Complete Summary

GUIDELINE TITLE

2007 guideline for the management of ureteral calculi.

BIBLIOGRAPHIC SOURCE(S)

EAU/AUA Nephrolithiasis Guideline Panel. Guideline for the management of ureteral calculi. Baltimore (MD): American Urological Association Education and Research, Inc., European Association of Urology; 2007. 61 p. [92 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Urological Association (AUA), Ureteral Stones Guidelines Panel. Report on the management of ureteral calculi. Baltimore (MD): American Urological Association, Inc; 1997 Sep. 72 p. (Clinical practice guidelines; no. 9/97)

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Ureteral stones (ureteral calculi, ureterolithiasis, nephrolithiasis)

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Pediatrics
Surgery
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide medical practitioners with a current understanding of the principles and strategies for the management of ureteral calculi

TARGET POPULATION

Adult and pediatric patients with ureteral calculi

INTERVENTIONS AND PRACTICES CONSIDERED

Management

1. Observation with periodic imaging studies
2. Antibiotic treatment of bacteriuria
3. Patient counseling
4. Urgent decompression of the collecting system with percutaneous drainage or ureteral stenting in septic patients

Treatment

1. Medical expulsive therapy (MET), e.g.,: alpha blockers (tamsulosin, terazosin, doxazosin) – preferred agents; calcium channel blockers (nifedipine); adjunctive corticosteroids
2. Shock-wave lithotripsy (SWL), e.g.,:
    - SWL with pushback
    - SWL with stent or catheter bypass*
    - SWL in situ
3. Ureteroscopy (URS)*: flexible vs. rigid or semirigid URS
4. Stenting after uncomplicated URS (optional)
5. Percutaneous antegrade URS in selected cases
6. Laparoscopic and open surgery

***Note**: Extraction with a basket without endoscopic visualization of the stone (blind basketing) and routine stenting as part of SWL were considered but not recommended.

MAJOR OUTCOMES CONSIDERED

- Spontaneous passage
- Stone-free rates (stratified by overall and pediatric population, stone size and location, and type of treatment)

- Procedure counts (stratified by overall and pediatric population, stone size and location, procedure type [primary, secondary, adjunctive], and type of treatment)
- Complication occurrence rates in the overall population (stratified by treatment and stone size and location)
- Complication occurrence rates in pediatric population (stratified by treatment)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search and Data Extraction

The review of the evidence began with a literature search and data extraction between April 2003 and February 2006 (see Appendix 4 of the original guideline document). 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 (see Appendix 5 in the original guideline document). 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.

NUMBER OF SOURCE DOCUMENTS

A total of 244 of the articles were initially accepted, although some were later rejected from inclusion in both the efficacy and complications analyses. Articles excluded from evidence combination remained candidates as references to support the discussion in the text of the Guideline.

See Appendices 6 and 7 in the original guideline document for a complete list of articles.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia Evidence obtained from meta-analysis of randomized trials

Ib Evidence obtained from at least one randomized trial

IIa Evidence obtained from at least one well-designed controlled study without randomization

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study

III Evidence obtained from well-designed nonexperimental studies, such as comparative studies, correlation studies, and case reports

IV Evidence obtained from expert committee reports, or opinions, or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

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, which provides methods for analyzing data from studies that are not randomized controlled trials (RCTs). The Fast*Pro computer software 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 (CI). 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 confidence intervals reflect available data, the probabilities for certain outcomes can vary widely from study to study within one treatment modality. In addition, the fact that data from only a few randomized controlled trials 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 examining the available evidence, the Panel determined that this breakdown was not useful. Several factors caused inaccuracy in the estimates, but did so in opposite directions, thereby reducing the magnitude of inaccuracy. For example, including studies that did not specifically mention that there were no occurrences of a specific complication may have led to overestimates of complication rates when meta-analyzed. By combining similar complications, the Panel also potentially mitigated the overestimate by making it more likely that a complication in the class was reported. The probability that a patient will have a complication may still be overstated slightly because some patients experienced multiple complications. Since the grouping of complications varies by study, the result of the meta-analysis is best interpreted as the mean number of complications that a patient may experience rather than as the probability of having a complication. Moreover, since reporting of complications is not consistent, the estimated rates given here are probably less accurate than the CIs would indicate. There were insufficient data to permit meaningful meta-analyses of patient deaths.

