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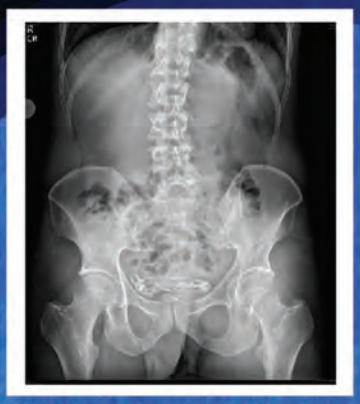
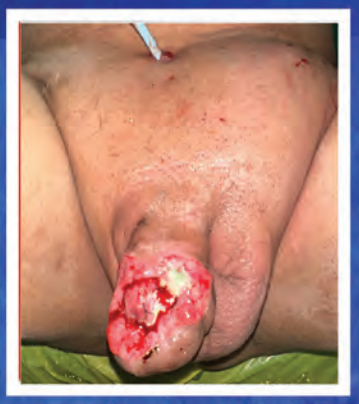


KUB X-ray showing radiopaque, coiled metallic densities



Fungating ulceroinfiltrative penile mass

ISSUE HIGHLIGHTS

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Editorial Board

SPECIAL ARTICLE

Philippine Clinical Practice Guidelines on the Management of Urolithiasis in Adults*

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Introduction: Urinary stone disease remains a significant global and national health concern. This underscores the need for measures to improve disease outcomes. The development and implementation of clinical practice guidelines for urolithiasis was deemed essential due to variations in practice, the evolving urologic field with its emerging interventions, which may have significant cost implications.
Methods: The CPG was developed following the GRADE Adolopment method, the CORE GRADE Approach and the GRADE Evidence to Decision framework, and utilized the Technical Manual for Clinical Practice Guideline Development of the Department of Health (2nd edition). The guideline development group was organized after review and management of the members' conflict of interest declarations. Clinical questions were prioritized and a systematic search and synthesis of the relevant literature to answer the questions was done. Considering the balance of benefits and harms, certainty of the evidence, cost and cost effectiveness, accessibility, acceptability and feasibility of the interventions, the guideline panel developed recommendations by consensus.
Results: The CPG addresses eleven priority clinical questions involving diagnosis and treatment of acute flank pain due to suspected urolithiasis among adults, minimally invasive treatment of nephrolithiasis measuring 1-2 cm and the use of alpha blockers after ESWL through twelve recommendations and one good practice statement.
Conclusion: The Philippine CPG on the management of urolithiasis in adults provides actionable recommendations to address important clinical questions on the diagnosis and management of urinary stone disease .The full text of the clinical practice guideline may be viewed and downloaded from https://doh.gov.ph/dpcb/doh-approved-cpg/

Key words: Clinical practice guidelines, urolithiasis

Introduction

Urolithiasis, commonly known as urinary stone disease, is the formation of stones in the urinary tract. This disease entity remains a significant global health concern. It has exerted a significant burden of disability, morbidity, mortality, and medical costs worldwide. In the Global Burden

* To be published concurrently in the Philippine Journal of Emergency Medicine

of Disease study in 2021, there were 106 million incident cases of urolithiasis, accounting for 17,700 deaths in both sexes. Urinary stone disease is also responsible for 694,000 disability adjusted life years (DALYs)[1]

In 2021, The Philippines accounted for 2,560,000 cases of urolithiasis, amounting to 20% of the total cases in Southeast Asia. This is second only to Indonesia in the region. Moreover, the Philippines recorded 22,600 age-standardized DALYs per 100,000, third highest in the world, and is also ranked fourth globally in age-standardized urolithiasis-related death rates at 0.7 per 100,000 cases, following Armenia, Kazakhstan, and Trinidad and Tobago.[1] This especially underscores the need for better preventive measures and standardization and a multidisciplinary initiative to improve disease outcomes.

National efforts include House resolutions urging legislation to facilitate comprehensive programs for prevention and treatment of urinary stone disease.[8] The development of local clinical practice guidelines is one such effort. Furthermore, the development and implementation of clinical practice guidelines for urolithiasis was essential due to several factors. Variations in clinical practice can lead to inconsistent patient outcomes. Evidence-based guidelines provide a standardized approach to diagnosis, treatment, and follow-up, ensuring uniform care of the highest quality. The field of urology is continually evolving, with new research introducing more effective diagnostic tools and treatment modalities. Regularly updated guidelines ensure that the latest evidence is integrated into clinical practice, optimizing patient outcomes. Certain interventions for urolithiasis can have significant cost implications. Guidelines help in making informed decisions about the most efficient use of resources, balancing efficacy and cost-effectiveness. Emerging interventions or those not previously covered necessitate the development of new guidelines to provide clear recommendations for clinicians.

The absence of local guidelines tailored to the specific epidemiological and socio-economic landscape of the country warranted an endeavor to factor in this context in patient management. Streamlined, appropriate, and accessible recommendations would address local practice variations, incorporate region-specific evidence, and provide direction on cost-effective interventions suitable for the country's healthcare system and patient demographic.

The Philippine Urological Association (PUA) in collaboration with various specialty societies and stakeholder organization, developed this clinical practice guidelines (CPGs) in the Philippines for the management of adult patients with urolithiasis across primary and specialty care settings, utilizing the best available scientific evidence and considering the economic implications of diagnostic tests and pharmacologic therapies.

Methods

In 2023, the PUA deputized its Clinical Practice Guideline Committee to spearhead the development of the CPG on Urolithiasis. In 2024, with the oversight of the PUA Executive Committee member in charge of CPGs, the Steering Committee Chair was appointed and the Conflict of Interest Review Committee (COIRC) was convened. The members of the different working groups were nominated and eventually appointed, after a review of the declarations of conflicts of interest by each nominee by the COIRC Committee. The working groups of the Guideline Development Group (GDG) included the Steering Committee (SC), the Technical Working Group (TWG), which included the Technical Lead (TL), the Evidence Reviewers (ERe) and the Technical Facilitator (TF), and the Guideline Panel (GP). The SC and GP were composed of representatives from the Philippine Urological Association, Philippine College of Emergency Medicine, Philippine Society of Nephrology, Philippine Academy of Family Physicians, Philippine Society of General Internal Medicine, Philippine Association of Nutritionists, Philippine Alliance of Patients Organizations and the Department of Health. The GDG received technical assistance from the Institute of Clinical Epidemiology of the University of the Philippines Manila – National Institutes of Health (ICE UPM-NIH).

The general methodology of the guideline development followed the provisions in the DOH Technical Manual for Clinical Practice Guidelines

Development, 2nd edition (https://doh.gov.ph/techmanual-for-cpg-development-2nd-edition)

A preliminary list of clinical questions on the diagnosis and management of urolithiasis was compiled during a CPG workshop attended by PUA and Philippine Urology Resident Association (PURA) members on May 25, 2024. The SC members representing non-urologic organizations also nominated clinical questions for possible inclusion in the CPG. The SC held prioritization meetings on March 20, 2025 and March 30, 2025 to short list the questions to 11, taking the following into consideration: uncertainty in practice / common question in practice, variation in practice, new evidence for consideration, cost considerations / significant resource use and clinical question not previously or sufficiently addressed in other guidelines. The guideline questions were converted to evidence review questions using the PICO (Population, Intervention, Comparator, Outcome) or PIRT (Population, Index Test, Reference Standard, Target Outcome) format.

A comprehensive list of outcomes across all clinical questions was generated. These outcomes were rated by the SC for their importance to decision-making using a 9-point GRADE scale, with scores 7 to 9 as critical for decision-making, 4 to 6 as important but not critical, and 1 to 3 being of low importance (REFERENCE). The thresholds for the minimally important benefit and the minimally important harm for each critical and important outcome was determined by consensus among the SC members. These thresholds were used in the interpretation of the pooled results. The ratings of the outcomes their thresholds for the minimally important differences were confirmed with the GP during the en banc meeting.

The protocol of the CPG was submitted to the DOH National Practice Guidelines Program (DOH NPGP) and was published in the Philippine Journal of Urology.[9]

The guideline was developed through the GRADE Adolopment approach.[10] An extensive search for existing clinical practice guidelines was undertaken in June 2024. Candidate CPGs were appraised using the AGREE II tool[11] by at least two independent reviewers who were members of the PUA and PURA, and the PUA-CPG Committee Chair. Guidelines were considered eligible if they demonstrated good quality (≥75% score) in at least five AGREE II domains, without any failing scores (≤40%) in the Scope and Purpose and Rigor of Development domains.

The guidelines assessed did not allow for adaptation for several reasons : (1) some of the questions were not included, (2) the evidence to decision issues taken into consideration in the drafting of the recommendations were not explicit or available, and (3) the evidence base used was not up to date. Likewise, no recent systematic reviews were identified for any of the questions. Hence, de novo systematic reviews and metanalyses were performed for all questions. Literature searches were performed in major international databases including MEDLINE (via PubMed), CENTRAL (Cochrane Central Register of Controlled Trials), and Google Scholar. Local databases such as HERDIN and the PCEDM registry of research outputs were also consulted to identify relevant Philippine-based studies. Searches were performed from April to September 2025.

Search strategies were designed around the structured PICO (Population, Intervention, Comparator, Outcome) or PIRT (Population, Index Test, Reference Standard, Diagnosis/Outcome; for diagnosis questions) framework of each guideline question. Search terms included both Medical Subject Headings (MeSH) and free-text keywords. Known researchers and authors of relevant articles, particularly local research, were contacted for full texts or clarifications.

Studies were included if they were aligned with the structured PICO or PIRT questions and reported patient-important outcomes identified as critical or important. Screening and selection of the studies were performed independently by two reviewers.

Quality and risk of bias assessments were conducted using validated tools appropriate to the study design: ROBUST RCT for randomized controlled trials, QUADAS-2 for diagnostic accuracy studies, and Newcastle-Ottawa Scale (NOS) for observational cohort and case-control studies. Two reviewers independently assessed the risk of bias for each included study. Discrepancies were resolved through consensus.

Separate literature searches were performed to identify relevant research on cost-effectiveness,

stakeholder values and preferences, acceptability and feasibility.

A customized data extraction form was used to systematically collect information on study characteristics and findings. The extracted data included the study design and setting, sample size and population characteristics, details of the intervention and comparator. Key outcomes such as stone-free rates, recurrence, and adverse events were recorded, along with the results, effect estimates, and corresponding confidence intervals. Two reviewers extracted the data independently, and any discrepancies were resolved through discussion.

Where appropriate, meta-analyses were performed using Review Manager (RevMan 5.4). Effect measures were expressed as risk ratios (RR), odds ratios (OR), mean differences (MD), and 95% confidence intervals (CI), depending on the outcome type. For diagnostic accuracy reviews, meta-analyses were performed using MetaDisc 2.0. Pooled sensitivity and specificity using bivariate analysis (or univariate analysis when less than 4 studies were included). In cases where meta-analysis was not appropriate due to heterogeneity in study design, populations, interventions, or outcome measurement, a narrative synthesis was conducted.

The Evidence Reviewers followed the CORE GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach11 to evaluate and summarize the certainty of the evidence across outcomes. Results were summarized in a Summary of Findings (SoF) table, supported by the GRADEpro online software (Evidence Prime, Ontario Canada), linking effect estimates, absolute effects, and certainty judgments to support transparent, patient-centered recommendations.

The guideline recommendations were developed using the GRADE Evidence-to-Decision (EtD) framework.[10] The EtD framework guided the panel in translating evidence into actionable recommendations, taking into account several key domains : Importance and rationale of the question, evidence of test accuracy (for diagnostic questions), evidence of benefit versus harm, including net benefit or harm, certainty of the evidence for benefit and harm, resource use, costs, and cost-effectiveness, availability and accessibility of the intervention, and values and preferences of patients and providers.

The GP members were furnished copies of the evidence summaries for all the guideline questions with corresponding GRADE EtD worksheets one week prior to the en banc meeting. The worksheet responses were collated and presented during the en banc meeting and used as touchpoints for discussion. The GP en banc session was held on October 11, 2025.

The recommendation for each question and its strength was determined through voting. A consensus decision was reached if 75% of all voting GP members agreed. When consensus was not reached in the first voting, questions and further discussions among the panel members were encouraged. A maximum of three rounds of voting was planned and If no consensus was still reached, a Delphi method of voting would have been implemented. None of the questions reached a third round of voting.

For one of the clinical questions, no direct evidence was found to provide quality scientific evidence to support a recommendation. The GP agreed to issue a Good Practice Statement after ascertaining that the requirements for the issuance of such a statement based on the criteria set by the GRADE group were met.[12] The Panel collectively believed that the public and the healthcare providers would undeniably benefit from a clear and actionable guidance for the clinical question.

Three independent external reviewers (a urologist, an emergency medicine physician and a family physician) were invited to evaluate the draft CPG using the AGREE-REX (Appraisal of Guidelines Research and Evaluation–Recommendation Excellence) tool and/or AGREE-II tool. All were not involved in the guideline development process. They were selected based on their professional expertise, independence from the CPG developers, and familiarity with clinical practice or health policy in the Philippine context.

All feedback from external reviewers were consolidated by the TWG and reviewed by the SC. Suggestions that improved the clarity, contextual relevance, or applicability of the recommendations were integrated into the final manuscript. For conflicting inputs, the SC deliberated and made consensus-based decisions grounded in evidence,

clinical judgment, and methodological standards. The final CPG manuscript was submitted to the DOH NPGP for review, approval and acceptance for inclusion into the DOH Compendium of Approved CPGs. The full text of this CPG is available at https://doh.gov.ph/dpcb/doh-approved-cpg/

This Guideline was developed with the financial support from the PUA. Logistical support to the GDG was provided by the PUA Secretariat and the PUA CPG Committee. Technical assistance was provided by the UPMNIH-ICE through a critical review of the CPG protocol, the evidence summaries and the final CPG manuscript. Training of some of the evidence reviewers was also provided by UPMNIH-ICE.

The PUA Executive Committee and the UPMNIH-ICE did not have any influence in the selection of the members of the CPG working groups, the prioritization of the guideline questions and in the formulation of the recommendations of the CPG.

Results

The CPG addresses eleven priority clinical questions involving diagnosis and treatment of acute flank pain due to suspected urolithiasis among adults, minimally invasive treatment of nephrolithiasis measuring 1-2 cm and the use of alpha blockers after ESWL through twelve recommendations and one good practice statement.

Guideline Question 1:

Should ultrasonography be used versus non-contrast computed tomography (NCCT or CT stonogram) in patients consulting for acute renal colic or flank pain suggestive of urolithiasis at the Emergency Department (ED)?

Recommendations

We suggest against the use of ultrasound alone to diagnose urolithiasis in patients with acute renal colic or flank pain suggestive of urolithiasis at the ED. (Low certainty, Weak strength rating)

We recommend the use of KUB xray with ultrasound rather than ultrasound alone to diagnose urolithiasis in the absence of CT scan in patients with acute renal colic or flank pain suggestive of urolithiasis at the ED. (Moderate certainty, Strong strength rating)

Key Findings and Statement of the Evidence

Eight studies evaluated imaging strategies for diagnosing urolithiasis in adults presenting to the emergency department, including one randomized controlled trial and seven observational diagnostic accuracy studies.

Ultrasound alone had variable sensitivity and was more likely to miss urolithiasis, while combining it with KUB X-ray improved detection but increased false positives. CT scan showed the highest diagnostic accuracy, consistently identifying stones with minimal missed diagnoses and false positives.

Ultrasound-based approaches were associated with shorter emergency department stays but higher return visits and may lead to more missed high-risk diagnoses, though these were rare.

The overall certainty of evidence was low for the use of ultrasound alone, and moderate for the use of KUB Xray with ultrasound versus ultrasound alone.

Key Considerations and Consensus Issues

For adult patients presenting at the emergency room with acute renal colic, the preferred initial imaging modality to diagnose urolithiasis is a non-contrast CT scan or CT stonogram. The consensus for this recommendation was met after the first round of voting, with a dissenting opinion due to the variability of diagnostic accuracy of ultrasound depending on stone location and the concomitant heterogeneity of included studies in this regard.

Although ultrasound is relatively more accessible, and its utility as a point-of-care diagnostic in the emergency room is increasing, training of technicians and ER doctors (in addition to radiologists) for POCUS (point-of-care ultrasound) is still in its infancy in the country. Although less costly and with a shorter turn-around time, a recommendation against the ultrasound as the sole diagnostic was based on a strong concern for missed diagnoses.

The Panel considered the evidence presented on the use of KUB X-ray in conjunction with a KUB ultrasound to strengthen the latter's diagnostic accuracy, for which the certainty of evidence was moderate. In the absence of CT scan, or for patients for whom computed tomography is contraindicated (pregnant women, children) it was a unanimous recommendation to use KUB X-ray (with or without an abdominal shield) in conjunction with a KUB ultrasound to diagnose urolithiasis with more certainty. Other options for pregnant women may be considered, depending on context, but is outside the scope of this guideline.

