INTERNATIONAL JOURNAL OF UROLOGY
International Journal of Urology (2025) 32, 462–474 doi: 10.1111/iju.70004

Guidelines

Summary of the clinical practice guideline for the management of urinary stones, third edition

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Abbreviations & Acronyms
CQs = clinical questions
EBM = Evidence-Based Medicine
ECIRS = endoscopic combined intrarenal surgery
ESWL = extracorporeal shock wave lithotripsy
FRQs = future research questions
f-TUL/URS = flexible-transurethral lithotripsy/ureteroscopy
PNL/PCNL = percutaneous nephrolithotripsy

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Received 4 November 2024; accepted 24 January 2025.
Online publication 11 February 2025

Abstract: This third edition of the Japanese Clinical Practice Guidelines for Urinary stones (2023) has been developed under the leadership of the Japanese Urological Association, the Japanese Society of Endourology and Robotics, and the Japanese Society on Urolithiasis Research. This revision adheres to the Minds Manual for Guideline Development (2017) and incorporates new findings from a nationwide survey conducted in 2015, which highlighted the epidemiological characteristics of urolithiasis in Japan since the previous guidelines were published in 2013. A significant advancement in this edition is the systematic review (SR) methodology applied to formulate recommendations for 12 clinical questions (CQs). Both quantitative and qualitative SRs were performed, leading to recommendations determined through consensus among 21 members of the guideline development group. Additionally, nine algorithms were created to support clinical decision-making based on these findings. Topics not addressed by the CQs, considered as foundational knowledge, are outlined in an "Explanation of Related Matters" section, which includes 26 items. This article provides an overview of these guidelines. This section ensures that practitioners have access to comprehensive information, covering aspects of urolithiasis management beyond the scope of the systematic reviews. This article provides an overview of the guidelines, emphasizing their relevance and importance in improving the management and treatment outcomes for patients with urinary stones. The guidelines are designed to be a practical resource for clinicians, facilitating evidence-based care in the evolving landscape of urolithiasis treatment.

Key words: diagnosis, guideline, lithotripsy, recurrence, urinary stone.

INTRODUCTION

The Japanese Urological Association, Japanese Society of Endourology (now the Japanese Society of Endourology and Robotics), and Japanese Society on Urolithiasis Research published the second edition of the clinical practice guideline for the management of urinary stones in 2013.

Since then, new data has been accumulated; a 2015 nationwide survey of the epidemiological characteristics of urolithiasis in Japan revealed clear evidence of its association with lifestyle-related diseases. The survey also indicated increased lower urinary tract stone incidence, reflecting an aging population. Additionally, the use of small-diameter endoscopes for percutaneous nephrolithotripsy (PNL/PCNL), the rapid spread of flexible-transurethral lithotripsy/ureteroscopy (f-TUL/URS), and establishment of endoscopic combined intrarenal surgery (ECIRS) techniques have resulted in significant changes in the endoscopic treatment of upper urinary stones. Therefore, in accordance with the manual for the development of practice guidelines (2017)[1] edited by the Japan Institute for Health Care Excellence Evidence-Based Medicine (EBM) Promotion Project (Medical Information Network Distribution Service: Minds), the three organizations mentioned above created the "Clinical practice guideline for the management of urinary stones, third edition."

CHANGES IN THE THIRD EDITION

In the second edition (2013), 38 clinical questions (CQs) were created based on key clinical issues. Corresponding clinical answers were derived through a literature search. However, as the CQs were not in the PICO (P: Patients, Problem, Population, I: Interventions, C: Comparisons, Controls, Comparators, O: Outcomes) format, the answers included some textbook descriptions. Since the publication of the second edition, there have been significant changes to the manner in which medical practice guidelines are developed. In addition to development methods that conform to the international EBM standards, comprehensive evidence evaluation that considers the balance between harms and benefits has become a greater focus. Hence, to ensure that the third edition guidelines are easier to understand for both patients and healthcare providers, a general introduction is provided to explain how to use the guidelines, practice algorithms, CQs and recommendations, key terms, and abbreviations. This includes recommendations and explanations for 9 algorithms and 12 CQs. The guideline development policy and process are also explained in detail.

Each section comprises the epidemiology and diagnosis of, conservative and active treatment for, recurrence prevention for, and supplementary information regarding urinary stones. The CQs were selected based on an algorithm developed to represent important clinical issues for which clinical judgments may vary between clinicians. For those portions of the CQs with insufficient levels of information in the commentary section, a 26-item "Explanation of Related Matters" section is provided.

ALGORITHM EXPLANATION

The algorithms were designed to assist clinical decision-making regarding the diagnosis, treatment, and prevention of stone recurrence.

Algorithms for diagnosis

Algorithm 1 (Figure 1) describes the general clinical procedure from initial evaluation to treatment of urinary stones. The key to initial diagnosis is basic evaluation of urinary stones and evaluation of their properties and level of obstruction. Conservative or surgical treatment is then selected depending on the presence or absence of hydronephrosis, as well as the size of the stone. Notably, patients with obstructive pyelonephritis should be referred to a urologist immediately. The CQs corresponding to these are CQ1, CQ2, CQ3, and CQ9.

Algorithm for treatment

Algorithm 2 (Figure 2) describes the treatment strategy for ureteral stone removal. Either TUL/URS or extracorporeal shock wave lithotripsy (ESWL) is recommended for ureteral stones with long diameters <10 mm. For those with diameters ≥10 mm, TUL/URS is recommended as the first choice and ESWL as the second choice. The corresponding CQ is CQ4.