Data analyses were conducted for two age groups. One analysis included studies of patients ages 18 or younger (or identified as pediatric patients in the article without specifying age ranges). The adult analysis included all other studies even if children were included.

Refer to Chapter 2 of the original guideline document for more detailed information on the methods used to analyze the evidence.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

After the evidence was combined and outcome tables were produced, the Panel met to review the results and identify anomalies. Additional teleconferences were held to review updates to the outcomes tables based on the problems identified. From the evidence in the outcome tables and expert opinion, the Panel drafted the treatment guideline.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

A "standard" has the least flexibility as a treatment policy, a "recommendation" has significantly more flexibility, and an "option" is even more flexible. These three levels of flexibility are defined as follows:

Standard: A guideline statement is a standard if: (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.

Recommendation: A guideline statement is a recommendation if: (1) the health outcomes of the alternative interventions are sufficiently well known to permit

meaningful decisions, and (2) an appreciable but not unanimous majority agrees on which intervention is preferred.

Option: A guideline statement is an option if: (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions, or (2) preferences are unknown or equivocal.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft of the guideline was sent to 81 peer reviewers of whom 26 provided comments; the Panel revised the document based on the comments received. The guideline was submitted first for approval to the Practice Guidelines Committee of the American Urological Association (AUA) and the Guidelines Office of the European Association of Urology (EAU) and then forwarded to the AUA Board of Directors and the EAU Board for final approval.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (**Ia-IV**), grades of the guideline statements (**Standard, Recommendation, Option**), and the index patient are defined at the end of the "Major Recommendations" field.

Treatment Guidelines for the Index Patient

For All Index Patients

Standard: Patients with bacteriuria should be treated with appropriate antibiotics. [Based on Panel consensus/**Level IV**]

Standard: Stone extraction with a basket without endoscopic visualization of the stone (blind basketing) should not be performed. [Based on Panel consensus/**Level IV**]

For Ureteral Stones <10 mm

Option: In a patient who has a newly diagnosed ureteral stone <10 mm and whose symptoms are controlled, observation with periodic evaluation is an option for initial treatment. Such patients may be offered an appropriate medical therapy

to facilitate stone passage during the observation period. [Based on review of the data and panel opinion/**Level IA**]

Standard: Patients should be counseled on the attendant risks of medical expulsive therapy (MET) including associated drug side effects and should be informed that it is administered for an "off label" use. [Based on Panel consensus/**Level IV**]

Standard: Patients who elect for an attempt at spontaneous passage or MET should have well-controlled pain, no clinical evidence of sepsis, and adequate renal functional reserve. [Based on Panel consensus/**Level IV**]

Standard: Patients should be followed with periodic imaging studies to monitor stone position and to assess for hydronephrosis. [Based on Panel consensus/**Level IV**]

Standard: Stone removal is indicated in the presence of persistent obstruction, failure of stone progression, or in the presence of increasing or unremitting colic. [Based on Panel consensus/**Level IV**]

For Ureteral Stones >10 mm

For Patients Requiring Stone Removal

Standard: A patient must be informed about the existing active treatment modalities, including the relative benefits and risks associated with each modality. [Based on Panel consensus/**Level IV**]

Recommendation: For patients requiring stone removal, both shock-wave lithotripsy (SWL) and ureteroscopy (URS) are acceptable first-line treatments. [Based on review of the data and Panel consensus/**Level IA-IV**]

Recommendation: Routine stenting is not recommended as part of SWL. [Based on Panel consensus/**Level III**]

Option: Stenting following uncomplicated URS is optional. [Based on Panel consensus/**Level IA**]

Option: Percutaneous antegrade ureteroscopy is an acceptable first-line treatment in select cases. [Based on Panel consensus/**Level III**]

Option: Laparoscopic or open surgical stone removal may be considered in rare cases where SWL, URS, and percutaneous URS fail or are unlikely to be successful. [Based on Panel consensus/**Level III**]

Recommendations for the Pediatric Patient

Option: Both SWL and URS are effective in this population. Treatment choices should be based on the child's size and urinary tract anatomy. The small size of the pediatric ureter and urethra favors the less invasive approach of SWL. [Based on review of data and Panel consensus/**Level III**]

Recommendations for the Nonindex Patient

Standard: For septic patients with obstructing stones, urgent decompression of the collecting system with either percutaneous drainage or ureteral stenting is indicated. Definitive treatment of the stone should be delayed until sepsis is resolved. [Based on Panel consensus/**Level III**]

Definitions:

Levels of Evidence

Ia Evidence obtained from meta-analysis of randomized trials

Ib Evidence obtained from at least one randomized trial

IIa Evidence obtained from at least one well-designed controlled study without randomization

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study

III Evidence obtained from well-designed nonexperimental studies, such as comparative studies, correlation studies, and case reports

IV Evidence obtained from expert committee reports, or opinions, or clinical experience of respected authorities

Grades of Guideline Statements

Standard: A guideline statement is a standard if: (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.