Guideline Question 2:

Should NSAIDs be used in patients consulting for acute renal colic at the emergency department?

Recommendation

We recommend the use of intravenous NSAIDs instead of opioids as the initial pain reliever in patients consulting for acute renal colic at the ED. (Very low certainty. Strong strength rating)

Key Findings and Statement of the Evidence

Fifteen (15) RCTs investigated the efficacy and safety of NSAIDs compared to opioids among adult patients presenting with acute renal colic. The studies were overall assessed to have moderate to high risk of bias.

Based on the available evidence, among adult patients with acute renal colic, NSAIDs, compared to opioids probably reduce the need for rescue analgesia slightly, may have little to no effect on total pain relief at 30 min but the evidence is very uncertain, reduce pain intensity measured by VAS pain score at 15 min but the degree is negligible, reduce pain intensity measured by VAS pain score at 30 min., may result in an at least 50% reduction in initial pain at 30 mins, may shorten the time to discharge slightly, may have little to no effect on total adverse events but the evidence is very uncertain, and likely reduces vomiting.

The overall certainty of the evidence is very low.

Key Considerations and Consensus Issues

On review of available evidence, NSAIDs as first-line therapy (when used as a single parenteral dose) appear to provide better pain reduction when compared to opioids, and decreased both the need for rescue analgesia and incidence of vomiting; however the certainty of the evidence was deemed to be low due to the risk of bias across the reviewed studies. The Guideline Panel unanimously strongly recommended NSAIDs despite overall low certainty of evidence, placing emphasis on overall favorable side-effect profile of NSAIDs over opioids. The panel also placed higher value on the shorter time to discharge associated with NSAIDs as compared to opioids particularly in high-turnover settings such as the Emergency Department. Furthermore, the panel emphasized the easier availability of NSAIDs in most healthcare settings, as special licensing is required for access to opioids.

The Panel also emphasizes that for patients with contraindications to NSAIDs, alternatives may be considered.

Guideline Question 3:

Should antispasmodics be used in patients consulting at the ED for acute renal colic or for flank pain suggestive of urolithiasis?

Recommendation

We suggest against giving intravenous hyoscine as an add-on to standard of care for patients consulting for acute renal colic or flank pain. (Low certainty. Weak strength rating)

Key Findings and Statement of the Evidence

Eight randomized controlled trials were included.

Based on the available evidence, among patients with acute renal colic, hyoscine, compared to placebo, may result in an increase in pain relief at 30 mins (VAS score). Hyoscine, compared to NSAIDs, probably results in lower proportions of patients achieving >50% pain reduction and may result in lower mean reductions in pain scores. Adding hyoscine to NSAIDs make little to no

difference in terms of achieving >50% reduction in pain, and makes little to no difference in terms of decreasing need for rescue medication. Hyoscine, when added to NSAID and opioid therapy, likely provides little to no additional benefit in reducing patient-reported pain scores and in reducing the use of rescue analgesia.

Overall, the certainty of the evidence is low.

Key Considerations and Consensus Issues

On review of the available evidence, the addition of hyoscine to NSAIDs and opioids provided little to no reduction in pain and need for rescue medication. Hyoscine-N-butylbromide specifically as monotherapy resulted in less pain reduction when compared to NSAIDs. However, the overall certainty of the evidence was low due to risk of bias and imprecision.

The dose of Hyoscine-N-butylbromide in most studies was 50mg given as a single parenteral dose. The panel emphasized the setting of the guideline question and subsequent recommendation as the emergency department wherein intravenous medications are available. Greater emphasis was placed on avoiding unnecessary additional medications that provide limited benefit. Issues about formulary availability, hidden costs of intravenous medication, and drug availability at different healthcare facility levels were also brought up. The question reached three rounds of voting before a consensus was met, with a dissenting opinion stating that any benefit, regardless of degree (i.e. even a difference of 1-2 VAS points), may be of significance in the acute setting; while some reinforced that ineffective adjunct medication may increase risk for additional treatment or may delay necessary surgery.

The Panel voted unanimously on the use of hyoscine in the setting where both NSAIDS and opioids are either contraindicated, or are unavailable. Similarly, the panel emphasized a step-wise approach to pain treatment (i.e. the pain ladder paradigm) as the standard of care in pain treatment. In this approach, step-up medication (rather than add-on medication) is the acceptable recourse for ineffective pain relief. It was also noted that step-up medications such as opioids may require special licenses limiting accessibility. Moreover, the panel emphasized that for pain refractory to medical treatment, a surgical consultation or referral may be considered.

Guideline Question 4:

Should propulsives be used in patients consulting for acute renal colic or for flank pain suggestive of urolithiases at the ED?

Recommendation

We recommend the use of intravenous metoclopramide as an add-on to NSAIDs in patients consulting for acute renal colic or flank pain suggestive of urolithiasis at the ED. (Low certainty. Strong strength rating)

Key Findings and Statement of the Evidence

Two randomized controlled trials with a total of 280 patients evaluated the use of metoclopramide for acute renal colic.

Based on the available evidence, in patients with acute renal colic, metoclopramide alone compared to NSAIDs likely results in little to no difference in reduction in pain scores (mm) and may slightly decrease need for rescue analgesia. Metoclopramide added to NSAIDs compared to NSAIDs alone may result in little to no difference in reduction in pain scores (mm) and probably results in a decrease in need for rescue medication. Metoclopramide alone versus combination/ spasmofen does not result in a reduction in pain scores (mm).

The overall certainty of evidence is low.

Key Considerations and Consensus Issues

On review of available evidence, metoclopramide monotherapy resulted in little or no pain reduction compared to NSAIDs, but reduced need for rescue medication when used with NSAIDs. The dose prescribed was 10mg as a single intravenous dose at the ED.

A consensus was reached after the first round of voting, with a dissenting opinion because of the availability of more effective step-up relief options and the low certainty of evidence of benefit. Hence, it was emphasized that the recommendation is

for metoclopramide as an add-on and not as a first line or step-up treatment for acute renal colic. A strong recommendation was given despite the low certainty of evidence due to a net benefit, particularly in the prevention of requiring additional medication for pain relief, the wide availability of metoclopramide, and the accepted beneficial effect of metoclopramide in addressing nausea and vomiting that is commonly seen among patients with acute renal colic.

Guideline Question 5:

Should uro-selective alphablockers be used in patients consulting for acute renal colic or flank pain suggestive of urolithiasis?

Recommendation

We suggest giving uroselective alpha blockers in patients consulting for acute renal colic. (Low certainty. Weak strength rating)

Key Findings and Statement of the Evidence

Fourteen RCTs were included with a total population of 3,622.

Based on the available evidence, it is uncertain if alphablockers reduce the risk of requiring analgesia and probably do not reduce the number of times requiring analgesia among patients with renal colic due to ureterolithiasis. Alphablockers may increase stone free rates and result in a slight decrease in the time to stone clearance. Alphablockers may result in little to no effect on orthostatic hypotension but probably increase abnormal ejaculation.

The overall certainty of the evidence is low

Key Considerations and Consensus Issues

On review of available evidence, uroselective alpha blockers increased stone-free rates and shortened time to stone passage but had little to no effect in reducing the need for analgesia. The certainty of evidence was deemed low due to imprecision and risk of bias. A unanimous consensus was reached after one round of voting for the direction of the recommendation. The Panel placed value on the significant benefit with comparatively minimal harm. The strength of the recommendation was weak, with one dissenting opinion for a strong recommendation in the context of consistent evidence of benefit with minimal harm.

The urologists in the panel emphasized the need for establishing a high degree of suspicion for the diagnosis of urolithiasis before starting alphablockers in the emergency room.

Guideline Question 6:

Should coconut water (i.e., buko juice) be used in patients consulting at the outpatient clinic for urolithiasis with a total stone burden less than 1cm?

Good Practice Statement

In patients with urolithiasis, clinicians should advise increased intake of water and low-sugar, noncarbonated drinks - which may include unprocessed and unsweetened coconut water - that will achieve a urine volume of at least 2.5L per day.

Key Findings and Statement of the Evidence

Only one small randomized crossover trial involving eight healthy volunteers was identified. The study reported that coconut water increased urinary citrate, potassium, and chloride, suggesting a possible biochemical benefit. However, it did not evaluate clinical outcomes such as stone-free rate, time to stone passage, recurrence, re-treatment, or adverse events. One additional randomized controlled trial (SLCTR/2019/031) on local fruits including coconut was registered in 2019, but results have not been published. There is no evidence on patient-important outcomes.

The certainty of the evidence is very low.

Key Considerations and Consensus Issues

The available evidence on coconut water for urolithiasis remains very limited. While small biochemical studies suggest increases in urinary citrate and potassium excretion, these surrogate markers have not been shown to translate into clinical outcomes such as stone passage, recurrence prevention, or reduction in stone size. Given its

composition and hydration-promoting properties, coconut water may be considered a safe and culturally acceptable component of adequate fluid intake.

Despite the absence of direct evidence on the effect of coconut water on patient important outcomes, the Panel had a strong collective belief that guidance regarding this clinical question is important. Patients often ask this question and given the relatively low health literacy rate in the country, physicians should be able to provide the proper advice to patients who often ask about this. Hence, the Panel agreed to issue a Good Practice Statement rather than a graded recommendation, after confirming that the situation met the criteria for the issuance of such.

The Panel agreed that clinicians should emphasize that coconut water should not replace medical therapy or guideline-based management. Its use should be framed as part of general hydration advice rather than as a therapeutic intervention. Acknowledging the minimal risk associated with its consumption, coconut water, when unprocessed and unsweetened, may be considered as a low-sugar, noncarbonated beverage that can help achieve a urine output of at least 2.5 liters per day. Clinicians are advised to exercise caution in recommending coconut water for patients with tenuous solute and electrolyte handling, for whom hyperkalemia may develop, and for those who are limiting sugar intake for other comorbidities.

Further local randomized controlled trials are encouraged to determine its true clinical benefit, optimal intake volume, and its role in the management of urolithiasis, within culturally relevant dietary practices among Filipino patients.

Guideline Question 7:

Should Sambong be used in patients consulting for urolithiasis with a total stone burden less than 1 cm?

Recommendation

We suggest the use of Sambong tablets in patients consulting for urolithiasis with a total stone burden less than 1 cm. (Low certainty. Weak strength rating)

Key Findings and Statement of the Evidence

Five (5) RCTs examined the effect of Sambong compared to standard care in patients with urolithiasis. These studies were generally assessed to have a high risk of bias.

Based on the available evidence, among adult patients with urolithiasis, Sambong may slightly increase the stone-free rate, may slightly decrease stone size/number, may slightly increase the stone dissolution rate, probably results in a faster time to stone passage (6 to 7 mm), probably results in a faster time to stone passage (8 to 10mm) and may result in little to no difference in adverse events.

The overall certainty of the evidence is low.

Key Considerations and Consensus Issues

A unanimous consensus was reached after one round of voting for the direction recommendation, with the Panel citing net benefit compared to possible harms. The Panel ascertained that no harms were reported in all the available studies and that the product insert declared no contraindications to the intake of Sambong. The panel was split, regarding the strength of the recommendation, with the final result in favor of a weak recommendation, citing that the low quality of the evidence and limited number of studies (as well as all studies not defining the comparator 'standard of care' in dietary advice and hydration) may have overestimated the effect.

The Panel emphasized that clinicians should prescribe the minimal required dosage of 40mg/kg/day for the duration of 4-16 weeks, as cited in the studies, in the use of Sambong for urolithiasis treatment. It should also be used only for non-obstructing stones.

Questions were raised regarding whether the effects may be extended to Sambong herbal tea, but the review of available evidence showed no information on non-tablet formulations and thus, the recommendation was limited to the tablet formulation. Patients should be informed of such lack of evidence of the effect of Sambong tea.

Another issue brought up was that some stones in the included studies were considered clinically insignificant but the decision of the steering committee was to cite clinical equipoise for the stone size that constitutes significance. Hence,

studies reporting on smaller stones were considered part of the evidence base.

Some Panel members brought up applicability for both outpatient and emergency settings, as the studies were largely heterogenous. It was thus emphasized that Sambong should only be used for non-obstructing stones.

One area of concern was that studies were not stratified according to stone location or composition. This may be a consideration for future studies.

Guideline Question 8:

Should terpene compounds be used in patients with urolithiasis?

Recommendation

We recommend against giving terpene compounds in patients with urolithiasis. (Very low certainty. Strong strength rating)

Key Findings and Statement of the Evidence

Evidence considered: One randomized control trial and two prospective cohort studies involving 303 participants were included in the review.

Based on the available evidence, among adults consulting for urolithiasis, terpene compounds, when compared to NSAIDs, have little to no effect in analgesic use, may slightly increase stone stone free rate and may reduce time to stone passage slightly. On the other hand, terpene compounds, when compared with alphablockers, may increase analgesic requirement slightly and may have little to no effect on the time to reach stone free status. They may lower stone passage rate but the evidence is uncertain. Mild gastrointestinal symptoms (e.g., dyspepsia, abdominal discomfort) were associated with terpene compounds. There were no serious or life-threatening adverse events reported.

The overall certainty of evidence is very low.

Key Considerations and Consensus Issues

The Panel issued a unanimous strong recommendation against the routine use of terpene compounds in patients with urolithiasis, because of the very low certainty of evidence. This indicated an uncertain benefit and reduced efficacy relative to alpha-blocker, signals toward harm particularly when compared to alphablocker use, the limited access due to non-inclusion in the national formulary, and the higher costs compared to standard therapy.

The Panel recognized the substantial research gap and emphasized the need for well-designed randomized controlled trials to clarify the role, if any, of terpene compounds in the management of urolithiasis.

Guideline Question 9:

Should sodium citrate be used instead of potassium citrate in patients consulting for urolithiasis?

Recommendation

We suggest against using sodium citrate instead of potassium citrate in patients with urolithiasis. (Very low certainty. Weak strength rating)

Key Findings and Statement of the Evidence

One randomized controlled trial compared a sodium citrate–based combination therapy with potassium citrate monotherapy, evaluating outcomes such as stone-free rate, probability and mean stone size reduction, and incidence of adverse events after 6 weeks of treatment.

Based on the available evidence, among patients consulting for urolithiasis, sodium citrate may result in little to no difference compared to potassium citrate in achieving stone-free status, may increase the probability of reducing stone size at 6 weeks. The evidence is very uncertain on the difference in the effect of sodium citrate on mean change in stone size when compared with potassium citrate, and may result in little to no difference on the occurrence of adverse events compared to potassium citrate but the evidence is very uncertain.

The overall certainty of the evidence is very low.

Key Considerations and Consensus Issues

Evidence directly comparing sodium citrate and potassium citrate for urolithiasis management is scarce and of very low certainty. Available data suggest that while both agents exert similar biochemical effects in alkalinizing urine, no study has demonstrated a clear clinical advantage for sodium citrate. Moreover, the additional sodium load may worsen hypertension, edema, or cardiovascular disease—conditions commonly observed among Filipino patients.

The Panel emphasized that most international guidelines recommend limiting sodium intake as part of non-pharmacologic management and recognize potassium citrate as the standard alkalinizing therapy. Because the guideline question involved a head-to-head comparison between sodium citrate (and not as a part of a mixture of compounds) and potassium citrate, and given the lack of compelling evidence of benefit for sodium citrate, the panel suggested a weak recommendation against its routine use in place of potassium citrate. Since only one brand of sodium citrate is available, access may be an issue and this was considered in suggesting against its routine prescription.

Nonetheless, sodium citrate may be considered in selected patients—particularly those with hyperkalemia (or at risk for hyperkalemia), with gastrointestinal intolerance to potassium citrate, or when potassium citrate is unavailable. Because of this limited utility, the strength of the recommendation was deemed weak. Clinicians should individualize therapy based on comorbid conditions, drug availability, and cost considerations.

Guideline Question 10:

Should extracorporeal shockwave lithotripsy (ESWL) be used in patients with nephrolithiasis with a total stone burden between 1 to 2 cm?

Recommendation

We suggest performing ESWL in patients with nephrolithiasis with a total stone burden of 1 to 2 cm. (Low certainty. Weak strength rating)

Key Findings and Statement of the Evidence

Twenty three randomized controlled trials compared ESWL to other minimally invasive procedures such as RIRS or PCNL and evaluated the outcomes such as stone-free rate at 3 months, retreatment rate, and adverse events for total stone burden of 1 to 2 cm. Subgroup analysis was also available for efficacy outcomes such as stone location (i.e., lower vs non-lower pole stones) and stone type (i.e., radio-opaque vs radiolucent stones).