Algorithm 3 (Figure 3) describes the treatment strategy for renal stone removal. For renal stones with long diameters <10 mm, ESWL or TUL/URS is recommended as the first choice and PNL/PCNL as the second choice. For renal stones with long diameters of 10–20 mm, TUL/URS or PNL/PCNL is recommended as the first choice and ESWL as the second. For renal stones with diameters ≥20 mm, PNL/PCNL (ECIRS/TAP) is recommended as the first choice, TUL/URS represents the second choice, and ESWL is the third choice. The corresponding CQs are CQ5 and CQ8.

These guidelines do not present a treatment strategy for removing lower urinary stones, according to the proposed algorithm. However, the concept of surgical treatment for bladder stone removal is presented in the "Surgical Treatment for Lower Ureteral Stone" section of Chapter 4. Because no clear evidence is available regarding the treatment of urolithiasis in pregnant women, children, and patients with urinary tract diversion or congenital urinary tract malformation, recommendations and cautions for the treatment of urolithiasis are presented in the "Active Treatment for Pregnant Women and Children" and "Active Treatment for Special Cases" sections of Chapter 4. Indications for conservative treatment and treatment of older and bedridden patients who are not suitable for active treatment are presented in the "Approaches to Renal/Ureteral Stone not Subjected to Active Treatment" section of Chapter 4.

Algorithm to prevent recurrence

Algorithm 4 (Figure 4) describes preventive approaches for stone recurrence in all patients with urolithiasis. Basic evaluations for this aspect comprise medical interviews (gathering information such as family history, medical history, current medical history, and medication history), analysis of stone composition, blood tests (for parameters such as creatinine, calcium, urate, albumin, phosphorus, sodium, potassium, and uric acid), and urinalysis as needed (typically pH and urinary sediment). To specifically evaluate individuals who are at high risk of urinary stone recurrence, the guidelines recommend recording the following parameters: blood tests (parathyroid hormone and blood gas analysis) and 24-h urine

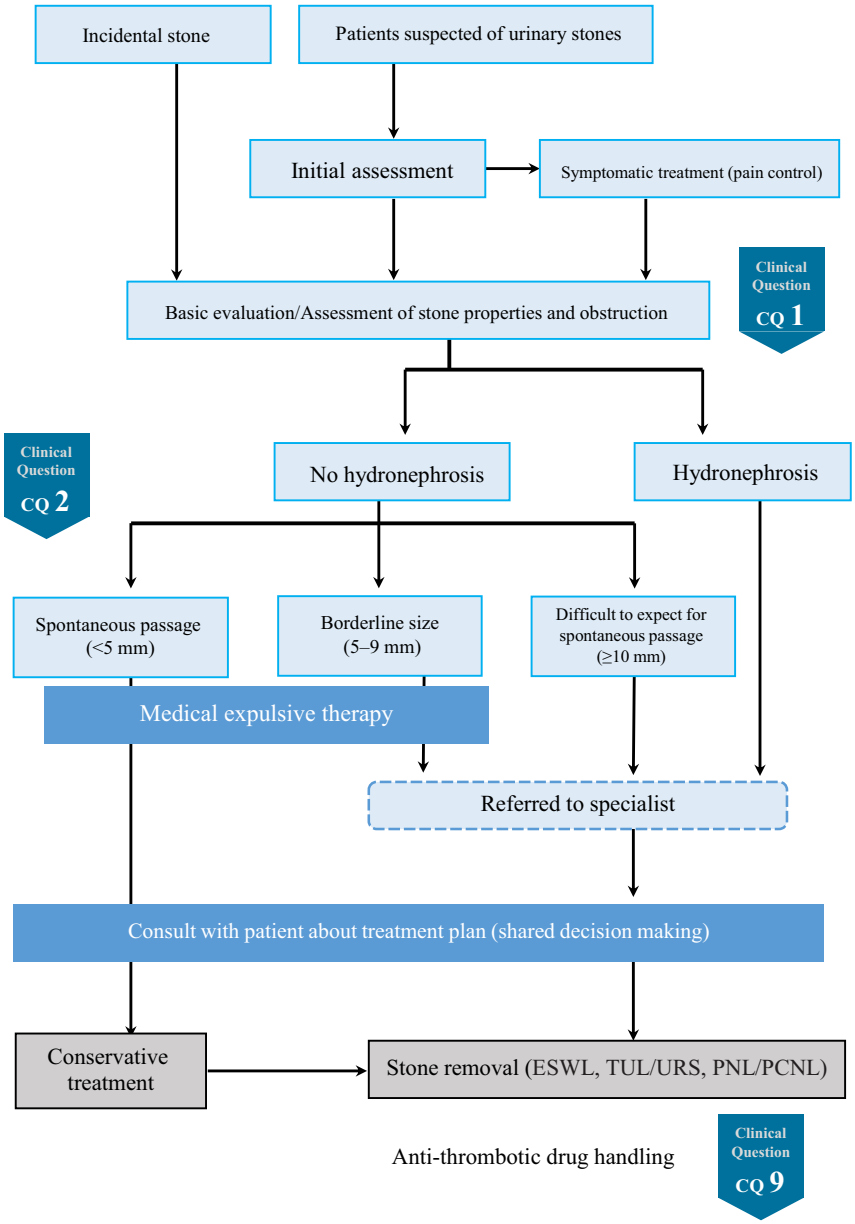


FIGURE 1 Algorithm 1: A patient's clinical course from initial evaluation until treatment completion. CQ, clinical questions; ESWL, extracorporeal shock wave lithotripsy; f-TUL/URS, flexible–transurethral lithotripsy/ureteroscopy; PNL/PCNL, percutaneous nephrolithotripsy.