Recommendation: A guideline statement is a recommendation if: (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) an appreciable but not unanimous majority agrees on which intervention is preferred.

Option: A guideline statement is an option if: (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions, or (2) preferences are unknown or equivocal.

Index Patient

In constructing these guidelines, an "index patient" was defined to reflect the typical individual with a ureteral stone whom a urologist treats. The following definition was created.

The index patient is a nonpregnant adult with a unilateral noncystine/nonuric acid radiopaque ureteral stone without renal calculi requiring therapy whose

contralateral kidney functions normally and whose medical condition, body habitus, and anatomy allow any one of the treatment options to be undertaken.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate selection of particular treatment modalities for ureteral calculi, taking into consideration such factors as stone size, and location

POTENTIAL HARMS

The following are the most relevant treatment complications:

1. Sepsis
2. Steinstrasse
3. Stricture
4. Ureteral injury
5. Urinary tract infection (UTI)

Serious complications, including death and loss of kidney, are rare.

Refer to Chapter 3 and Tables 5 and 6 in the original guideline document for more information on complications associated with shock-wave lithotripsy (SWL) and ureteroscopy (URS).

Although highly effective, laparoscopic ureterolithotomy is not a first-line therapy in most cases because of its invasiveness, attendant longer recovery time, and the greater risk of associated complications compared to SWL and URS.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- 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.
- Some of the medical therapies currently employed in the management of ureteral calculi have not been approved by the US Food and Drug Administration for this specific indication. Thus, doses and dosing regimens may deviate from that employed for the Food and Drug Administration-approved indications, and this difference should be considered in the risk-versus-benefit assessment.
- This document provides guidance only, and does not establish a fixed set of rules or define the legal standard of care. As medical knowledge expands and technology advances, this guideline will change. Today it represents not absolute mandates but provisional proposals or recommendations for treatment under the specific conditions described. For all these reasons, the guideline does not preempt physician judgment in individual cases. Also, treating physicians must take into account variations in resources, and in patient tolerances, needs and preferences. Conformance with the guideline reflected in this document cannot guarantee a successful outcome.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Dissemination

The guideline is posted on the American Urological Association Web site www.auanet.org and on the European Association of Urology Web site www.uroweb.org. Chapter 1 will be published in *The Journal of Urology* and in *European Urology*.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

EAU/AUA Nephrolithiasis Guideline Panel. Guideline for the management of ureteral calculi. Baltimore (MD): American Urological Association Education and Research, Inc., European Association of Urology; 2007. 61 p. [92 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 Sep (revised 2007 Dec)

GUIDELINE DEVELOPER(S)

American Urological Association Education and Research, Inc. - Medical Specialty Society
European Association of Urology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American Urological Association (AUA) and the European Association of Urology provided the funding.

GUIDELINE COMMITTEE

EAU/AUA Nephrolithiasis Guideline Panel and Consultants

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Names of Panel Members: Glenn M. Preminger, MD, (*Chair*); Hans-Göran Tiselius, MD, PhD, (*Co-Chair*); Dean G. Assimos, MD, (*Vice Chair*); Peter Alken, MD, PhD; Colin Buck, MD, PhD; Michele Gallucci, MD, PhD; Thomas Knoll, MD, PhD; James E. Lingeman, MD; Stephen Y. Nakada, MD; Margaret Sue Pearle, MD, PhD; Kemal Sarica, MD, PhD; Christian Türk, MD, PhD; J. Stuart Wolf, Jr., MD

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Panel members received no remuneration for their work. Each member of the Practice Guidelines Committee and of the Panel furnished a current conflict of interest disclosure to the American Urological Association (AUA).

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This is the current release of the guideline.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the American Urological Association (AUA) Web site and the European Association of Urology (EAU) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on September 1, 1998. It was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI Institute on March 21, 2008. The updated information was verified by the guideline developer on April 1, 2008.

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Date Modified: 11/3/2008