Based on the available evidence, among patients with nephrolithiasis with a total stone burden of 1 to 2 cm, ESWL probably results in a lower stone-free rate at 3 months compared to PCNL or RIRS. ESWL probably increases the need for retreatment versus PCNL or RIRS procedures.

With respect to safety outcomes, ESWL results in lower bleeding risk or need for blood transfusion versus PCNL. ESWL, however, probably results in little to no difference in bleeding risk or need for blood transfusion when compared to RIRS. ESWL probably results in little to no difference in urinary tract infection or urosepsis incidence compared to PCNL and RIRS. Regarding postoperative pain, ESWL may result in little to no difference compared to PCNL and probably results in little to no difference compared to RIRS.

The overall certainty of evidence is low.

Key Considerations and Consensus Issues

The Panel voted unanimously in both direction and strength of recommendation after one round of voting. Despite the higher retreatment rate for ESWL and the low certainty of evidence in its benefit, the panel put higher value in its lower adverse event rate, its wider availability and the equivalence in attaining stone-free rate when compared to PCNL and RIRS.

The Panel emphasized the variability of patient preferences and values in voting for the strength of recommendation. A shared decision between the patient and doctor was stressed, and the following points may be emphasized: in patients who prefer a single treatment, the recommendation of RIRS or PCNL over ESWL may be more prudent; while in

those patients who prefer a shorter convalescence, less risk, and less cost, ESWL may be suggested.

Guideline Question 11:

Should uro-selective alpha-blockers (alfuzosin, silodosin, or tamsulosin) be used in patients undergoing extracorporeal shockwave lithotripsy?

Recommendation

We recommend the use of uroselective alphablockers in patients who underwent extracorporeal shockwave lithotripsy. (Low certainty. Strong strength rating)

Key Findings and Statement of the Evidence

Twenty-six randomized controlled trials with a total of 3045 participants investigated the effect of uro-selective alpha blockers in patients undergoing extracorporeal shockwave lithotripsy

Based on the current available evidence, uro-selective alphablockers may increase stone free rate, reduce the need for retreatment and decrease the risk of steinstrasse and has little to no effect on ER visit, on pain score measured by VAS and on the time to stone free status. The side effects with use of alpha blockers include ejaculatory dysfunction, dizziness and hypotension, but their occurrences are rare.

Overall certainty of the evidence is low.

Key Considerations and Consensus Issues

The Panel voted unanimously in both strength and direction of the recommendation after the first round of voting.

The certainty of evidence was deemed low due to risk of bias, imprecision, and inconsistency. The Panel made a strong recommendation despite a low certainty of evidence, due to the favorable benefit to risk ratio of the intervention. The Panel placed a high value on the benefits of increased stone free rate, retreatment reduction, and steinstrasse reduction, with the minimal possible harm due to a favorable side-effect profile with low incidence of associated adverse events. Other considerations of availability and inclusion in the national formulary contributed to the strength of the recommendation.

Discussion

Most recommendations are technically feasible within tertiary-level hospitals and urban centers. However, implementation at lower levels of care will require investment in diagnostic infrastructure, referral systems, and capacity building. Guideline Questions 1 and 10 entail infrastructure building and expansion of diagnostic capacity, including procurement of CT scan and ultrasound units and training of imaging personnel. Particularly in the Philippine setting, the majority of stand-alone ESWL centers are private-owned, and government efforts need to be strengthened to allay geographic and socioeconomic disparities.

Variations in the market availability and cost of key pharmacologic agents may limit access, particularly for those that are not yet included in the Philippine National Drug Formulary (PNDF). Some of the drugs mentioned in Guideline Questions 8 and 11 are not listed in the PNDF such as Silodosin. Similarly, although compounded costs are known and included in the guideline, there are no local cost-effectiveness or budget-impact analyses for several interventions (e.g., alpha-blocker use after ESWL and herbal therapies such as Sambong). Local data generation is necessary to guide resource allocation and reimbursement policies.

The recommended interventions align with current clinical practice trends and are perceived to be acceptable among urologists and other clinicians familiar with evidence-based management of urolithiasis. However, implementation strategies should prioritize equitable distribution of resources, training, and patient education across all regions.

The value of a clinical practice guideline is in its implementation. Incorporation of its recommendations into the clinical workflow is key (Figure 1). The anticipated facilitators for implementation of this CPG include the strong support and leadership from the PUA, the availability of trained specialists and increasing interest in guideline-concordant care, government programs that provide financial assistance for diagnostics and procedures, and the integration of

guideline content into residency training programs and institutional protocols.

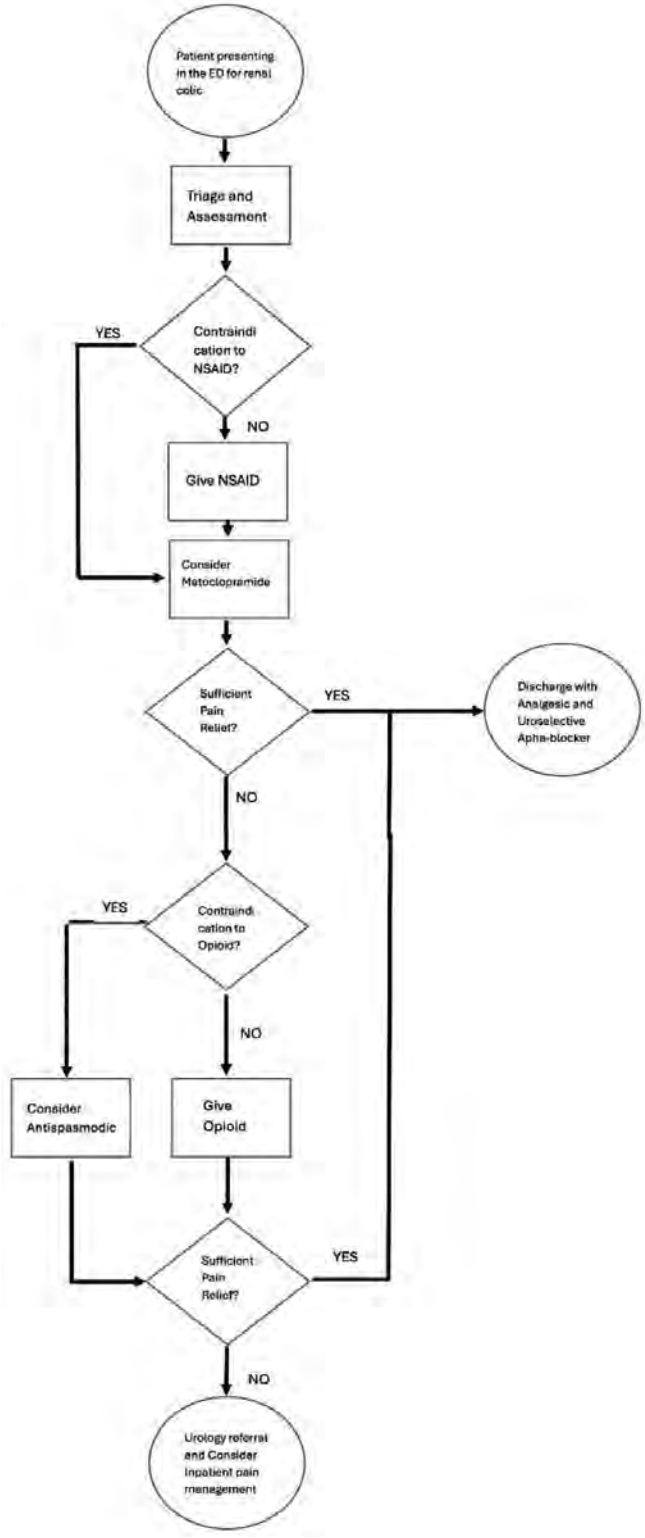

Figure 1. Algorithm for pain management at the emergency department.

On the other hand, several potential barriers to the adoption and implementation of this CPG's recommendations are present. One is diagnostic resource limitations. Access to key diagnostic tools such as non-contrast computed tomography (CT) scans, metabolic work-ups, and stone analysis laboratories remains limited in many primary and secondary care facilities, particularly in rural and underserved regions. This barrier may be addressed In the CPG, as alternative pathways are provided for limited-resource settings. Second, out-of-pocket expenses for diagnostic procedures, medications, and surgical interventions may hinder compliance, particularly among low-income patients and those without adequate insurance coverage. Inclusion in the Philippine National Drug Formulary and routine availability in subsidized local health centers may address this barrier. Third barrier is the variability in clinical practice and knowledge. Differences in practitioner familiarity with evidence-based recommendations and variations in management approaches contribute to inconsistent care, especially outside tertiary centers. Dissemination of the CPG and a multidisciplinary collaboration in guideline development may address this barrier. Systemic and logistical challenges in the current healthcare system may also prevent guideline implementation. Fragmented referral pathways, limited availability of urology specialists in non-urban areas, and lack of structured follow-up systems impede continuity of care and uniform implementation. Empowerment and involvement of frontline practitioners in the ED (Emergency Department) and primary care practitioners may help address this barrier. Finally, access to multidisciplinary care components such as nutrition counseling and long-term metabolic assessment remains suboptimal, reducing opportunities for preventive interventions. Incorporating proper health seeking behaviors, with the aid of specific guidelines at every level of care, with an emphasis on universal healthcare, may help address this barrier.

The Guideline Development Group identified several gaps in the current evidence base for the diagnosis and management of urolithiasis. Future research should aim to generate high-quality, locally relevant data to strengthen future updates of the CPG and guide clinical and policy decisions. In

this regard, research on the following topics should be pursued: economic evaluations on alpha-blocker use post-ESWL; cost-effectiveness of ESWL, RIRS, PCNL stratified according to stone hardness, size, location; optimal combination pain-regimens as initial, and step-up at emergency department and outpatient settings; high-quality studies on terpene compounds and Sambong that establishes causality, either with dose-response, reproducibility, strength of association, or comparison to a stated standard therapy; head-to-head trials of potassium citrate and sodium citrate. Lastly, evaluating the real-world uptake of the CPG recommendations across levels of healthcare is also recommended as part of guideline monitoring and evaluation.

Conclusion

The Philippine CPG on the management of urolithiasis in adults provides actionable recommendations to address important clinical questions on the diagnosis and management of urinary stone disease. The full text of the clinical practice guideline may be viewed and downloaded from https://doh.gov.ph/dpcb/doh-approved-cpg/

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ORIGINAL RESEARCH

Training Satisfaction Among Urology Residents in the Philippines: Validation of a Structured Questionnaire and National Cross-Sectional Survey

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Background and Objective: Residency satisfaction is an important indicator of training quality and may influence physician well- being and performance. Surgical trainees are generally reported to have lower satisfaction compared to other specialties. This study assessed satisfaction among urology residents in the Philippines and evaluated a structured questionnaire for measuring training experience.

Materials and Methods: A cross-sectional survey was conducted among residents in accredited urology programs (2024–2025). A 12-domain Likert-scale questionnaire was developed and validated. Internal consistency and test– retest reliability were assessed. Satisfaction scores were analyzed overall and across subgroups.

Results: A total of 106 residents participated. The instrument demonstrated good internal consistency (Cronbach's $\alpha = 0.879$) and strong test–retest reliability ($r = 0.896$). Overall satisfaction was high (52.4± 5.4/60). Clinical exposure was the highest-rated domain, while work-life balance was the lowest. No significant differences were observed by gender, training year, or institution type. Key areas for improvement were case exposure and academic learning.

Conclusion: Urology residents in the Philippines report high overall satisfaction. The validated questionnaire is reliable and useful for assessing multidimensional aspects of residency training. Improvements in case exposure, academic support, and work-life balance may further enhance training quality.

Key words: Urology residency, training satisfaction, surgical education, questionnaire validation, cross-sectional study

Introduction

Residency training plays a critical role in shaping the clinical competence and professional development of physicians. In addition to acquiring technical and cognitive skills, residents contribute substantially to healthcare delivery within training institutions. Satisfaction with residency training has been associated with physician well-being, retention, and patient outcomes.[1,2]

Multiple factors influence satisfaction, including workload, mentorship, case exposure, academic support, and institutional resources.[3,4] Prior studies suggest that surgical residents may experience lower satisfaction compared to their non-surgical counterparts, largely due to higher

workload and training demands.[5] Within surgical specialties, variability in satisfaction has also been reported depending on subspecialty and training environment.[6]

Despite growing interest in residency satisfaction, there is limited data specific to urology training in the Philippines. Furthermore, existing studies often utilize general job satisfaction measures, which may not fully capture the multidimensional nature of surgical training.

This study aimed to (1) validate a standardized questionnaire for assessing residency satisfaction among urology trainees, (2) determine overall satisfaction levels, and (3) identify key factors contributing to satisfaction.

Methods

Study Design and Participants

A cross-sectional survey was conducted among residents enrolled in urology training programs accredited by the Philippine Urological Association from 2024 to 2025. Eligible participants were residents with at least 6 months of training. Those no longer actively training were excluded.

Questionnaire Development and Validation

A 12-item questionnaire was developed by a panel of five urologists involved in residency training. Content and face validity were established through expert consensus and iterative revision. Items were scored on a 5-point Likert scale (1 = poor to 5 = excellent).

Construct validity was assessed using principal component analysis with varimax rotation. Internal consistency was evaluated using Cronbach's alpha, with values >0.80 considered acceptable. Test– retest reliability was assessed in a subset of residents using the Pearson correlation coefficient.

Measurement of Satisfaction

The questionnaire assessed the following domains: teaching, clinical exposure, case volume, research support, mentorship, educational resources, organizational processes, facilities and equipment, training environment, work-life balance, peer relations, and overall satisfaction. A composite score (range 12–60) was calculated.

Statistical Analysis

Descriptive statistics were used for demographic data. Mean scores were calculated for each domain. Independent t-tests and one-way ANOVA were used to compare satisfaction across gender, institution type, and year of training. Qualitative responses were categorized into themes and analyzed descriptively.

Results

Participant Characteristics

A total of 106 residents participated. Most were male (80.2%) and from government institutions (82.1%). The majority were in later years of training.

Questionnaire Validity and Reliability

Principal component analysis revealed a three-factor structure. The first factor (interpersonal and educational support) included teaching and mentorship, clinical exposure, communication, mentor relations, and peer relations. The second factor (workload and academic support) included work-life balance, research support, and educational resources. The third factor (structural and resource adequacy) included case volume and diversity and facility and equipment quality. Two items (training environment and overall satisfaction) did not load significantly on any factor but were retained as global indicators.

Internal consistency was good (Cronbach's α = 0.879). Test–retest reliability demonstrated strong correlation (r = 0.896), indicating stability over time.

Satisfaction Scores

Overall satisfaction was high, with a mean composite score of 52.4 ± 5.4. Most domains were rated between "good" and "excellent."

- Highest-rated: Clinical exposure (4.7 ± 0.5)
- Lowest-rated: Work-life balance (3.5 ± 1.0)
- Overall satisfaction: 4.5 ± 0.6

Subgroup Analysis

No statistically significant differences were observed:

- Gender: p = 0.063
- Year of training: p = 0.45
- Institution type: p = 0.89

Qualitative Findings

Commonly identified areas for improvement included:

- Case exposure
- Academic learning
- Equipment availability
- Consultant guidance
- Work-life balance

Discussion

This study shows that urology residents in the Philippines generally have high satisfaction with their training. Overall, most trainees feel that their programs are doing well in providing the needed experience for their development as future urologists. This reflects that accredited training institutions are able to deliver the basic requirements of surgical residency, especially in terms of clinical exposure and mentorship.

Among all domains, clinical exposure and hands-on experience received the highest scores. This suggests that residents feel they are getting enough operative and clinical experience, which is very important in a surgical specialty like urology. Previous studies in surgical training also show that case exposure and actual operative experience are some of the strongest factors that affect how satisfied residents are with their training.[6,10]

On the other hand, work-life balance received the lowest score and also had the widest variation in answers. This is consistent with what is seen in other surgical training programs, where residents often have heavy workloads and long duty hours.[5] While satisfaction remains generally high, this finding is important because poor work-life balance has been linked to burnout, fatigue, and even medical errors in previous studies.[16] This means that even if residents are generally satisfied, there is still a need to look into workload and rest conditions.

There were no significant differences in satisfaction when grouped according to gender, year level, or type of institution. Satisfaction was similar across training years, which suggests that the overall training experience is fairly consistent from junior to senior levels. The small variation seen may be due to changes in workload and increasing independence as residents advance in training.[14] The lack of difference between government and private institutions may mean that differences in resources and case volume balance each other out in actual training experience.

From the open-ended responses, residents commonly mentioned the need for better case exposure and more academic activities. This suggests that while residents are generally satisfied, they still want more structured learning such as conferences, lectures, and subspecialty exposure. Equipment availability was also mentioned, which is important because limitations in resources can affect both training and patient care.