chemistry profiles (creatinine, calcium, uric acid, oxalic acid, citrate, sodium, magnesium, phosphorus, urine volume, and amino acids). To prevent recurrence in patients with urolithiasis, the following measures are recommended: (1) recommending patients to drink at least 2000 mL of water per day, in addition to meals, to generate a daily urine volume ≥2000 mL; (2) providing dietary guidance, including (a) a well-balanced diet, (b) adequate calcium intake of 600–800 mg/day, (c) limiting excessive animal protein intake (<1.0 g/kg/day), and (d) limiting excessive salt intake (<7.5 g/day for men and <6.5 g/day for women); and (3) providing lifestyle guidance, such as prevention of obesity and moderate exercise. Specific treatments for high-risk patients may include dietary guidance and drug therapy, depending on the stone composition.

Algorithms 5–9 (Figure 5; Figures S1–S4) describe specific preventive measures for calcium oxalate, calcium phosphate, uric acid, infection, and cystine calculi. The CQs corresponding to these algorithms are CQ10, CQ11, and CQ12.

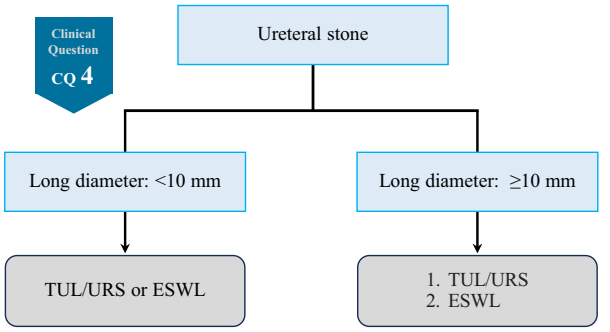
EXPLANATION OF CLINICAL QUESTIONS

The guidelines adopted three CQs concerning diagnosis and conservative treatment, six concerning surgical treatment, and three focused on recurrence prevention (Table 1).

CQs on diagnosis and conservative treatment

CQ1: Is interventional treatment (nephrostomy or ureteral stent placement) recommended compared to conservative treatment for patients with obstructive pyelonephritis caused by urinary stones?

Recommendation: For patients with obstructive pyelonephritis caused by urinary stones, interventional treatment



1: Conservative treatment (follow-up and MET) is recommended for a certain period for patients with ureteral stones that are expected to spontaneously pass (CQ2).
2: The effectiveness and complications of ESWL and TUL/URS should be carefully explained to the patient.
3: When treatment-resistant ureteral stones are suspected, TUL/URS by percutaneous approach or open surgery should be considered.
4: TUL/URS is the first choice for patients with severe obesity.

FIGURE 2 Algorithm 2: Treatment strategy for the removal of ureteral stone. CQ, clinical questions; MET, medical expulsive therapy; ESWL, extracorporeal shock wave lithotripsy; f-TUL/URS, flexible-transurethral lithotripsy/ureteroscopy.

(nephrostomy or ureteral stent placement) is recommended under certain conditions.[2–10]

Certainty of evidence: C (weak)

This CQ discusses whether, how, and when to intervene via drainage therapy for patients with obstructive pyelonephritis caused by urinary stones. This CQ cannot be evaluated through randomized control trials and does not provide a uniform view of conditions such as patient age, general condition, and stone size. The recommendation is not necessarily applicable in patients with good general condition and no complications as well as those for whom improvements can be expected using antibiotics alone.

CQ2: Compared to surgical treatment (stone removal), is conservative treatment (observation and expulsion therapy) for a certain period recommended for patients with upper urinary tract stones that are expected to be spontaneously passed?

Recommendation: For patients with upper urinary tract stones that are expected to be spontaneously passed, conservative treatment (observation and stone expulsion therapy) is recommended for a certain period.[11–20]

Certainty of evidence: C (weak)

This CQ examines whether surgical treatment should be performed for patients with upper urinary tract stones that are expected to be spontaneously passed or whether conservative treatment should be implemented for a certain period before considering surgical treatment if the stone is not expelled. For stones expected to be spontaneously passed, it is necessary to consider their size and location, as well as imaging findings such as computed tomography results. Stones with sizes >10 mm are generally difficult to pass. Although there is currently no clear evidence regarding the optimal duration of conservative treatment, empirically, patients are followed up for at least 1 month, and active treatment is performed when no stone movement is expected.

CQ3: Compared to no pharmaceutical intervention, is the administration of drugs (α1 receptor blockers, anticholinergics, calcium antagonists, *Quercus salicina* extract, and herbal medicines) recommended for patients with ureteral calculi to promote stone expulsion?

Recommendation: It is recommended that patients with ureteral stones be conditionally treated with α1 receptor blockers to promote stone expulsion.[12,13,19–43]

Certainty of evidence: B (moderate)

This CQ examines the effectiveness of medical therapy for expelling ureteral stones. Many publications in the literature have reported on the use of α1 receptor blockers for promoting stone expulsion, and some have presented relatively high-quality evidence supporting the use of tamsulosin. Drugs other than α1-receptor blockers were excluded from the recommendation because no randomized control trials with robust levels of evidence for other drugs have been conducted. However, as α1-receptor blockers are not covered by health insurance for accelerating urinary tract stone expulsion in Japan, informed consent should be obtained for off-label use.

