical, model was used to combine the studies.

Evidence from the studies meeting the inclusion criteria and reporting a given outcome was combined within each treatment modality. Graphs showing the results for each modality were developed to demonstrate similarities and differences between treatments.

The available data for procedures per patient would not permit a statistical analysis using these techniques. Unlike the binary outcome of stone-free status (the patient either is or is not stone free), the number of procedures per patient is a discrete rate. In some cases discrete rates can be approximated with a continuous rate, but in order to meta-analyze continuous rates, a measure of variance (e.g., standard deviation, standard error) is needed in addition to the mean. Unfortunately, measures of variance were rarely reported in the studies reviewed. As a result, numbers of procedures per patient were evaluated by calculating the average across studies weighted by the number of patients in each study. Procedures per patient were counted in three totals: primary procedures, secondary procedures, and adjunctive procedures. Primary procedures were all consecutive procedures of the same type aimed at removing the stone. Secondary procedures were all other procedures used to remove the stone. Adjunctive procedures were defined as additional procedures that do not involve active stone removal. One difficulty in estimating the total number of procedures per patient is that secondary and adjunctive procedures were not reported consistently. Since the Panel had decided to analyze primary, secondary, and adjunctive procedures separately, only studies that specifically reported data on a type of procedure were included in estimates for that procedure type. This approach may have overestimated numbers of secondary and adjunctive procedures because some articles may not have reported that procedures were not performed.

It is important to note that, for certain outcomes, more data were reported for one or another treatment modality. While resulting CIs reflect available data, the probabilities for certain outcomes can vary widely within one treatment modality. In addition, the fact that data from only a few RCTs could be evaluated may have somewhat biased results. For example, differences in patient selection may have had more weight in analyses than differing treatment effects. Nevertheless, the results obtained reflect the best outcome estimates presently available.

Studies that reported numbers of patients who were stone free after primary procedures were included in the stone-free analysis. Studies that reported only the combined number of patients who either were stone free or had "clinically insignificant fragments" were excluded. Many studies did not indicate how or when stone-free status was determined. The stone-free rate was considered at three time points: after the first procedure, after all consecutive procedures using the primary treatment, and after the total treatments.

Initially, the Panel divided complications into three broad categories: acute, long-term, and medical; however, after