Overall, the findings suggest that urology training programs in the Philippines are performing well, but there is still room for improvement in work-life balance, academic structure, and availability of equipment. Addressing these concerns may further improve both resident satisfaction and training quality.

The study has limitations. Being cross-sectional, it only captures satisfaction at one point in time. Self- reported answers may also be affected by personal bias. It also did not assess burnout or patient outcomes, which may be important related factors.

Conclusion

Urology residents in the Philippines are generally satisfied with their training, with strengths seen in clinical exposure and mentorship. Key areas for improvement include work-life balance, academic learning, and training resources.

The standardized questionnaire developed and validated in this study was shown to be effective in assessing residency satisfaction, demonstrating good reliability and internal consistency. It was able to capture multiple relevant domains of training

experience and may be useful for future evaluation of urology residency programs in the country.

Appendix 1. Urology training institutions accredited by the Philippine Board of Urology, Inc. (2025)

1. Batangas Medical Center
2. Corazon Locsin Montelibano Memorial Regional Hospital
3. Dr. Paulino J. Garcia Memorial Research and Medical Center
4. East Avenue Medical Center
5. Jose Reyes Memorial Medical Center
6. National Kidney and Transplant Institute
7. Philippine General Hospital
8. Southern Philippines Medical Center
9. St. Luke's Medical Center
10. UERM Memorial Medical Center
11. University of Santo Tomas Hospital
12. Veterans Memorial Medical Center
13. Vicente Sotto Memorial Medical Center
14. V.Luna Medical Center
15. Northern Mindanao Medical Center
16. Ilocos Training and Regional Medical Center
17. Western Visayas Medical Center

Appendix 2: Data collection form

Residency satisfaction reflects training quality and affects professional well-being, retention, and patient outcomes. This study aims to assess satisfaction levels and contributing factors among Urology residents in the Philippines.

If you wish to participate, please complete and submit this form. Submission implies informed consent. All data will be kept confidential in compliance with privacy regulations.

Name

Age

Year of Training

Training Institution

Category of Training Institution (Government or Private)

Encircle the rating most reflective of your experience for each item

1. Rate the quality of teaching and mentorship you have received*

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

2. How would you rate the clinical exposure and hands-on experience in the program?*

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

3. Evaluated the work-life balance provided by the program *

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

4. How effective is the program in proving research opportunities and support?*

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

5. Rate the quality of facilities and equipment available for training.*

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

6. Rate the volume and diversity of cases available for training*

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

7. How do you find the accessibility and usefulness of educational resources (library, online materials, etc.)?*

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

8. How effective is the communication within the program (feedback, announcements, Information cascading, transparency, approachability, etc.)?*

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

9. Rate your mentor/mentee relationship between you and your program's faculty, not in terms of teaching per se, but in approachability, mutual respect and professionalism?*

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

10. Rate your relationship with your peers and co-residents *

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

11. Rate your satisfaction with the environment within your hospital as a training institution.*

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

12. Overall how satisfied are you with your experience in the Residency Program?*

1-Poor	2- Below Average	3- Average	4- Good	5-Excellent

13. What aspects of the program do you think require improvement?

14. Additional comments and suggestions?

Signature over Printed Name

Date

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ORIGINAL RESEARCH

Association Between Preoperative Hydronephrosis and Perioperative Outcomes Among Patients Undergoing Percutaneous Nephrolithotomy: A Single-Center Prospective Cohort Study

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Background: Staghorn calculi are complicated renal stones that are frequently linked to hydronephrosis, a parameter that can have a major impact on the results of surgery. Percutaneous nephrolithotomy (PCNL) is widely recognized as the gold standard for treating large kidney stones and staghorn calculi. Data on the effect of preoperative hydronephrosis on PCNL perioperative outcomes is still limited.
Objective: This study aimed to investigate the association between preoperative hydronephrosis and perioperative outcomes among patients undergoing PCNL in a tertiary government hospital in Manila.
Methods: A single-center prospective cohort study was conducted, involving 90 patients diagnosed with staghorn calculi and scheduled for elective PCNL. Patients were categorized into two groups based on the presence or absence of moderate-to-severe hydronephrosis as determined by preoperative imaging. Perioperative outcomes, including total operative time, access time, lithotripsy rate, and perioperative complications such as bleeding and sepsis, were evaluated. Data were analyzed using linear and logistic regression models to assess associations between hydronephrosis and perioperative outcomes.
Results: The presence of hydronephrosis was associated with a statistically significant reduction in access time ($p = 0.036$), likely due to the dilation of renal structures facilitating easier entry. However, hydronephrosis was linked to a borderline significant reduction in lithotripsy rate ($p = 0.051$), indicating potential challenges in stone fragmentation. No significant association was found between hydronephrosis and total operative time or perioperative complications, such as bleeding and sepsis.
Conclusion: While hydronephrosis may make kidney access and other technical aspects of PCNL easier, it may also make stone fragmentation more difficult. Larger stone size and stone location were significant predictors of longer operative times and slower lithotripsy rates, underscoring their critical role in surgical outcomes.

Key words: Pre-operative hydronephrosis, staghorn calculi, perioperative outcome

Introduction

Staghorn calculi are upper urinary tract stones that extend into at least two calyces and involve the renal pelvis. In most times, they are composed of struvites (magnesium ammonium phosphate crystals), which are linked to recurrent urinary tract infections by urease-producing pathogens.[1]

The gold standard and primary option for renal stones greater than 20 mm is percutaneous

nephrolithotomy (PCNL), according to guidelines published by the European Association of Urology (EAU). It may also be an alternative to retrograde intrarenal surgery (RIRS) for the treatment of stones measuring between 10 mm and 20 mm due to better stone-free rates achieved by a single procedure.[2]

Despite recent advancements, complications are still frequent, affecting almost 25% of patients (23.3%).[3] Infection, bleeding, damage to nearby organs, retained stone, loss of kidney function, and even death can occur as a result of PCNL. Fever was the most frequent complication of all, followed by bleeding.[4] In order to lower the rate of complications and enhance the quality of care provided to patients, it is crucial to investigate the factors that influence PCNL complications.[5] Larger stone sizes have been identified as risk factors that may raise the rates of complications, including bleeding, fever, sepsis, and retained stones following PCNL.[6]

Hydronephrosis was another factor that has been shown to be connected to PCNL success and problems.[7] According to previous research, the lack of hydronephrosis was a predictor of PCNL problems, such as significant bleeding following PCNL, for a number of reasons.[8] The difficulty of accessing the kidney decreases as the degree of hydronephrosis increases. On the other hand, hydronephrosis dilates the calyceal system, and may mobilize stones and complicate ongoing fragmentation during lithotripsy.

In a tertiary government hospital in Manila, the urology department performs around 90-100 PCNL cases per year. Due to their size, location, and possible complications, staghorn calculi are a difficult subset of renal stones. The study's foundation is the clinical difficulties associated with staghorn calculus and PCNL. Kidney stones are commonly connected with the presence of hydronephrosis, a condition characterized by obstruction of the urinary tract that could influence the outcome of surgery. However, even though PCNL is becoming increasingly popular as an effective treatment option, there are still few comprehensive research studies on the precise connection between hydronephrosis and the perioperative outcomes of PCNL, particularly in the Philippines because there are no local data available. Hence, the study aimed to compare the perioperative outcomes of patient undergoing percutaneous nephrolithotomy in patients with pre-operative (moderate to severe) hydronephrosis versus patients with absent-mild hydronephrosis.

The objective of this study was to determine the association between pre-operative hydronephrosis and perioperative outcome among patients undergoing percutaneous nephrolithotomy at a tertiary government hospital in Manila. It determined the demographics of moderate-to-severe hydronephrosis among patients undergoing percutaneous nephrolithotomy based on age, sex and BMI. It also determined the incidence of perioperative complications after PCNL (bleeding and sepsis) and the association between preoperative moderate-to-severe hydronephrosis and perioperative outcomes (Total operative time, access time and lithotripsy rate).

Methods

Study Design

This prospective cohort study examined adult patients undergoing PCNL in a tertiary government hospital in Manila. Data were collected via history, physical examination, direct observation and review of patient charts. Patient participation was up to day of discharge or in-hospital death.

Study Population

Adult patients undergoing percutaneous nephrolithotomy in a tertiary government hospital in Manila from September 2023 to September 2024.

Inclusion criteria

1. Age >18 years old
2. Patients with staghorn calculi confirmed through imaging studies
3. Scheduled to undergo elective PCNL
4. Patients who provided informed consent to participate in the study

Exclusion criteria

1. Patients with severe comorbidities. Severe comorbidities are characterized by patients classified as ASA Physical Status class IV or higher, indicating an elevated risk of perioperative complications.

2. Unwillingness to participate

Withdrawal criteria

1. Deferred surgery
2. Malfunction of equipment
3. Lost to follow-up patients

Sample Size and Sampling Methodology

PASS 2021 software was used to calculate the minimum sample size requirement. Specifying an odds ratio of perioperative complications equal to 5.07[7] and alpha set at 0.05, a minimum of 87 patients were required to achieve 90% statistical power. Sample size was increased to 97 to account for 10% potential dropout.

The researchers utilized a convenience sampling design to select study participants. Consecutive patients who underwent PCNL were invited to participate in the study.

Statistical Analysis

Data were encoded in MS Excel by the researcher. Stata MP version 17 software was used for data processing and analysis. Continuous variables were presented as mean (standard deviation/SD) or median (interquartile range/IQR) depending on the data distribution. Shapiro-Wilk's test was used to assess normality. Categorical variables were presented as frequencies and percentages. Independent t-test or Mann-Whitney U test was used to compare continuous variables, while Chi-square test or Fisher's Exact test was used for categorical variables. Linear regression analysis was conducted to examine the association between moderate-to-severe hydronephrosis and continuous outcomes such as total operative time, access time, and lithotripsy rate. Logistic regression analysis was used to determine the association between moderate-to-severe hydronephrosis and

PASS 2021, v21.0.3 25 Aug 2023 10:05:36 am 1

Logistic Regression (Legacy)

Numeric Results

Power	N	Pcnt N X=1	P0	P1	Odds Ratio	R Squared	Alpha	Beta
0.79355	87	39	0.125	0.42	5.06897	0.2	0.05	0.20645

References

Hsieh, F.Y., Block, D.A., and Larsen, M.D. 1998. 'A Simple Method of Sample Size Calculation for Linear and Logistic Regression', Statistics in Medicine, Volume 17, pages 1623-1634.

Report Definitions

Power is the probability of rejecting a false null hypothesis. It should be close to one.
N is the size of the sample drawn from the population.
P0 is the response probability at the mean of X.
P1 is the response probability when X is increased to one standard deviation above the mean.
Odds Ratio is the odds ratio when P1 is on top. That is, it is [P1/(1-P1)]/[P0/(1-P0)].
R-Squared is the R2 achieved when X is regressed on the other independent variables in the regression.
Alpha is the probability of rejecting a true null hypothesis.
Beta is the probability of accepting a false null hypothesis.

Summary Statements

A logistic regression of a binary response variable (Y) on a binary independent variable (X) with a sample size of 87 observations (of which 61% are in the group X=0 and 39% are in the group X=1) achieves 79% power at a 0.05 significance level to detect a change in Prob(Y=1) from the baseline value of 0.125 to 0.42. This change corresponds to an odds ratio of 5.06897. An adjustment was made since a multiple regression of the independent variable of interest on the other independent variables in the logistic regression obtained an R-Squared of 0.2.

perioperative complications (e.g., bleeding, sepsis). Missing values were neither replaced nor estimated. P-values ≤ 0.05 were considered statistically significant.

The data collection for this study involved prospectively collecting data from patients who underwent PCNL for the treatment of kidney stones. Patients who met the inclusion criteria were approached and provided with an explanation of the study.

The researcher oriented the RODs assigned to the outpatient department and hospital ward regarding the study. Recruitment took place at the outpatient department and hospital ward. Patients scheduled to undergo elective PCNL were referred to the researcher for further screening and consent administration.

The researcher explained the study objectives, procedures, risks and benefits to each eligible patient. In order to affirm voluntary participation, patients were asked to sign a written consent form.

After obtaining informed consent, baseline demographic data were collected through face-to-face interview. Data included age, sex, and body mass index (BMI). Baseline data were recorded in a Baseline Data Collection Form.

The diagnosis was established through a preoperative CT scan done within 6 months, with all CT images assessed by a radiologist. Patients were categorized into two groups based on the presence or absence of moderate to severe hydronephrosis.

Antibiotic prophylaxis was administered consistently to all patients in accordance with a standard dosage regimen. The PCNL procedure was done by the Senior urology residents assisted by a urology consultant/fellow. Following the administration of anesthesia, a ureteric catheter was introduced and secured to a Foley catheter. The patient was then positioned in the prone position. A retrograde pyelogram was performed, and an initial puncture was carried out using an 18-gauge needle, followed by progressive tract dilation. An 18 Fr Amplatz sheath with suction capability was introduced. Subsequently, a 12 Fr rigid nephroscope was utilized for lithotripsy, employing an EMS pneumatic lithoclast. Prior to concluding the procedure, a nephrostomy tube was inserted.

Outcome Assessment

Two independent outcome assessors, not involved in any other study procedure and blinded to presence of preoperative hydronephrosis, collected the outcomes of interest. These data were recorded in an Outcome Assessment Form.

Total operative time, access time and lithotripsy time were obtained via chart review. A post-operative CBC was obtained and patients were monitored daily at the hospital ward for any complications, including sepsis and bleeding.

Results & Discussion

A total of 90 patients were included in the study where proportion of hydronephrosis was 48.9%. Their mean age was around 50 years old (SD=13.2) and they were mostly male (64.4%). Only 36.7% had normal BMI while 44.4% were pre-obese, 8.9% classified as obese I and 6.7% obese II. The average stone size was 743.3 (SD=646.7) while 56.7% of them had multiple stone location. Thirty percent of stones were located on the renal pelvis. Results further revealed no significant difference on the mean age, sex distribution, BMI and stone size between patients with and without hydronephrosis. On the other hand, significant difference existed on stone location where having multiple locations is associated among those without hydronephrosis. On the other hand, renal pelvis was significantly associated with hydronephrosis.

Table 3 shows that hydronephrosis is not significantly associated with total operative time. In the crude model, the presence of hydronephrosis was associated with a reduction of 2.24 minutes in total operative time (β = -2.24, 95% CI: -20.32, 15.83, p = 0.8057). After adjusting for confounders like stone size and stone location, hydronephrosis was associated with a slight, non-significant increase in operative time (β = 7.91, 95% CI: -10.31, 26.13, p = 0.39). Importantly, stone size significantly affected total operative time, with each additional millimeter of stone size associated with an increase in operative time by 0.017 minutes (β = 0.017, 95% CI: 0.003, 0.031, p = 0.015).

In table 4, the crude model, hydronephrosis was not significantly associated with access time (β = -1.67, 95% CI: -5.79, 2.45, p = 0.4228). However,

after adjusting for confounders, hydronephrosis was associated with a statistically significant reduction in access time, with patients with hydronephrosis showing a 4.94-minute shorter access time (β = -4.94, 95% CI: -9.55, -0.32, p = 0.036). This suggests that hydronephrosis may facilitate easier access to the kidney during surgery, potentially due to the dilation of the renal structures. Additionally, stone size was significantly associated with access time in both crude and adjusted models. For every additional millimeter in stone size, access time increased by 0.0123 minutes (β = 0.0123, 95% CI: 0.0088, 0.0158, p < 0.001), reflecting the technical difficulty in accessing larger stones.

Table 5 shows the presence of hydronephrosis was associated with a lower lithotripsy rate, though this was a borderline significant result. In the crude model, hydronephrosis reduced the lithotripsy rate by 4.82 mm/min (β = -4.82, 95% CI: -9.88, 0.24, p = 0.0616). After adjusting for confounders, the reduction was slightly larger, with patients with hydronephrosis having a 5.11 mm/min slower lithotripsy rate (β = -5.11, 95% CI: -10.26, 0.03, p = 0.051), but the result remained on the borderline of statistical significance. This suggests that hydronephrosis may negatively impact the efficiency of stone fragmentation during lithotripsy.

Table 6 shows the association between hydronephrosis and the likelihood of developing perioperative complications, specifically sepsis and bleeding, using both crude and adjusted odds ratios (ORs). This was done through logistic regression to assess whether hydronephrosis significantly affects the odds of these complications after accounting for potential confounders such as age, BMI, gender, stone size, and stone location.

Table 1. Demographic and clinical characteristics of patients .