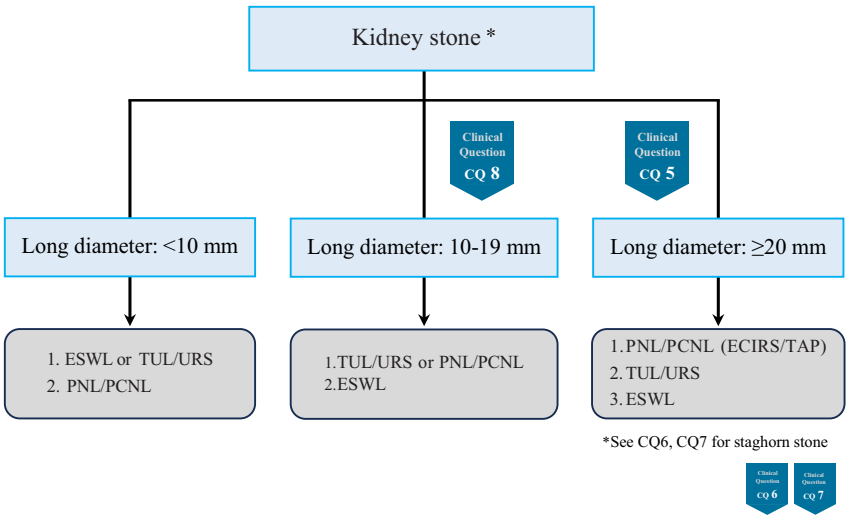
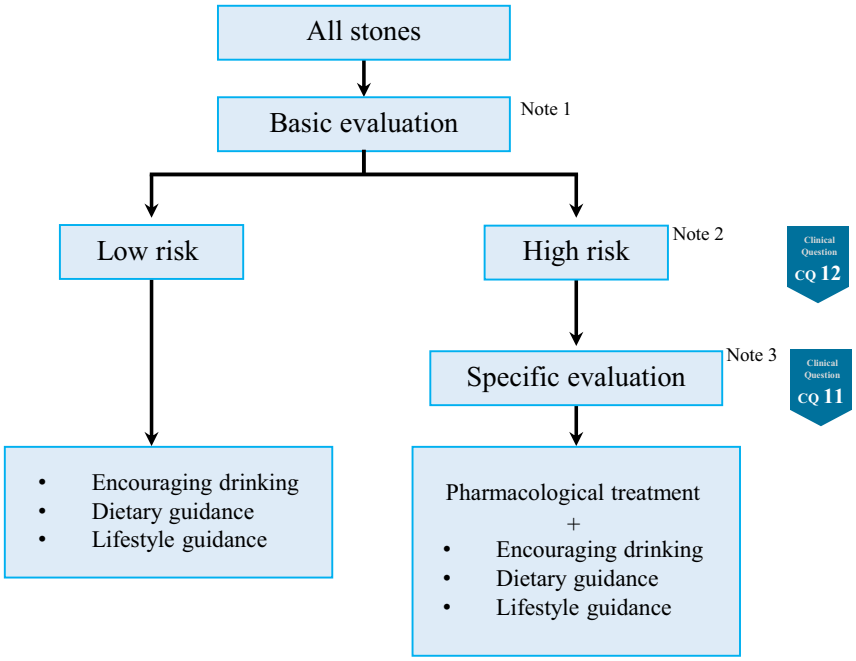


FIGURE 3 Algorithm 3: Treatment strategy for the removal of renal stone. CQ, clinical questions; ESWL, extracorporeal shock wave lithotripsy; f-TUL/URS, flexible-transurethral lithotripsy/ureteroscopy; PNL/PCNL, percutaneous nephrolithotripsy.



Note 1: Medical interview (gathering information such as familial history, past history, present illness, medication history), stone content analysis, blood chemistry profiles (Cr, Ca, uric acid, albumin, P, Na, K, Cl), spot urine (pH, sediment).
Note 2: Patients corresponding to the criteria listed in Table 1 (p.154) are considered at high-risk.
Note 3: Blood tests (parathyroid hormones, blood gas analysis), 24-hour urine chemistry profiles (Cr, Ca, uric acid, oxalic acid, citric acid, Na, Mg, P, amino acids), and daily urine volume Urinary citrate is not covered by insurance.

FIGURE 4 Algorithm 4: Prevention of stone recurrence. C, chlorine; Ca, calcium; Cr, creatinine; K, potassium; Mg, magnesium; Na, sodium; P, phosphorus.

CQ on surgical treatment

CQ4: Is TUL/URS recommended over ESWL for patients with ureteral stones <10 mm?

Recommendation: TUL/URS, rather than ESWL, is conditionally recommended for patients with ureteral stones <10 mm.[44–57]

Certainty of evidence: C (weak)

This CQ examined whether there were any significant differences in terms of therapeutic effects between TUL/URS and ESWL for treating small upper ureteral stones <10 mm. When choosing surgical treatment (stone removal therapy) for ureteral stones <10 mm, TUL/URS or ESWL should be selected after the patient receives a complete explanation regarding the advantages and disadvantages of TUL/URS (for instance, the stone removal rate is slightly higher, but so is the complications rate compared to ESWL).

CQ5: Is ECIRS/TAP recommended for patients with kidney stones ≥20 mm compared to PNL/PCNL (alone), f-TUL/URS (alone), or ESWL?