	All	Hydronephrosis		p value
		Yes	No	
n	**90**	**44**	**46**	
Age (years), mean ± sd	49.6 ± 13.2	51 ± 12.5	48.2 ± 14	0.3013
Sex				
Male	58 (64.4)	30 (68.2)	28 (60.9)	0.4713
Female	32 (35.6)	14 (31.8)	18 (39.1)	
BMI				
Underweight	3 (3.3)	1 (2.3)	2 (4.3)	0.7808
Normal	33 (36.7)	17 (38.6)	16 (34.8)	
Overweight	40 (44.4)	18 (40.9)	22 (47.8)	
Obesity I	8 (8.9)	3 (6.8)	5 (10.9)	
Obesity II	6 (6.7)	5 (11.4)	1 (2.2)	
Stone size, mean ± sd	743.3 ± 646.7	693.6 ± 759.2	789.6 ± 524.8	0.0578
Stone Location				
Multiple	51 (56.7)	20 (45.5)	31 (67.4)	0.0281
Renal pelvis	27 (30.0)	19 (43.2)	8 (17.4)	
Others	12 (13.3)	5 (11.4)	7 (15.2)	
Inferior Pole	7 (7.8)	2 (4.5)	5 (10.9)	
Middle Pole	2 (2.2)	2 (4.5)	0 (0.0)	
Upper Pole	3 (3.3)	1 (2.3)	2 (4.3)	

Table 2. Clinical outcomes of patients.

	All	Hydronephrosis		p value
		Yes	No	
n	**90**	**44**	**46**	
Total Operative Time (Minutes), mean ± sd	105.8 ± 42.6	104.6 ± 39.3	106.8 ± 45.9	0.9313
Access Time (Minutes), mean ± sd	17.6 ± 9.7	16.7 ± 7.1	18.4 ± 11.7	0.8239
Lithotripsy Rate (mm/min), mean ± sd	16.14 ± 12.19	13.49 ± 10.72	18.95 ± 13.18	0.0291
Perioperative complications				
Yes	20 (21.3)	11 (25.6)	9 (17)	0.3191
No	70 (77.5)	31 (72.1)	38 (80.9)	
Sepsis	11 (12.4)	6 (14)	5 (10.6)	0.6904
Bleeding	9 (10.1)	5 (11.6)	4 (8.5)	0.7365

Table 3. Association between hydronephrosis and total operative time.

	Crude β	(95% CI)	p value	Adjusted β	(95% CI)	p value
Hydronephosis	-2.24	(-20.32,15.83)	0.8057	7.91	(-10.31,26.13)	0.39

Table 4. Association between hydronephrosis and access time.

	Crude β	(95% CI)	p value	Adjusted β	(95% CI)	p value
Hydronephosis	-1.67	(-5.79, 2.45)	0.4228	-4.94	(-9.55, -0.32)	0.036

Table 5. Association between hydronephrosis and lithotripsy rate.

	Crude β	(95% CI)	p value	Adjusted β	(95% CI)	p value
Hydronephosis	-4.82	(-9.88, 0.24)	0.0616	-5.11	(-10.26, 0.03)	0.051

Table 6. Association between hydronephrosis and perioperative complications.

Bleeding

	Univariate			Multivariate		
	Crude OR	95% CI	p value	Adjusted OR	95% CI	p value
Hydronephosis	1.38	(0.35,5.53)	0.6481	1.26	(0.26,6.11)	0.7721

Sepsis

	Univariate			Multivariate		
	Crude OR	95% CI	p value	Adjusted OR	95% CI	p value
Hydronephosis	1.33	0.37,4.72	0.6594	2.22	(0.50,9.79)	0.2921

For sepsis, the crude odds ratio indicates that hydronephrosis was associated with a 33% increase in the odds of developing sepsis during the perioperative period (Crude OR: 1.33, 95% CI: 0.37, 4.72). However, this result was not statistically significant (p = 0.659), as reflected by the wide confidence interval, which suggests uncertainty in the estimate. After adjusting for confounders, the odds of sepsis in patients with hydronephrosis more than doubled (Adjusted OR: 2.22, 95% CI: 0.50, 9.79), but this result also remained not statistically significant (p = 0.292). Although the adjusted model shows a larger increase in the odds of sepsis in the presence of hydronephrosis, the lack of statistical significance indicates that the relationship between hydronephrosis and sepsis is weak and likely influenced by other factors.

For bleeding, the crude odds ratio showed that hydronephrosis was associated with a 38% increase in the odds of perioperative bleeding (Crude OR: 1.38, 95% CI: 0.35, 5.53). However, this association was not statistically significant (p = 0.648). Similarly, after adjusting for confounders, the odds of bleeding in patients with hydronephrosis remained slightly elevated (Adjusted OR: 1.26, 95% CI: 0.26, 6.11), but this result was also not statistically significant (p = 0.772). These findings suggest that hydronephrosis does not play a significant role in increasing the risk of bleeding during the perioperative period.

The aim of this study was to look at the association among patients undergoing percutaneous nephrolithotomy with preoperative hydronephrosis and perioperative outcomes. The study investigated the lithotripsy rate, total operating time, access time, and perioperative complications, including bleeding and infection.

Hydronephrosis and Total Operative Time

There was no discernible correlation between the amount of time spent during surgery and the presence of hydronephrosis. The crude model indicated a weak and non-significant correlation

between hydronephrosis and a shorter operating time. subsequently after adjusting for variables including the location and size of the stone, hydronephrosis was associated with a little increase in overall operating time; however, this association was not statistically significant. The influence of stone size was more pronounced, with each additional millimeter of stone size leading to a significant increase in operative time. This aligns with previous studies that have identified larger stone sizes as a key factor in prolonging operative time due to the technical difficulties posed by their removal.

Hydronephrosis and Access Time

It is interesting to note that in the adjusted model, hydronephrosis was found to considerably decrease access time. Due to the dilatation of the renal collecting system, patients with this parameter had faster access to the collecting system during PCNL. The additional space in the renal pelvis and calyces likely contributed to easier puncture and navigation to the stones, which reduced the amount of time needed to gain access. This finding supports the notion that moderate-to-severe hydronephrosis can simplify certain technical aspects of PCNL.

Hydronephrosis and Lithotripsy Rate

The lithotripsy rate was shown to be a bit significantly lower in patients with hydronephrosis, indicating a tendency for slower stone fragmentation. The lithotripsy rate decreased according to the crude model, but it decreased even more according to the corrected model, although it remained on the threshold of statistical significance. This result suggests the possibility that hydronephrosis could impede stone breakup during PCNL because of the stones' greater mobility in the dilated renal pelvis and calyces. When these structures dilate, it may be more difficult to stabilize the stones during lithotripsy, which reduces the effectiveness of fragmentation.

Hydronephrosis and Perioperative Complications

In both crude and adjusted models, the relationship between hydronephrosis and perioperative complications—more especially, bleeding and sepsis—was not statistically significant. In the basic model, hydronephrosis was linked to a 33% increase in the odds of sepsis, and in the adjusted model, this risk more than doubled. Nevertheless, neither of these results attained statistical significance. The broad confidence intervals show ambiguity and suggest that sepsis risk may be more significantly influenced by other factors, such as the amount of stone burden or pre-existing infections.

Similarly, there was a marginally significant correlation found between hydronephrosis and an increased risk of bleeding. The modified model indicated a little increase in the risk of bleeding, which may be related to the technical difficulties caused by hydronephrosis during stone removal. While hydronephrosis makes access easier, in individuals with severe hydronephrosis, the thinner renal cortex may also increase the risk of bleeding. Due to their thinner renal cortex, patients with hydronephrosis may be more susceptible to bleeding during surgery. The delicate, stretched tissue may bleed more easily when punctured or manipulated.

Conclusion

This study evaluated the impact of moderate-to-severe hydronephrosis on perioperative outcomes in patients undergoing percutaneous nephrolithotomy. While hydronephrosis did not have a statistically significant association with total operative time or perioperative complications, it was linked to a significant reduction in access time, likely due to the dilated renal structures facilitating easier entry. Conversely, hydronephrosis was associated with a borderline significant reduction in lithotripsy rate, indicating challenges in stone fragmentation during surgery.

Overall, the findings suggest that while hydronephrosis may ease certain aspects of the procedure, such as kidney access, it may also introduce complexities in stone management underscoring its critical role in surgical outcomes. Future research should focus on evaluating long-term outcomes and optimizing surgical techniques for patients with hydronephrosis, especially those presenting with larger or more complex stone

burdens, to further enhance treatment efficacy and patient safety.

Conflict of Interest: All researchers involved in the study declare no conflicts of interest that could potentially bias the study design, conduct, or outcomes.

By adhering to these ethical considerations, this study aimed to uphold the highest standards of research ethics, ensuring the well-being of participants and the integrity of the research process.

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ORIGINAL RESEARCH

Analysis of Risk Factors for Developing Sepsis in Patients Who Underwent Percutaneous Nephrolithotomy at the National Kidney and Transplant Institute: A Retrospective Study

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Objective: This study aimed to identify the different risk factors for developing sepsis in patients undergoing percutaneous nephrolithotomy
Methods: This is a case-control study of all patients who underwent percutaneous nephrolithotomy in the National Kidney and Transplant Institute from 2017 to 2021. Demographic, stone characteristics, perioperative data and post-operative parameters were recorded. The association of clinical variables and sepsis was determined using logistic regression analysis.
Results: A total of 586 patients who underwent percutaneous nephrolithotomy were included in the study with 58 of them suffering from sepsis with a prevalence rate of 9.9%. The majority [392 (67.82%)] of the patients were 31-59 years old. Majority of patients suffering from sepsis also belonged to the same age group were predominantly male [33 (56.9%)], mostly diabetic [15 (26.32 %)] and hypertensive [14 (24.56%)] and underwent previous PCNL [49 (8.45%)]. Imaging of patients who had sepsis showed staghorn calculus [30 (51.72%)] with mild [20 (34.48%)] and moderate hydronephrosis [23 (39.66%)] seen on imaging. Patients who were requiring transfusion post operatively (Grade II Clavien-Dindo Classification) were seen to have sepsis.
Conclusion: The following factors are contributory to the development of sepsis: a high Guy's stone score, high degree of obstruction or hydronephrosis, previous stone surgery and a higher volume of blood loss.

Key words: Guy stone score, nephrolithomy, sepsis, hydronephrosis

Introduction

Sepsis is a life-threatening multi organ dysfunction caused by a dysregulated host response to infection. It presents as a clinical deterioration of common and preventable infections. It is a medical emergency and over the years, technological advancements have led to a better understanding and management.[1] Despite advances in medicine, sepsis remains one of the major causes of morbidity and mortality especially in critically-ill patients. Nephrolithiasis is one of the most common benign urologic diseases and classified by composition, size, location and stone hardness. Percutaneous Nephrolithotomy, a minimally invasive procedure, has become the gold standard in eradicating stone burden more than 2 cm and provides a better clinical outcome for the patient. However, it carries a risk of developing septic complications. Factors found to have caused increase in the incidence of urosepsis include diabetes mellitus, high stone burden, prolonged operative time and

preoperatively positive urine culture. Other factors include presence of multiple tracts and significant blood loss. Other methods in relieving stone burden besides doing percutaneous nephrolithotomy include. Retrograde Intrarenal Surgery (RIRS) and Extracorporeal Shockwave Lithotripsy (ESWL). There are also acceptable means of rendering the patients stone free but can also cause sepsis due to manipulation.

Pre-op evaluation is important and Yang et al noted that patients with recurrent urinary tract infection have a higher risk of developing SIRS after percutaneous nephrolithotomy.[2] Urinary tract infection was commonly seen in patients with renal stones especially those with struvite stones. Studies have shown that bacteria grow slowly in infection calculi and form a biofilm which makes the antibiotics less effective in eliminating infection. During the surgical procedure, bacteria and endotoxins are released upon disintegration of the stone which causes fever. The timeliness and effective treatment of sepsis in the first 6 hours which includes effective antibacterial treatment and maintenance of circulatory perfusion, can significantly reduce the lethal rate of urosepsis[3]. Fever is one of the most common symptoms of sepsis and in a study done by Rashid et al, fever was documented to have originated from the release of systemic inflammatory mediators, noted after surgical manipulation.[4] In another study by Shoshany et al., it was noted that there was a high probability of sepsis in patients with a larger stone burden and a history of recurrent urinary tract infection.[5] Fan et al studied the factors that can cause septic shock in patients undergoing percutaneous nephrolithotomy and they noted that prolonged operating time hydronephrosis and presence of nitrite on urinalysis are factors in causing sepsis.[6] Similarly, Chugh et al showed that the most common factors that cause septic complications in patients undergoing percutaneous nephrolithotomy include a higher Charlson comorbidity index, procedure time, patients with Double J stents and female gender.[7] Liang et noted that those who have obstructing lithiasis were at the greatest risk because of the urgency of the surgery to relieve obstruction which puts the judgement of the urologist in the spotlight. In the same study, they also took into account the timing of surgery since patient would likely be subjected to insufficient preparation which leads to septic complications.[8] Part of the pre-operative preparation is doing a pre-operative urine culture since it is important to give culture guided antibiotics to help lessen occurrence of septic complications. This was proven in a study done by Lai & Assimos in which administration of culture guided antibiotics pre operatively helped lessen the occurrence of SIRS in patients with culture positive urine who underwent surgery.[9]

Most patients diagnosed with renal stones and who underwent percutaneous nephrolithotomy were elderly. They were diagnosed to have calcium oxalate stones which are a lot harder and take a longer operative time due to difficulty in rendering the patient stone free. This was confirmed in the study of Fan et al. in which patients who underwent percutaneous nephrolithotomy, had septic shock and significantly large stone burden, longer operative time and lower postoperative white blood cell count. A study conducted by Nakamon et al showed that patients aged 60 and above were more at risk in terms of having septic complications. Patient comorbidities, cardiac reserve and stone burden, are more evident in this set of patients as compared to the pediatric population.[10] However, despite all these complications, PCNL is still a relatively safe procedure in the hands of experts. Dela Rosette, et al. proved that patients undergoing PCNL have low Clavien scores and major complications have <3% risk of occurring.[11]

Methods

Research Design

This research outlines a retrospective case-control study conducted at the National Kidney and Transplant Institute (NKTI), focusing on identifying risk factors for sepsis and analyzing complications in patients with nephrolithiasis undergoing percutaneous nephrolithotomy (PCNL). The study compared patients who developed postoperative sepsis with a control group who did not, examining various pre-operative, intraoperative, and post-operative factors. Demographic (Age, sex, BMI, comorbidities); Stone characteristics (Guy's stone score, Hounsfield Unit, stone size and location, urine culture), Perioperative data (Operative time,

blood loss, irrigant volume, number of tracts), post-operative parameters (Blood Units transfused, Changes in hemoglobin levels, length of hopsital stay, ICU admission, pain control and antibiotics) were recorded.

Sampling

Patients 18 years old and above who underwent Percutaneous Nephrolithotomy for Nephrolithiasis at the National Kidney and Transplant Institute were considered. All patients had pre-operative imaging study done and patients who were diagnosed with sepsis based from SIRS criteria and were evaluated during their post-operative course were selected for this study during period 2017-2021.

Data Collection & Analysis

This statistical methodology outlines a robust analysis of patient characteristics and sepsis risk factors, utilizing descriptive statistics (mean/SD, median/range, frequencies) to summarize data. Comparative analyses were performed using appropriate parametric (T-test) or nonparametric tests (Mann-Whitney/Wilcoxon), with logistic regression defining associations (odds ratios).

Ethical Consideration

This research adhered to the International ethical standards of research involving human subjects. Privacy and confidentiality were safeguarded during the research by assigning alphanumeric codes and putting records and other data in a secure cabinet that only the researcher and members of the REC have access. The study commenced under the guidance and approval of NKTI-REC.

Results

The prevalence of sepsis in percutaneous nephrolithotomy patients was 58 in 586 or 9.9% (95% CI) as shown in table 1.

A total of 586 PCNL patients were analyzed for this study, 528 and 58 without and with sepsis, respectively (Table 1). With male dominance (51.19% vs 48.81%), majority (67.82%) were from age group of 31-59 years. The median BMI was 24.883 kg/m2 (IQR 22.039-28.194) [n=534]. The two most common comorbidities were hypertension (34.53%) and diabetes mellitus (22.05%). Majority (77.24%) had no history of stone treatment (n=580), and all of them were non-septic ($p < .001$). For those who had history of PCNL, about 49 (90.74%) were septic ($p < .001$).

Table 2 shows the stone features such as stone burden, degree of hydronephrosis, stone size in Hounsfield units (HU). Guy's stone score of each patient were investigated for their relationship to sepsis. Only the degree of hydronephrosis indicated a statistically significant relationship with sepsis ($p < .001$). Sepsis was more prevalent in those who had severe hydronephrosis.

Many (46.26%) had an operative time duration of 1-2 hours (n=521). A blood loss of more than 500 ml was seen in the septic group (48.98% vs 12.41%, $p < .001$) [n=460].

More patients had Clavien-Dindo classification of surgical procedure of grade 2-3A in the non-septic group (82.95% vs 72.73% and 7.20 vs 3.64%, respectively) while there were more patients with grade 1, 3b and 5 in the septic group (12.73 % vs 8.14%; 5.45% vs 0.95% and 5.45% vs 0.76%, respectively) [$p = .003$].

Table 3 shows the postoperative parameters of the patients, which are classified according on whether or not they had sepsis. Patients with sepsis had a substantially longer hospital stay (median of 9 days) than those without sepsis (median of 7 days) ($p < .001$). In both groups, ICU admission was infrequent, with no statistically significant difference detected between patients with and without sepsis ($p > .999$).

In total, 96.18% of the patients did not require any blood transfusions, although only a small percentage did ($p = .327$). The overall group's median hemoglobin level is 11.75 (IQR: 10.10-13.30). Patients who do not have sepsis have a median hemoglobin level of 11.80 (IQR: 10.20-13.30). Patients with sepsis, on the other hand, have a considerably lower median hemoglobin level of 10.55 (IQR: 8.825-12.475, $p = .001$). White blood cell count (WBC) and serum creatinine levels were among the blood test data examined. There were no statistically significant differences in WBC levels between patients with and without sepsis ($p =$

Table 1. Incidence of sepsis in PCNL patients.

	n/N	Incidence (95% CI)
Sepsis in PCNL patients	58/586	9.90 (7.60-12.61)

Table 2. Demographic and clinical profile of patients.

	Total (n=586)	Without Sepsis (n=528)	With Sepsis (n=58)	p-value
	Frequency (%); Median (IQR)			
Age, years [n=578]		[n=523]	[n=55]	.447‡
18 - 30	26 (4.50)	22 (4.21)	4 (7.27)	
31 - 59	392 (67.82)	357 (68.26)	35 (63.64)	
60 above	160 (27.68)	144 (27.53)	16 (29.09)	
Sex				.427†
Male	300 (51.19)	267 (50.57)	33 (56.90)	
Female	286 (48.81)	261 (49.43)	25 (43.10)	
BMI, kg/m^2 [n=534]	24.883 (22.039 - 28.194)	24.977 (22.10 - 28.209)	24.22 (21.23 - 26.30)	.115§
Comorbidities [n=585]				
Diabetes mellitus	129 (22.05)	114 (21.59)	15 (26.32)	.516†
Hypertension	202 (34.53)	188 (35.61)	14 (24.56)	.129†
Others	65 (11.11)	58 (10.98)	7 (12.28)	.941†
Previous stone tx [n=580]		[n=526]	[n=54]	**<.001**‡
PCNL	49 (8.45)	0	49 (90.74)	
Open stone surgery	10 (1.72)	8 (1.52)	2 (3.70)	
ESWL	1 (0.17)	1 (0.19)	0	
Laser lithotripsy	47 (8.10)	45 (8.56)	2 (3.70)	
Others	25 (4.31)	24 (4.56)	1 (1.85)	
None	448 (77.24)	448 (77.24)	0	
Stone burden				
Staghorn calculus [n=566]	289 (51.06)	259 (50.98)	30 (51.72)	>.999†
Superior calyceal calculus [n=566]	13 (2.30)	10 (1.97)	3 (5.17)	.139‡
Inferior calyceal calculus [n=566]	113 (19.96)	104 (20.47)	9 (15.52)	.471†
Pelvolithaisis [n=565]	74 (13.10)	67 (13.21)	7 (12.07)	.968†
Middle calyceal calculus [n=565]	28 (4.96)	27 (5.33)	1 (1.72)	.344‡
Others [n=567]	142 (25.04)	128 (25.15)	14 (24.14)	.994†
Degree of hydronephrosis [n=548]		[n=490]	[n=58]	**<.001**†
None	255 (46.53)	252 (51.43)	3 (5.17)	
Mild	107 (19.53)	87 (17.76)	20 (34.48)	
Moderate	107 (19.53)	84 (17.41)	23 (39.66)	
Severe	79 (14.42)	67 (13.67)	12 (20.69)	
Laterality [n=585]		[n=527]	[n=58]	
Left	214 (36.58)	193 (36.62)	21 (36.21)	>.999†
Right	229 (39.15)	203 (38.52)	26 (44.83)	.428†
Bilateral	141 (24.10)	130 (24.67)	11 (18.97)	.423†
Guy's stone score [n=300]	3 (2-3)	3 (2-3)	3 (2-3)	.220§
Houndsfield units [n=218]		[n=175]	[n=43]	.127†
<500 HU	39 (17.89)	35 (20)	4 (9.30)	
501 – 999 HU	64 (29.36)	47 (26.86)	17 (39.53)	
>1000 HU	115 (52.75)	93 (53.14)	22 (51.16)	

Mean Stone HU [n=302]	982.40 (650-1220)	1008 (650-1250)	821.50 (650.60-1141.50)	.145§
Urine culture, mL [n=566]	1200 (900-1598)	1200 (900-1580)	1200 (770-1780)	.726§
Operative time [n=521]		[n=467]	[n=54]	.106†
<1 hr	167 (32.05)	155 (33.19)	12 (22.22)	
1 - 2 hrs	241 (46.26)	216 (46.25)	25 (46.30)	
>2 hrs	113 (21.69)	96 (20.56)	17 (31.48)	
Estimated blood loss [n=460]		[n=411]	[n=49]	**<.001**‡
<500 cc	385 (83.70)	360 (87.59)	25 (51.02)	
501 – 999 cc	49 (10.65)	32 (7.79)	17 (34.69)	
>1000 cc	26 (5.65)	19 (4.62)	7 (14.29)	
Irrigant volume, cc/hr [n=583]	100 (80-100)	100 (80-100)	100 (80-107.50)	.999§
Number of tracts [n=583]		[n=525]	[n=58]	.405†
Single	443 (75.99)	402 (76.57)	41 (70.69)	
Multiple	140 (24.01)	123 (23.43)	17 (29.31)	
Urine CS [n=586]		[n=527]	[n=58]	.073†
Positive	280 (47.86)	244 (46.30)	36 (62.07)	
Negative	119 (20.34)	110 (20.87)	9 (15.52)	
None	186 (31.79)	173 (32.83)	13 (22.41)	
Clavien-Dindo classification [n=583]		[n=528]	[n=55]	**.003**‡
GR 1	50 (8.58)	43 (8.14)	7 (12.73)	
GR 2	478 (81.99)	438 (82.95)	40 (72.73)	
GR 3A	40 (6.86)	38 (7.20)	2 (3.64)	
GR 3B	8 (1.37)	5 (0.95)	3 (5.45)	
GR 4A	0	0	0	
GR 4B	0	0	0	
GR V	7 (1.20)	4 (0.76)	3 (5.45)	

Statistical tests used: §–Mann-Whitney U test; †–Chi-square test; ‡–Fisher's exact test.

.623). Serum creatinine levels, on the other hand, were significantly higher in patients with sepsis compared to those without (p = .001).

The use of different pain control and antibiotics did not show significant differences between the two groups. Septic complications, such as septic shock, death, and recovery, were investigated. Out of 227 patients with septic complications, five were diagnosed with sepsis, and all five recovered. In either group, there were no incidences of septic shock.

Age, sex, BMI, and various comorbidities were all evaluated, but none of them were statistically significant predictors of sepsis (Table 3). It was discovered that previous stone therapy has a significant impact on the risk of sepsis. Patients who had PCNL, open stone surgery, ESWL, laser lithotripsy, or other treatments were much more likely to develop sepsis than those who had no previous stone therapy. Stone burden, which includes several types of kidney stones, was not found to be associated with sepsis. Sepsis was substantially associated with the degree of hydronephrosis. Patients with mild, moderate, or severe hydronephrosis were much more likely to develop sepsis than those with no hydronephrosis.

Stone size, laterality, and Guy's stone score were not statistically associated with sepsis however, a higher Guy stone score is associated with patients who underwent percutaneous nephrolithotomy. Hounsfield units (HU) of kidney stones showed a borderline association with sepsis. Patients with kidney stones ranging from 501 to 999 HU had a higher ratio of developing sepsis, although the association was not statistically significant (p = .054).

When compared to operations lasting less than one hour, operations lasting more than two hours were associated with a considerably higher risk of sepsis. Estimated blood loss during the surgery was found to be significantly associated with sepsis. Patients who lost more than 1000 cc of blood had

Table 3. Postoperative parameters.

	Total (n=586)	**Without Sepsis (n=528)**	**With Sepsis (n=58)**	**p-value**
	Frequency (%); Median (IQR)			
Length of hospital stay, days	7 (5-10)	7 (5-9)	9 (6-14.75)	**<.001**§
ICU admission [n=577]	1 (0.17)	1 (0.19)	0	>.999‡
Blood units transferred [n=576]				.327‡
None	554 (96.18)	497 (95.95)	57 (98.28)	
1 unit	16 (2.78)	16 (3.09)	0	
2 units	5 (0.87)	4 (0.77)	1 (1.72)	
3 units	0	0	0	
4 units	1 (0.17)	1 (0.19)	0	
Hemoglobin levels [n=582]	11.75 (10.10-13.30)	11.80 (10.20-13.30)	10.55 (8.825-12.475)	**.001**§
WBC after surgery [n=582]				.623†
< 12	393 (67.53)	356 (67.94)	37 (63.79)	
> 12	189 (32.47)	168 (32.06)	21 (36.21)	
Serum creatinine [n=576]				**.001**†
< 1	351 (60.94)	328 (63.32)	23 (39.66)	
> 1	225 (39.06)	190 (36.68)	35 (60.34)	
Pain control and antibiotics [n=396]		[n=383]	[n=13]	
Dolcet	139 (35.10)	136 (35.51)	3 (23.08)	.556‡
Tramadol	122 (30.81)	118 (30.81)	4 (30.77)	>.999‡
Paracetamol	131 (33.08)	123 (32.11)	8 (61.54)	.055†
Tramadol + Paracetamol	42 (10.61)	40 (10.44)	2 (15.38)	.638‡
Cefuroxime	140 (35.35)	135 (35.25)	5 (38.46)	>.999†
Levofloxacin	26 (6.57)	25 (6.53)	1 (7.69)	.592‡
Algesia	8 (2.02)	8 (2.09)	0	>.999‡
Co-amoxiclav	10 (2.53)	10 (2.61)	0	>.999‡
Ciprofloxacin	33 (8.33)	32 (8.36)	1 (7.69)	>.999‡
Cefixime	5 (1.26)	5 (1.31)	0	>.999‡
Ceftriaxone	45 (11.36)	43 (11.23)	2 (15.38)	.650‡
Ampicillin-Sulbactam	13 (3.28)	12 (3.13)	1 (7.69)	.357‡
Celecoxib	9 (2.27)	9 (2.35)	0	>.999‡
Morphine	8 (2.02)	8 (2.09)	0	>.999‡
Meropenem	6 (1.52)	6 (1.57)	0	>.999‡
Piperacillin Tazobactam	16 (4.04)	15 (3.92)	1 (7.69)	.420‡
Nalbuphine	12 (3.03)	12 (3.13)	0	>.999‡
Others	33 (8.33)	32 (8.36)	1 (7.69)	>.999‡
Septic complications [n=227]		[n=222]	[n=5]	>.999‡
Septic shock	0	0	0	
Death	2 (0.88)	2 (0.90)	0	
Recovered	225 (99.12)	220 (99.10)	5 (100)	

Statistical tests used: §–Mann-Whitney U test; †–Chi-square test; ‡–Fisher's exact test.

a higher risk of sepsis than those who lost less blood. The number of tracts (single or multiple) had no significant relationship with sepsis. When compared to negative urine cultures, positive urine cultures were significantly associated with an elevated risk of sepsis. The final multivariable model is shown on Table 4.

The authors performed a multivariable logistic regression to determine independent factors for sepsis. This model shows the following factors

Table 4. Factors associated with sepsis.

	Crude Odds Ratio (95% CI)	p-value
Age, years		
18 - 30	Reference	-
31 - 59	0.54 (0.19-1.92)	.280
60 above	0.61 (0.20-2.28)	.415
Sex		
Male	Reference	-
Female	0.77 (0.44-1.34)	.361
BMI, kg/m^2	0.96 (0.90-1.01)	.137
Comorbidities		
Diabetes mellitus	1.30 (0.67-2.37)	.415
Hypertension	0.59 (0.30-1.08)	.099
Others	1.13 (0.45-2.47)	.768
Previous stone treatment		
PCNL	88803 (4493.60- 27420160)	**<.001**
Open stone surgery	263.82 (19.60- 37506.24)	**<.001**
ESWL	299 (1.40- 66463.13)	**.004**
Laser lithotripsy	49.29 (3.93-6838.66)	**<.001**
Others	54.92 (2.85- 8100.16)	**.001**
None	Reference	-
Stone burden		
Staghorn calculus	1.03 (0.60-1.78)	.915
Superior calyceal calculus	2.72 (0.60-9.19)	.138
Inferior calyceal calculus	0.71 (0.32-1.43)	.373
Pelvolithiasis	0.90 (0.36-1.95)	.806
Middle calyceal calculus	0.31 (0.02-1.51)	.257
Others		.866
Degree of hydronephrosis		
None	Reference	-
Mild	19.31 (6.43-83.39)	**<.001**
Moderate	23 (7.76-98.70)	**<.001**
Severe	15.04 (4.62-67.42)	**<.001**
Stone size, HU [n=302]	0.999 (0.999-1)	.224
Laterality		
Left	0.98 (0.55-1.71)	.950
Right	1.30 (0.75-2.23)	.351
Bilateral	0.71 (0.34-1.37)	.337
Guy's stone score [n=300]	0.72 (0.48-1.10)	.119
Hounsfield units		
<500 HU	Reference	-
501 – 999 HU	3.16 (1.06-11.74)	.054
>1000 HU	2.07 (0.72-7.45)	.209
Urine culture, mL [n=566]	0.999 (0.999-1)	.634
Operative time		
<1 hour	Reference	-
1 - 2 hours	1.49 (0.74-3.17)	.273
>2 hours	2.29 (1.05-5.11)	**.038**
Estimated blood loss		
<500 cc	Reference	-
501 – 999 cc	7.65 (3.71-15.62)	**<.001**
>1000 cc	5.31 (1.92-13.38)	**.001**
Irrigant volume, cc/hr [n=583]	1 (0.99-1.003)	.600
Number of tracts		
Single	Reference	-
Multiple	1.36 (0.73-2.43)	.321

Urine CS		
Positive	1.96 (1.04-3.94)	**.046**
Negative	1.09 (0.44-2.61)	.850
None	Reference	-
Clavien-Dindo classification		
GR 1	Reference	-
GR 2	0.56 (0.25-1.44)	.189
GR 3A	0.32 (0.05-1.43)	.175
GR 3B	3.69 (0.64-18.92)	.119
GR 4A	-	-
GR 4B	-	-
GR V	4.61 (0.78-25.76)	.078

Note: Multivariate analysis is not practical, due to the significant correlation between several of the variables.

Table 4.1 Factors associated with sepsis using multivariable logistic regression (n=424)

	Adjusted Odds Ratio (95% CI)	**p-value**
Age, years		
18 - 30	Reference	-
31 - 59	0.05 (0.001-0.75)	.052
60 above	0.07 (0.002-1.28)	.100
Sex		
Male	Reference	-
Female	1.27 (0.36-4.70)	.710
Previous stone treatment		
With	332.89 (44.20-42085.72)	**<.001**
Without	Reference	-
Degree of hydronephrosis		
None	Reference	-
Mild	73.58 (10.66-1573.69)	**<.001**
Moderate	64.44 (9.78-133.09)	**<.001**
Severe	28.20 (3.50-628.03)	**.006**
Estimated blood loss		
<500 cc	Reference	-
>500 cc	7.81 (2.32-32.57)	**.002**
Urine CS		
Positive	1.05 (0.30-3.68)	.934
Negative/ none	Reference	-

Blood loss was retained for the final model while we removed operative time because we cannot have correlated variables in a multivariable analysis.
R^2= 0.7071; p-value= <.001

associated with sepsis even after adjusting for covariates: previous stone treatment, presence of hydronephrosis, and blood loss > 500 cc. However, despite these findings, there is no sufficient evidence to show that there is an association with degree of hydronephrosis with sepsis who underwent percutaneous nephrolithotomy.

The most common urine culture isolates are shown in Table 5. The pathogen *Escherichia coli* was found to be the most prevalent among the patients, accounting for 18.97% of the cases. Following closely, *Proteus mirabilis* was identified in 12.07% of the samples. Other pathogens detected were Klebsiella species (6.90%), Proteus species (8.62%), Staphylococcus (10.32%), and Pseudomonas (5.17%), though at varying frequencies

Table 6 presents the common clinical presentations of sepsis. Tachycardia was the most common presentation among patients who developed sepsis, occurring in 27.59% of cases. This was followed by fever, which was reported in 18.97% of patients. Tachypnea was observed in 13.79% of patients, whereas leukocytosis, characterized by an elevated white blood cell count, was observed in 17.24%.