Recommendation: ECIRS/TAP is conditionally recommended for patients with kidney stones ≥20 mm.[58–63]

Certainty of evidence: B (moderate)

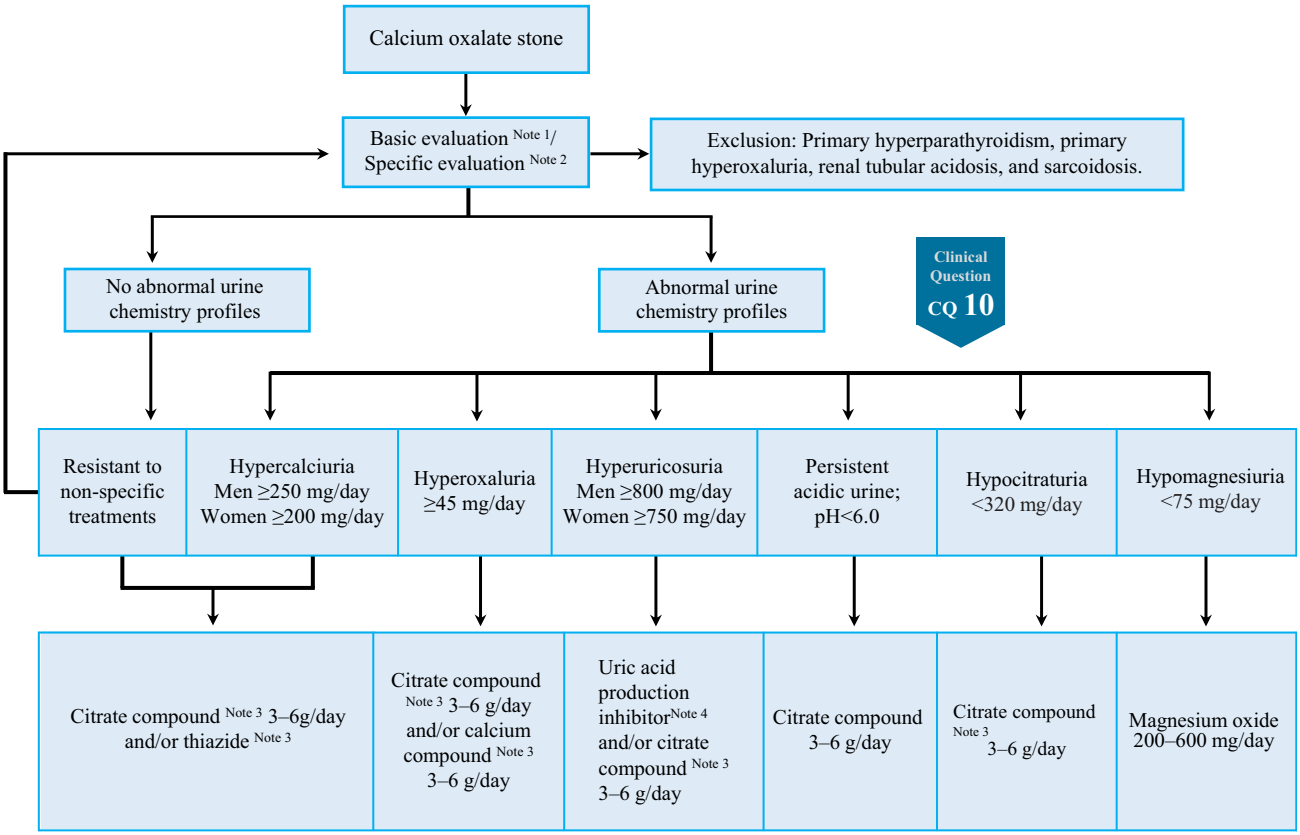
This CQ examines the efficacy of these therapeutic methods for kidney stones of ≥20 mm. The second edition of the clinical practice guideline for the management of urinary stones recommended PNL/PCNL as the first choice for treating kidney stones ≥20 mm. However, owing to recent advances in endourology devices, ECIRS/TAP, which combines PNL/PCNL and TUL/URS, has become increasingly recommended. The indications for f-TUL/URS are also expanding, and ESWL is also being performed for such urinary stones. Consequently, ECIRS/TAP has now been recommended for staghorn stones.

CQ6: Is follow-up recommended for patients with asymptomatic staghorn stones over surgical treatment (stone removal therapy)?

Recommendation: It is conditionally recommended not to proceed with observation alone for patients with asymptomatic staghorn stones.[64–71]

Certainty of evidence: C (weak)

Staghorn stones are stones that occupy the renal pelvis and multiple calyces. Given the higher probability of reduced renal function and urinary tract infections associated with these stones, patients who have them are generally recommended to undergo aggressive treatments. On the other hand, some staghorn stones may be asymptomatic for extended periods and do not impair renal function. In older patients and those with poor performance status, therapeutic intervention may lead to declines in activities of daily living and renal function. This CQ examined whether treating such stones (stone removal therapy) or observation was more appropriate for staghorn stones from the perspectives of overall condition, renal function, and urinary tract infection. The additional condition for this recommendation is that patients could be followed up according to an overall clinical



Note 1: Medical interview (gathering information such as familial history, past history, present illness, medication history), blood chemistry profiles (Cr, Ca, uric acid, albumin, P, Na, K, Cl), spot urine (pH, sediment).
Note 2: Blood tests (parathyroid hormones, blood gas analysis), 24-hour urine chemistry profiles (Cr, Ca, uric acid, oxalic acid, citric acid, Na, Mg, P, amino acids), and daily urine volume. Urinary citrate is not covered by insurance.
Note 3: Not covered by insurance/Off label use.
Note 4: Not covered by insurance (covered if complicated by hyperuricemia)/Off label use (Applicable with hyperuricemia).
Figure 5. Algorithm 5: Prevention of recurrence for calcium oxalate stone.