Discussion

The prevalence of nephrolithiasis is common among elderly male and female over 65 years old with metabolic abnormality being the most common cause. Majority of stone formers are males within the ages of 31-59 years old. Since cardiopulmonary and renal function of these patients are compromised, along with the presence of other lifestyle diseases such as hypertension and diabetes places elderly patients are at risk of septic complications following PCNL. The most common presentation of sepsis in patients who underwent PCNL was Tachycardia while the *E. coli* was still the most common isolate seen in urine culture in patients having sepsis who underwent PCNL. This is confirmed as well in the study of Lojanapiwat and Kitinarattrakan. In their study, the most commonly identified infection is *Escherichia coli* which is treatable with culture guided antibiotic.[12] In this study, pre-operative urine culture that tested positive can induce septic shock thru the positive pressure provided which causes absorption systemically hence the importance of antibiotic treatment. However, the study done by Liu et al showed that

Table 5. Most common urine culture.

	Frequency (%)
Urine CS	
E.coli	11 (18.97)
Proteus mirabilis	7 (12.07)
Klebsiella Sp	4 (6.90)
Proteus Sp	5 (8.62)
Staphylococcus	6 (10.32)
Pseudomonas	3 (5.17)

Table 6. Most common presentations of sepsis (n=58).

	Frequency (%)
Fever	11 (18.97)
Tachycardia	16 (27.59)
Tachypnea	8 (13.79)
Leukocytosis	10 (17.24)

a standard urine culture has rather low predictive value for an infection complication and that a direct culture from the renal pelvis and stone culture are better predictors of infection.[13] All patients undergoing PCNL did have basic laboratory work up but septic work up is not routinely requested. Despite its fatal complications, PCNL is one of the important treatment options in the management of nephrolithiasis. PCNL is a relatively safe procedure in the hands of trained urologist in the treatment of nephrolithiasis >2cm. Given the risks of complications in doing percutaneous nephrolithotomy, how safe really is performing percutaneous nephrolithotomy in patients with nephrolithiasis? In a study conducted by Darabi et al, patients who underwent this procedure were at risk of having massive blood loss, colon perforation, pneumothorax and hydrothorax. These were the common complications observed on top of sepsis which is common in patients undergoing this procedure.[14] Studies have shown that previous stone surgeries, degree of hydronephrosis on CT scan, prolonged operative time and blood loss are associated with sepsis among patients who underwent percutaneous nephrolithotomy which is equivalent to a longer hospital stay. In the study of Michel et al., general complications are classified into access and those related to stone removal.[15] Parenchymal bleeding from laceration for access, development of pseudoaneurysm and arteriovenous fistula are some of the more common complications experienced. Correct patient selection is important for all percutaneous endourologic procedures. This study also showed that any age or gender with comorbidities are at risk for septic complications. Previous stone treatment, degree of hydronephrosis and blood loss are all interrelated as one leads to another in developing complications across all age groups. This study showed that majority of the patients who suffered from sepsis are those patients who had moderate to severe hydronephrosis on CT scan with previous stone surgery with a blood loss of more than 500 cc can cause sepsis. This was in contrast to the study of Wang et al which stated that percutaneous nephrolithotomy can be safely carried until 90 minutes.[16] The current study showed that majority of the population who had sepsis belonged to the patients with Guy stone score of I however it had no significant correlation. Patients with Guy stone score of II-IV were statistically significant showing that patients with a rather complex stone anatomy caused sepsis in patients who underwent percutaneous nephrolithotomy. Majority of the reported complications needed blood transfusion (Clavien II) which is can happen in these kinds of surgeries. In a study done by Khalil et al., patients with Guy stone score of II-IV showed correlation with complications of the surgery particularly in patients with staghorn calculus or guy stone score IV.[17] Degree of hydronephrosis, higher volume of blood loss, previous stone surgery and higher Guy's stone core all point to a significant stone burden that is the man attribute of patients that developed sepsis. Although, the blood loss may also reflect the skill level of the surgeon which was not delineated in this study. It would have been interesting to note whether majority of the cases that developed sepsis were done by residents who were still negotiating their learning curve or were performed by consultant who are supposed to be more experienced and competent.

Conclusion

This study was able to identify through regression analysis that the following factors are contributory to the development of sepsis: a high Guy's stone score, high degree of obstruction or hydronephrosis, previous stone surgery and a higher volume of blood loss. This should serve as cautionary indicators in the evaluation who patients who will undergo PCNL treatment. Once these are criteria are identified in patients who are candidates for surgery then preparations should be done to mitigate the risk of sepsis.

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CASE REPORT

The Battle Within: Command Hallucinations Driving Recurrent Urethral Foreign Body Insertion in Schizophrenia – A Case Report

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Objectives: To present a rare case of recurrent urethral and intravesical foreign body insertion driven by command hallucinations in schizophrenia, to describe the surgical and psychiatric management strategies employed, and to emphasize the importance of interdisciplinary care and treatment adherence in preventing recurrence.
Methods: Reported here is the case of a 37-year-old male with schizophrenia who presented with multiple episodes of urethral and intravesical foreign body insertion over a six-year period (2018–2025). Inserted objects included metallic wires, electrical cords, and a LED Christmas light rope, each requiring surgical removal via cystoscopy or open cystotomy. Psychiatric evaluation revealed poor adherence to antipsychotic medication, with recurrent episodes associated with command hallucinations. Psychiatric management was reinitiated with olanzapine and structured follow-up to improve treatment compliance.
Results: Six documented episodes of self-inflicted urethral and intravesical trauma required repeated urologic interventions. Despite recurrent instrumentation and foreign body insertion, serial cystoscopic evaluations demonstrated preserved urethral and bladder integrity without evidence of stricture formation. The most recent episode required open cystotomy for removal of a coiled LED light rope, which was successfully extracted without complications. Following coordinated psychiatric management and improved adherence to antipsychotic therapy, the patient remained asymptomatic and free of recurrence at three months follow-up.
Conclusion: This case highlights the unusual preservation of urethral integrity despite recurrent traumatic self-insertion. Effective management requires sustained psychiatric stabilization, multidisciplinary collaboration, and strict treatment adherence. Integration of psychiatric and urologic care is essential to prevent recurrence and improve long-term outcomes in patients with schizophrenia-related self-inflicted genitourinary injury.

Key words: Urethral foreign bodies, schizophrenia, cystoscopy, self-injurious behavior, psychotic disorders

Introduction

Foreign body insertion into the urethra is an uncommon but clinically significant urologic presentation. Its true incidence is difficult to determine due to underreporting, but available literature confirms that it remains rare in the general population.[1,2] Motivations for urethral foreign body insertion are varied and include autoerotic practices, sexual curiosity, intoxication,

and psychiatric disorders.[1-3] Among psychiatric conditions, schizophrenia is particularly important because command hallucinations may drive repetitive self-injurious behaviors, including the insertion of objects into the urinary tract.[4,5] Patients frequently delay seeking medical attention because of embarrassment or social stigma, increasing the risk of complications such as urinary tract infection, urethral trauma, urinary extravasation, and urethral stricture formation.[1,3,6]

Several reports have described the clinical presentation, diagnostic approach, and management of urethral foreign bodies. Diagnosis typically relies on a thorough history and physical examination, supported by imaging modalities such as plain radiography, ultrasonography, or computed tomography to identify and localize the foreign object.[6,7] Most cases can be managed with minimally invasive endoscopic techniques, while open surgical procedures are reserved for complicated cases or failed endoscopic retrieval.[1,2,8] However, the literature primarily focuses on single-episode cases, and limited data exist regarding recurrent foreign body insertion associated with psychiatric illness. Furthermore, standardized management protocols addressing the psychiatric component and strategies to prevent recurrence remain insufficiently described.

This report aimed to present a rare case of recurrent urethral and intravesical foreign body insertion in a patient with schizophrenia driven by command hallucinations. Despite multiple episodes and repeated urologic interventions, the patient maintained preserved urethral integrity, an uncommon finding in the context of recurrent trauma. This case highlights the importance of multidisciplinary collaboration between urologists and psychiatrists in managing psychiatric-driven genitourinary self-injury and preventing recurrence.

The Case

Patient Information

A 37-year-old male with a history of schizophrenia presented to the emergency department with suprapubic pain and dysuria for two days. He reported inserting a flexible LED Christmas light rope into his urethra, prompted by command auditory hallucinations instructing him to expel a perceived urinary tract "stone." The patient believed the object would aid stone removal and described temporary relief and satisfaction after insertion. His psychiatric history included multiple prior episodes of self-inflicted urethral foreign body insertion in 2019, 2023, and 2024, all requiring surgical removal. He had a documented history of noncompliance with olanzapine, poor psychiatric follow-up, and limited family supervision. Socially, he was unemployed with minimal social engagement, and there was no family history of psychiatric illness.

Clinical Findings

On examination, the patient was alert, oriented, and in no acute distress. Abdominal examination revealed suprapubic tenderness without bladder distension. External genitalia appeared normal, and no foreign body was visible at the urethral meatus. Other systemic examinations were unremarkable.

Diagnostic Assessment

Kidney-Ureter-Bladder (KUB) radiography revealed radiopaque, coiled metallic densities within the pelvic region, consistent with an intravesical foreign body (Figure 1). Urinalysis demonstrated microscopic hematuria. Cystoscopic evaluation showed no urethral masses or strictures; however, multiple false tracts along the urethra were noted, indicative of prior trauma. The bladder mucosa appeared intact, with both ureteral orifices clearly visualized. A coiled metallic foreign body was observed near the bladder neck (Figure 2).

Therapeutic Intervention

Initial endoscopic retrieval was unsuccessful due to the object's size and configuration. The patient underwent open cystotomy via a Pfannenstiel incision approximately 2 cm above the pubic symphysis. Dense adhesions were encountered intraoperatively. The bladder was opened, revealing a coiled LED light rope, which was extracted intact without mucosal injury. The bladder was closed in two layers with absorbable sutures, and the abdominal wall was closed

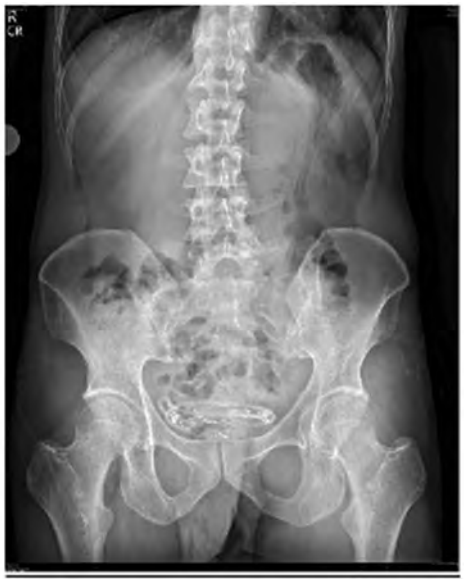

Figure 1. KUB X-ray showing radiopaque, coiled metallic densities consistent with intravesical foreign bodies in the pelvic region (2025).

routinely. A Foley catheter was left in place for two weeks. Postoperative care included oral antibiotics and resumption of olanzapine under behavioral medicine supervision.

Previous surgeries included:

- 2019: Urethroscopic and cystolithotomy removal of an ovoid radiopaque object
- 2023: Cystoscopic extraction of a knotted TV Plus cord
- 2024: Cystoscopic removal of an electric wire
- 2025 (current): Open cystotomy for the LED Christmas light rope (Figure 3)

Earlier procedures in 2018 and 2020 also documented similar foreign body removals, confirming a longstanding pattern of recurrent self-insertion.

Follow-up and Outcomes

Cystoscopic monitoring throughout multiple episodes revealed no urethral strictures. At the most recent follow-up, the patient reported no urinary symptoms and demonstrated improved adherence to psychiatric medications. He attended outpatient appointments regularly and engaged in recreational activities such as bicycling. These combined factors were considered critical in reducing the risk of recurrence and optimizing long-term recovery.

Ethical Considerations

Written informed consent for publication of this case report and accompanying images was obtained from the patient's legally authorized representative (his mother), as the patient was not competent to provide consent. This case report was conducted in accordance with the Declaration of Helsinki.

Discussion

Recurrent self-inflicted urethral and intravesical foreign bodies are uncommon and often linked to psychiatric disorders, particularly schizophrenia. Our case illustrates how psychosis, poor medication adherence, and limited social support contribute to repeated genitourinary self-injury, emphasizing the interplay between psychiatric illness and urologic complications.

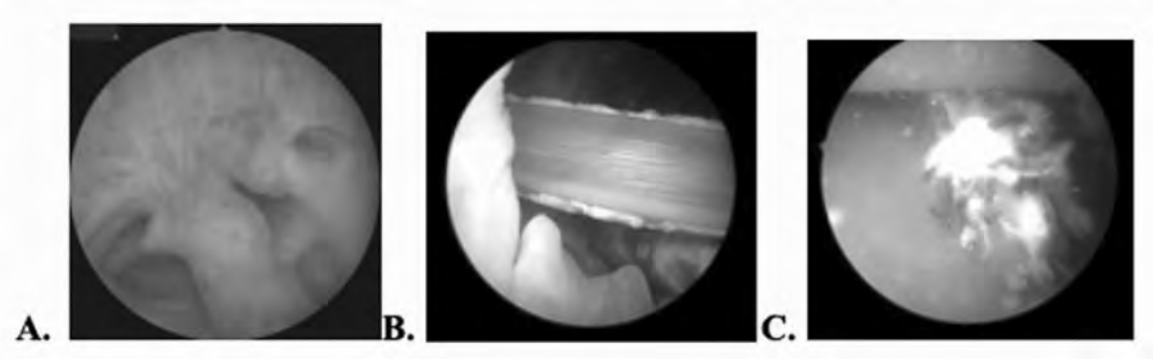

Figure 2. Cystoscopy findings: A. Multiple false tracts in urethra (2025), B. Foreign body (cable wire) near bladder neck (2024), C. Tip of foreign body (knotted wire) (2024).

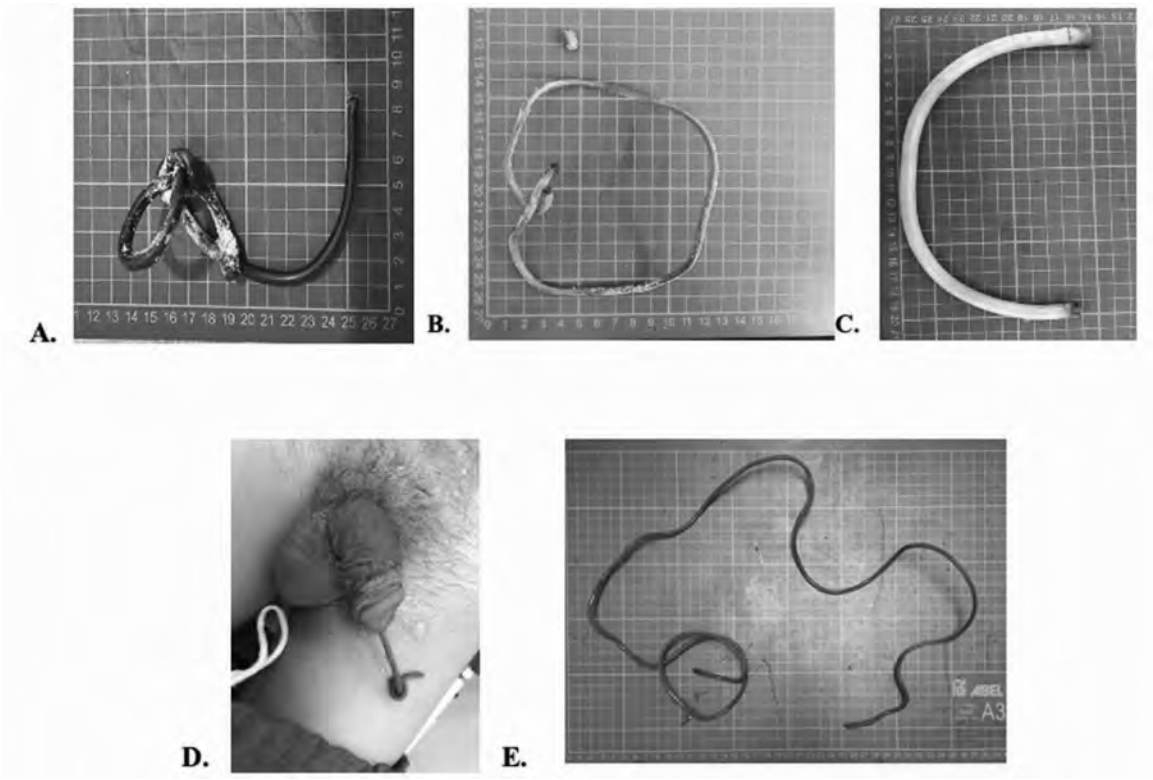

Figure 3. Extracted foreign bodies over multiple years: A. Knotted TV Plus cord (2023), B. Electric wire (2024), C. Flexible LED Christmas light rope (2025), D. Preoperative image of the foreign body inserted in the urethra-insulated wire (2020), E. Actual specimen of the foreign body removed-insulated wire (2020).

From a urological standpoint, repeated insertion of rigid objects increases the risk of chronic inflammation, urethral strictures, bladder injury, and upper urinary tract compromise. Interestingly, despite multiple traumatic insertions in our patient, no urethral strictures or bladder fibrosis developed, suggesting possible individual anatomical resilience and highlighting the need for tailored follow-up. Imaging for localization and characterization remains essential, while endoscopic retrieval is preferred, reserving open surgery for complex cases.

Psychiatric management is critical in preventing recurrence. Sustained antipsychotic therapy, psychoeducation, behavioral interventions, and caregiver involvement improve adherence and reduce relapse risk. Coordinated multidisciplinary care is essential, as surgical management alone rarely prevents recurrence.

Current APA and NICE guidelines advocate individualized risk assessments, long-term psychiatric follow-up, and interdisciplinary collaboration.[9,10] However, formal urological protocols for self-inflicted genitourinary foreign bodies remain lacking, particularly in recurrent cases. In the Philippine context, financial constraints, limited access to long-acting antipsychotics, and insufficient specialized psychotherapy pose additional challenges, underscoring the need for locally adapted integrated care pathways.

This case contributes novel insight by demonstrating preserved urethral and bladder integrity despite repeated traumatic insertions, contrasting with typical reports of high stricture incidence. Current findings reinforce the importance of psychiatric-centered care and individualized surveillance to minimize recurrence and long-term morbidity in this vulnerable population. Future research should focus on standardized management guidelines and preventive strategies integrating urology and psychiatry.

Conclusion

In this case of recurrent self-inflicted urethral foreign bodies in a patient with schizophrenia, surgical removal effectively managed the acute urological injury, while psychiatric noncompliance contributed to repeated episodes. Despite multiple traumatic insertions, no urethral stricture or bladder fibrosis developed, suggesting individual anatomical resilience. These findings support the importance of coordinated urologic and psychiatric care, emphasizing adherence to antipsychotic therapy, psychoeducation, and caregiver involvement to reduce recurrence.

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CASE REPORT

Bilateral Single-Curvilinear Inguinal Incisions in Advanced Penile Cancer: A Novel Approach to Inguinal and Pelvic Lymphadenectomy

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Background: Penile squamous cell carcinoma (SCC) is rare in high-income regions but remains a significant oncologic burden worldwide. Nodal involvement is the most important prognostic factor, and early identification is critical.
The Case: A 56-year-old circumcised male presented with a six-month history of a progressively enlarging, foul-smelling fungating penile mass and bilateral inguinal lymphadenopathy. Biopsy confirmed moderately differentiated SCC. Imaging showed large bilateral inguinal nodal disease without distant metastasis. Laboratory findings revealed leukocytosis, thrombocytosis, and mildly deranged coagulation parameters. The patient underwent total penectomy with perineal urethrostomy, followed by bilateral inguinal and pelvic lymph node dissection through single-curvilinear incisions. Frozen-section analysis confirmed extensive bilateral nodal metastasis. Postoperatively, a localized left inguinal surgical site infection was treated conservatively. He was discharged on postoperative day seven with drains in situ and was recommended adjuvant chemoradiotherapy in accordance with NCCN Guidelines.
Conclusion: This case highlights the challenges of managing advanced penile SCC with bulky bilateral inguinal metastasis and demonstrates the utility of single-curvilinear inguinal incisions for comprehensive lymphadenectomy. Early recognition, accurate staging, and guideline-based multimodal treatment remain essential for optimizing outcomes.

Key words: Penile squamous cell carcinoma, inguinal lymphadenopathy, total penectomy, inguinal lymph node dissection, pelvic lymph node dissection.

Introduction

Penile cancer accounts for approximately 0.4–0.6% of male malignancies in North America and Europe, with regional prevalence reaching up to 10% in parts of Asia, Africa, and South America.[1] In 2020, the age-standardized global incidence and mortality rates were 0.80 and 0.29 per 100,000, respectively, corresponding to an estimated 36,000 new cases and 13,000 deaths worldwide.[2] The disease predominantly affects older men, with incidence peaking during the sixth decade of life.[3]

Socioeconomic disparities substantially influence disease burden. Patients in low-income regions commonly present with advanced disease due to limited access to healthcare, inadequate screening, and cultural stigma related to genital examination.[4] Delayed consultation often occurring months to years after symptom onset is observed in up to 50% of cases and contributes to the high rate of nodal involvement at diagnosis.[5] Established risk factors for penile cancer include poor genital hygiene, phimosis, tobacco use, obesity, and oncogenic HPV infection, while neonatal

circumcision provides protection by reducing smegma-associated chronic inflammation.[6,7]

HPV-related tumors, particularly those driven by HPV-16, account for 30–50% of cases and are typically of basaloid or warty histology. These variants exhibit distinct molecular characteristics and may have a slightly better prognosis compared with HPV-negative keratinizing subtypes.[8]

Clinically, penile carcinoma often begins as a localized lesion with potential extension into the glans, shaft, and corpora cavernosa. Flat, ulcerative tumors demonstrate earlier nodal dissemination and poorer five-year survival compared with papillary or exophytic lesions. Despite a clinically normal inguinal examination, 20–25% of patients harbor occult metastasis, emphasizing the need for accurate nodal staging.[9] Metastatic spread typically follows a predictable sequence involving the superficial inguinal, deep inguinal, and subsequently pelvic lymph nodes, including the external iliac, internal iliac, and obturator groups.[10] Nodal involvement remains the most important prognostic factor in penile cancer.

Negative FNAC in the context of persistent clinical suspicion should prompt repeat aspiration or consideration of excisional biopsy. While limited nodal disease may still be curable, extra nodal extension and pelvic metastasis are associated with markedly poorer outcomes.[11-13] Inguinal lymphadenectomy offers potential cure in appropriately selected patients but is associated with substantial morbidity, with reported complication rates of 30–50%, including wound breakdown, lymphedema, and lymphocele formation.[14]

Contemporary guidelines recommend fine-needle aspiration cytology (FNAC) rather than empirical antibiotic therapy for evaluating palpable inguinal nodes, with FNAC endorsed as the preferred first-line staging modality (ASCO–EAU 2024). Ultrasound-guided FNAC further enhances diagnostic accuracy, achieving near-100% specificity, although sensitivity for detecting micrometastases remains limited.[15]

This report describes a case of penile squamous cell carcinoma presenting with bulky bilateral inguinal lymphadenopathy, managed through total penectomy with perineal urethrostomy and bilateral pelvic and inguinal lymph node dissection performed via bilateral single-curvilinear inguinal incisions.

The Case

A 56-year-old circumcised male presented with a six-month history of a progressively enlarging, foul-smelling fungating penile mass associated with increasing pain and bilateral inguinal swelling. He reported having more than ten previous female sexual partners but denied any history of sexually transmitted infections. Physical examination revealed an ulceroinfiltrative lesion involving the glans and proximal shaft, accompanied by firm, fixed, bulky inguinal lymphadenopathy, more pronounced on the left (Figure 1).

Incisional biopsy of the primary lesion confirmed squamous cell carcinoma, whereas ultrasound-guided core biopsy of the inguinal lymph nodes was inconclusive.

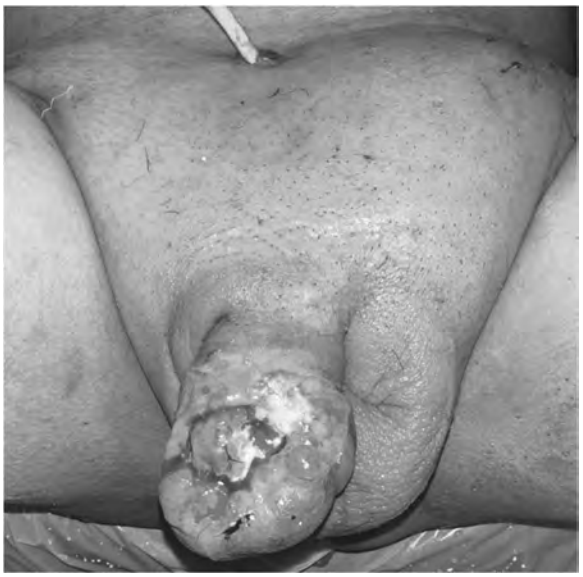

Figure 1. Fungating ulceroinfiltrative penile mass involving the glans and penile shaft associated with bulky bilateral inguinal lymph adenopathy.

Laboratory results showed leukocytosis, thrombocytosis, and mildly deranged coagulation parameters, all of which were medically optimized prior to surgery. Contrast-enhanced abdominopelvic and chest CT imaging revealed bilateral inguinal lymphadenopathies (Figure 2), measuring 9cm × 6cm on the left and 4cm × 2cm on the right, with no evidence of pelvic or distant metastasis. Renal and hepatic function tests were within acceptable perioperative limits. Following multidisciplinary

tumor board discussion, definitive surgical management was recommended.

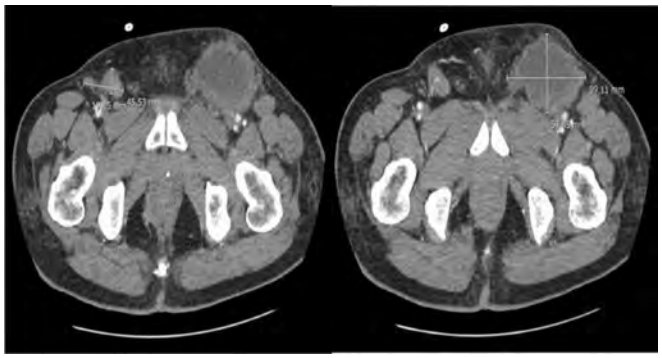

Figure 2. Contrast-enhanced abdominopelvic CT scan demonstrating bilateral inguinal lymphadenopathies measuring 9cm x 6cm on the left and 4cm x 2cm on the right with no radiologic evidence of distant metastasis.

Surgical Technique

The patient underwent total penectomy with perineal urethrostomy, followed by bilateral inguinal and pelvic lymph node dissection. Adequate exposure of both the superficial and deep inguinal nodal basins was achieved through bilateral single-curvilinear inguinal incisions (Figure 3), which also permitted superior extension for access to pelvic lymphatic drainage pathways.

Intraoperative frozen-section analysis demonstrated metastatic carcinoma in five of six (5/6) left inguinal lymph nodes and two of five (2/5) right lymph nodes, prompting immediate bilateral pelvic lymph node dissection through the same incisions.

The procedure was carried out with the dissection planes clearly exposed the femoral artery and vein, saphenous vein, and the iliac vessels within the pelvic field (Figure 4), allowing safe and systematic retrieval of nodal tissue while preserving critical vascular structures. Upon completion of lymphadenectomy, bilateral inguinal Jackson-Pratt (JP) drains were placed to reduce the risk of postoperative seroma and lymphocele formation. Graduated compression stockings were applied to minimize the risk of venous thromboembolism, given the extensive inguinal and pelvic dissection The total operative time was 7 hours, with an estimated blood loss of 0.5 L, and no intraoperative complications were encountered.

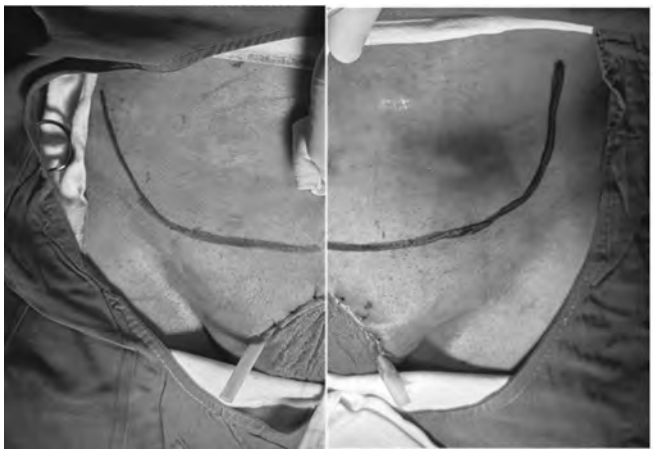

Figure 3. Intraoperative view illustrating bilateral single-curvilinear inguinal incisions used to access superficial, deep inguinal nodal basins. This approach permits superior extension toward the pelvic lymphatic drainage pathways when pelvic lymph node dissection is required.

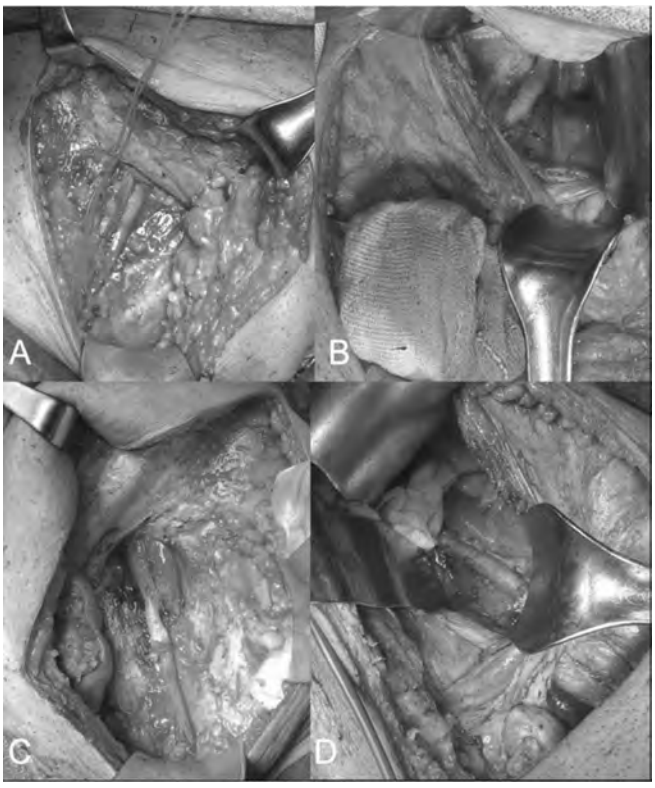

Figure 4. Intraoperative images demonstrating bilateral inguinal and pelvic lymph node dissections with clear exposure of major vascular structures. A. Right inguinal lymph node dissection showing the femoral artery, femoral vein, and saphenous vein. B. Right pelvic lymph node dissection illustrating the external and internal iliac vessels during nodal clearance. C. Left inguinal lymph node dissection demonstrating the femoral vessels and saphenous vein. D. Left pelvic lymph node dissection revealing the iliac vessels.

Postoperative Course

The patient recovered in the surgical ward, where early mobilization and drain monitoring were initiated. The perineal urethrostomy catheter was removed on postoperative day 5, following confirmation of adequate healing and patency.

On day five post-op, SSI was noted presenting with erythema, mild purulent discharge, and localized tenderness. There was no systemic involvement. The SSI was managed conservatively with wound irrigation, daily dressing changes, and culture-directed oral antibiotics, resulting in progressive clinical improvement. He was discharged on 7th post-op day with bilateral JP drains in situ, provided with detailed drain-care instructions and scheduled for close outpatient follow-up for wound evaluation and drain output assessment.

In accordance with NCCN Guidelines for penile cancer, the patient was counseled regarding the need for adjuvant chemoradiotherapy due to bilateral nodal metastasis and high-risk pathological features.

Discussion

Penile squamous cell carcinoma is aggressive when presenting with bulky nodal metastasis. FNAC remains first-line for palpable nodes, but false-negatives occur, particularly in necrotic nodes. Surgery remains the cornerstone for nodal control in advanced disease, while pelvic lymphadenectomy is indicated when multiple inguinal nodes are positive. The single-curvilinear incision allowed effective en bloc dissection while preserving vascular integrity.

Postoperative complications, particularly SSI, are common following groin dissections; conservative management is often effective in localized infections. Due to bilateral nodal disease, adjuvant chemoradiotherapy was recommended, consistent with NCCN guidelines supporting multimodal therapy in high-risk cases.

Conclusion

This case illustrates the complexity of managing advanced penile SCC with bulky bilateral nodal metastasis. Early recognition, accurate staging, and guideline-driven multimodal therapy remain essential. Bilateral single-curvilinear incisions provided safe and effective access for comprehensive lymphadenectomy. The patient was appropriately counseled for adjuvant chemoradiotherapy based on high-risk pathological features.

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