FIGURE 5 Algorithm 5: Prevention of recurrence for calcium oxalate stone. C, chlorine; Ca, calcium; Cr, creatinine; K, potassium; Mg, magnesium; Na, sodium; P, phosphorus.

judgment, as many patients cannot undergo aggressive treatments for stones, owing to their general condition or the wishes of their family members.

CQ7: Is ECIRS/TAP recommended over PNL/PCNL alone for patients with staghorn stones?

Recommendation: ECIRS/TAP is conditionally recommended for patients with staghorn stones.[56,57,59,72,73]

Certainty of evidence: C (weak)

Staghorn stones require multiple PNL/PCNL or a combination of PNL/PCNL and ESWL. However, for larger and more complex stones, ECIRS/TAP, which involves concurrent PNL/PCNL and TUL/URS, is considered more effective. This CQ examines whether ECIRS/TAP is more successful and safer than PNL/PCNL for the initial treatment of staghorn stones. ECIRS/TAP is recommended to be performed in centers with extensive experience in using the technique or by trained practitioners who are familiar with perioperative management that may include periprocedural complications.

CQ8: Is f-TUL/URS recommended for patients with renal stones ≥10 mm but <20 mm over ECIRS/TAP, PNL/PCNL, or ESWL?

Recommendation: f-TUL/URS is conditionally recommended for patients with renal stones of ≥10 mm but <20 mm.[74–80]

Certainty of evidence: B (moderate)

This CQ re-examined which treatments should be recommended for renal stones measuring 10–20 mm. The second edition of the clinical practice guideline for the management of urinary stones recommended the following treatment strategies: ESWL, PNL/PCNL, and f-TUL/URS for the renal pelvis, upper calyx, and middle calyx; and PNL/PCNL and f-TUL/URS for the lower calyx. Given the recent advances in endoscopic technology, ESWL may be selected in facilities where TUL/URS cannot be performed because of the medical environment. In some cases, PNL/PCNL is recommended when the stone volume is under consideration rather than length. The advantages and disadvantages of each treatment

TABLE 1 A list of CQs and the corresponding recommendations and certainty (strength) of evidence.

	Topic	Clinical question	Recommendation	Certainty (strength) of evidence
CQ1	Management of obstructive pyelonephritis	Is aggressive treatment (nephrostomy or ureteral stent placement) recommended compared to conservative treatment for patients with obstructive pyelonephritis due to urinary tract stones?	Aggressive treatment (nephrostomy or ureteral stent placement) for patients with obstructive pyelonephritis due to urinary tract stones is conditionally recommended.	C (weak)
CQ2	Management of urinary tract stones that can be naturally excreted	Is conservative treatment (follow-up observation or expulsive therapy) recommended for a certain period of time compared to aggressive treatment (stone removal) for patients with urinary tract stones that are expected to naturally pass?	Conservative treatment (follow-up observation or expulsive therapy) for a certain period of time for patients with upper urinary tract stones that are expected to naturally pass is recommended.	C (weak)
CQ3	Medical expulsive therapy (MET)	Is the administration of drugs for promoting stone passage (α1 receptor blockers, anticholinergics, calcium antagonists, Quercus salicina extract, herbal medicines) recommended to non-administration for patients with ureteral stones?	Administration of drugs to promote stone passage (α1 receptor blockers) for patients with ureteral stones is conditionally recommended.	B (moderate)
CQ4	Treatment of ureteral stones (<10 mm)	Is TUL/URS compared to ESWL recommended for patients with ureteral stones (<10 mm)?	TUL/URS for patients with ureteral stones (<10 mm) is conditionally recommended compared to ESWL.	C (weak)
CQ5	Treatment of kidney stones (≥20 mm)	Is ECIRS/TAP compared to PNL/PCNL (alone), f-TUL/URS (alone), or ESWL recommended for patients with renal stones (≥20 mm)?	ECIRS/TAP for patients with renal stones (≥20 mm) is conditionally recommended.	B (moderate)
CQ6	Management of asymptomatic staghorn stones	Is follow-up observation compared to active treatment (stone removal therapy) recommended for patients with asymptomatic staghorn stones?	No follow-up observation for patients with asymptomatic staghorn stones is conditionally recommended.	C (weak)
CQ7	Treatment of staghorn stones	Is ECIRS/TAP compared to PNL/PCNL monotherapy recommended for patients with staghorn stones?	ECIRS/TAP for patients with staghorn stones is conditionally recommended.	C (weak)
CQ8	Treatment of kidney stones (10–20 mm)	Is f-TUL/URS compared to ECIRS/TAP, PNL/PCNL, or ESWL recommended for patients with kidney stones (10–20 mm)?	f-TUL/URS for patients with renal stones (≥10 mm, <20 mm) is conditionally recommended.	B (moderate)
CQ9	Management of patients on antithrombotic therapy	Is TUL/URS while continuing antithrombotic drug administration compared to TUL/URS after discontinuation of antithrombotic drug administration recommended for patients with upper urinary tract stones undergoing antithrombotic therapy?	TUL/URS while continuing antithrombotic drugs for upper urinary tract stone patients undergoing antithrombotic therapy is conditionally recommended.	C (weak)
CQ10	Calcium oxalate stones	Is the administration of various drug therapies (thiazides, citric acid preparations, uric acid production inhibitors, magnesium preparations) for patients with calcium oxalate stones with abnormal urinary chemistry test results compared to non-medicated cases recommended for preventing recurrence of calcium oxalate stones?	The administration of various drug therapies (thiazides, citric acid preparations, uric acid production inhibitors, magnesium preparations) for patients with calcium oxalate stones with abnormal urinary chemistry test results is conditionally recommended.	B (moderate)
CQ11	Usefulness of 24-hour urine chemistry tests	Is implementing urinary chemistry tests using 24-hour urine collection or random urine samples for patients at low or high risk of urinary tract stone recurrence compared to non-implementation cases recommended for investigating the cause of urinary tract stones and preventing recurrence?	Undergoing urinary chemistry tests using 24-hour urine collection for patients at risk of urinary tract stone recurrence is conditionally recommended.	C (weak)
CQ12	Usefulness of treatment for complications	Is treatment of complications for urinary tract stone patients with lifestyle-related diseases or metabolic syndrome (e.g., diabetes, hypertension, dyslipidemia) compared to non-treatment cases recommended for reducing the stone recurrence rate?	Treatment of complications for urinary tract stone patients with lifestyle-related diseases or metabolic syndrome (e.g., diabetes, hypertension, dyslipidemia) is conditionally recommended.	C (weak)

should be explained, and the ultimate decision should consider the patient's preference.

CQ9: Is continuing antithrombotic therapy and performing TUL/URS recommended for patients with upper urinary stones who are undergoing antithrombotic therapy over discontinuing antithrombotic therapy and performing TUL/URS?

Recommendation: Patients with upper urinary stones are conditionally recommended to undergo TUL/URS while continuing antithrombotic therapy.[81–87]

Certainty of evidence: C (weak)

In recent years, an increasing number of patients have been taking anticoagulants and antiplatelet agents to treat and prevent cerebrovascular diseases. This current CQ examines the safety and efficacy of performing TUL/URS under continued antiplatelet medications in patients with upper urolithiasis. Although the reduction of perioperative cerebrovascular and cardiovascular complications is uncertain when antithrombotic therapy is continued during TUL/URS, it also has no effect on the stone removal rate and only tends to increase the incidence of minor bleeding complications. Therefore, the additional condition is that TUL/URS should be performed only after the patient is provided with a full explanation concerning the advantages and disadvantages of continuing or discontinuing antithrombotic therapy.

CQs on prevention of recurrence

CQ10: Is it recommended to administer various drug therapies (such as thiazides, citric acid preparations, uric acid inhibitors, and magnesium preparations) to patients with calcium oxalate stones and abnormal urine chemistry test results, over nonadministration, to prevent the recurrence of calcium oxalate stones?

Recommendation: Various drug therapies, such as thiazides, citric acid preparations, uric acid inhibitors, and magnesium preparations, are conditionally recommended for patients with calcium oxalate stones and abnormal urine chemistry test results.[88–108]

Certainty of evidence: B (moderate)

No drugs that can definitively prevent the recurrence of calcium oxalate stones, which represent the most common stone type, are currently available. However, patients with calcium oxalate stones often have other abnormal findings, such as deficiencies in certain substances that inhibit stone formation or excess levels of other substances that promote it. This CQ examines whether drug therapy is effective for reducing these abnormalities. Drug therapy is ultimately indicated only for patients who are at high risk of recurrence, on the condition that it is accompanied by guidance regarding healthy diet and fluid intake.

CQ11: Is 24-hour or spot urine collection recommended for patients at low or high risk of urolithiasis recurrence, compared to non-testing, to identify the causes of their urinary stones and prevent recurrence?

Recommendation: Patients who are at risk for urinary stone recurrence are conditionally recommended to undergo a 24-hour urine collection.[109–127]

Certainty of evidence: C (weak)

While performing 24-h urine collection is considered useful for identifying the cause of urolithiasis and preventing its recurrence, the procedure is fairly complicated in practice. This CQ examines the effectiveness and methods used for 24-h urine collection, including whether spot urine samples could be substituted. In clinical practice, some patients cannot undergo 24-h urine collection due to inability to collect urine, time constraints, and medical costs. In such cases, a concession was made that attempts to diagnose the cause of urinary stones using other tests should not be ruled out.

CQ12: Is the treatment of other comorbid diseases recommended in patients with urolithiasis who have lifestyle-related diseases or metabolic syndrome (e.g., diabetes, hypertension, or dyslipidemia), over non-treatment, to reduce the rate of recurrence of urolithiasis?

Recommendation: Patients with urolithiasis who have comorbid lifestyle-related diseases or metabolic syndrome (e.g., diabetes, hypertension, dyslipidemia, and other related conditions) are conditionally recommended to undergo appropriate treatments for the comorbid diseases.[92,107,128–131]

Certainty of evidence: C (weak)

Urolithiasis is a recurrent disease that is associated with lifestyle-related diseases and metabolic syndrome. This CQ examines whether appropriate treatments for diabetes, hypertension, or dyslipidemia are effective for preventing urinary stone recurrence. The additional condition is that therapeutic agents with evidence to support their recommendation should be limited to allopurinol for hyperuricemia, as well as eicosapentaenoic acid and statin preparations for dyslipidemia.

EXPLANATION OF RELATED MATTERS

The CQs focused on important clinical issues and examined branching points in the algorithms where clinical judgments often diverge. Other items that were not incorporated into the above text but are important in real-world clinical practice (26 items) are explained in the "Explanation of Related Matters" section.

Diagnosis and conservative treatment of urinary stones

This subsection explains the basics of interview-based and physical findings, as well as clinical tests, diagnostic imaging, pain relief, medical expulsive therapy, initial evaluation, and conservative treatment for patients with obstructive pyelonephritis, older patients, long-term bedridden patients, pregnant women, and children.

Surgical treatment of urinary stones

This subsection explains the basic concepts of surgical terminology—including ESWL, TUL/URS, PNL/PCNL, ECIRS/TAP, surgical treatment for lower urinary calculi, preferred

surgical treatments for pregnant women, children, and special cases, new surgical therapies that are expected to be introduced in coming years, and renal or ureteral calculi that should not be treated surgically.

Prevention of urinary stone recurrence

This subsection explains basic information regarding clinical tests, follow-up observational approaches, lifestyle advice, and drug therapy to prevent recurrence.

Complementary items related to urolithiasis

This supplementary section regarding urolithiasis provides explanations on the comparison between the American Urological Association[132,133] and European Association of Urology[134] guidelines, genetic testing and counseling, drug-related urolithiasis, the current state of research concerning the occurrence and treatment of urolithiasis, the medical economic evaluation of this condition, and basic information regarding the content of stone-related substances in foods.

CONCLUSION

The clinical practice guideline for the management of urinary stones (third edition) is based on medical and scientific evidence, whenever possible. Therefore, these guidelines should preferably be used as a reference when determining treatment courses for urolithiasis. However, when deciding on a policy for each patient, their individual values should be respected, and decisions should be made in conjunction with medical personnel while considering the patient's history and other factors. This guideline is intended to provide guidance for treatments and is subject to change with the development and advancement of therapeutic techniques. Therefore, it is necessary to make flexible clinical decisions according to the constantly evolving medical environment and each patient's unique circumstances. The current clinical research on urolithiasis does not include many studies with high levels of evidence, particularly in Japan. In addition to the CQs that were not adopted in this study, many other important clinical issues have been listed as future research questions (FRQs) in this guideline. We hope that clinical research will be actively conducted to build new evidence, using these FRQs as a reference, and that the guideline will be revised in the future to better meet the needs of the times.

ACKNOWLEDGMENTS

We would like to thank Editage (www.editage.jp) for English language editing.

AUTHOR CONTRIBUTIONS

Katsuhito Miyazawa: Conceptualization; methodology; data curation; formal analysis; supervision; funding acquisition; project administration; writing – original draft; writing – review and editing. **Satoshi Yamaguchi:** Conceptualization; methodology; investigation; validation; formal analysis; writing – original draft; supervision. **Taro Iguchi:** Conceptualization; methodology; investigation; validation; formal analysis; writing – original draft; supervision. **Ippei Chikazawa:** Conceptualization; methodology; investigation; validation; formal analysis; writing – original draft. **Takahiro Yasui:** Investigation; writing – original draft; formal analysis. **Satoru Takahashi:** Formal analysis. **Shiro Hinotsu:** Conceptualization; methodology; supervision. **Koichiro Akakura:** Investigation; writing – original draft; formal analysis. **Shizuka Iida:** Investigation; writing – original draft; formal analysis. **Noritaka Ishito:** Investigation; formal analysis; writing – original draft. **Takaaki Inoue:** Investigation; formal analysis; writing – original draft. **Yasuo Kohjimoto:** Investigation; writing – original draft; formal analysis. **Shinichi Sakamoto:** Investigation; formal analysis; writing – original draft. **Yoshikazu Sato:** Investigation; writing – original draft; formal analysis. **Ryoji Takazawa:** Investigation; writing – original draft; formal analysis. **Tatsuya Takayama:** Investigation; formal analysis; writing – original draft. **Masao Tsujihata:** Investigation; formal analysis; writing – original draft. **Yukio Naya:** Investigation; formal analysis; writing – original draft. **Shuzo Hamamoto:** Investigation; formal analysis; writing – original draft. **Motoyuki Masai:** Investigation; writing – original draft; formal analysis. **Takuro Masaki:** Investigation; writing – original draft; formal analysis. **Junichi Matsuzaki:** Investigation; formal analysis; writing – original draft. **Soichi Mugiya:** Investigation; formal analysis; writing – original draft.

CONFLICT OF INTEREST STATEMENT

The Japanese Association of Medical Sciences (JAMS) COI management guidance on eligibility criteria for clinical practice guideline formulation 2017 was used to monitor each member's COI. COI declarations by all members involved in the development of these guidelines have been carefully examined by the COI committee of JUA and published on the website (https://www.urol.or.jp/lib/files/other/guideline/46_urolithiasis_supplement.pdf). When voting on the recommendation, the committee members with COI regarding the content of the CQ were to abstain from voting. Katsuhito Miyazawa, Taro Iguchi, Takahiro Yasui, Satoru Takahashi, and Shinichi Sakamoto are Editorial Board members of the *International Journal of Urology* and co-authors of this article. To minimize bias, they were excluded from all editorial decision-making related to the acceptance of this article for publication.

APPROVAL OF THE RESEARCH PROTOCOL BY AN INSTITUTIONAL REVIEWER BOARD

N/A.

INFORMED CONSENT

N/A.

REGISTRY AND THE REGISTRATION NO. OF THE STUDY/TRIAL

N/A.

ANIMAL STUDIES

N/A.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Figure S1.
Figure S2.
Figure S3.
Figure S4.