



## Clinical Trial Update

# To Stent or Not? A Pragmatic, Multicenter, Combined Randomized and Observational Clinical Trial Evaluating the Impact of Stent Omission Versus Placement After Uncomplicated Ureteroscopy

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## Article info

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## 1. Guidelines versus practice: stenting after ureteroscopy

Ureteroscopy is the procedure most frequently performed for nephrolithiasis in the USA [1,2]. At the end of the procedure, the surgeon may insert a ureteral stent. Stents are important for urinary drainage and can prevent pain due to trauma or stone fragments. However, they may also impact a patient's quality of life [3]. Some patients seek emergency care because of a stent [4]. Guidelines state that stents may be omitted following uncomplicated ureteroscopy [5,6]. Despite these recommendations, stents are routinely placed in 73–86% of cases in the USA [4,7].

One reason for routine stent placement is the low quality of evidence available. A Cochrane review comparing stent omission versus placement after ureteroscopy noted that

stenting may slightly reduce the number of unplanned return visits, although these findings were very uncertain. Similarly, there was low certainty for evidence that stent placement reduces pain, infection rates, and hospitalizations [8]. The review highlighted the need for large-scale trials to generate definitive evidence for clinical decision-making.

## 2. The SOUL trial

The Michigan Urological Surgery Improvement Collaborative (MUSIC) is a partnership to improve patients' lives via data-driven best practices, education, and innovation. Encompassing diverse practices, MUSIC aims to improve health care value [9]. The Reducing Operative Complications from Kidney Stones (ROCKS) program was developed in 2017 to address the quality of ureteroscopy [10]. In 2023, MUSIC launched the Stent Omission after Ureteroscopy and Lithotripsy (SOUL) clinical trial [11]. Funded by the Patient-Centered Outcomes Research Institute, SOUL is a pragmatic, multicenter trial comparing stent versus no stent after uncomplicated ureteroscopy. The intervention is stent omission, with stent placement as the comparator. We hypothesized that stent omission is associated with improvements in health-related quality of life (HRQOL) and 30-d health care utilization.

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The two primary outcomes are the changes in PROMIS pain interference scores on days 7–10 from baseline, and unplanned health care use within 30 d. [Table 1](#) lists the eligibility criteria. Before the trial, MUSIC developed stent omission guidelines [\[12\]](#).

### 3. Study protocol

Patients are invited to participate in a randomized cohort. Those declining randomization are invited to join a real-world observational cohort. Participants complete questionnaires, with follow-up at 7–10 d and 4–6 wk ([Fig. 1](#)). The aim is to enroll 792 patients over 2 yr.

A number of factors set SOUL apart, as follows:

- 1 Patient engagement: Patient involvement is at the core of the development and implementation of SOUL. Patients provided feedback on the study design, and their voices are heard all the way through the process via regular stakeholder meetings [\[13\]](#).
- 2 Combined study design: Surgical clinical trials face challenges because of patient reluctance to undergo randomization [\[14\]](#). It is estimated that two-thirds of patients decline randomization, which leads to loss of a significant number of participants and lower generalizability [\[15\]](#). In SOUL, if patients decline randomization, we offer the option to join the observational cohort, in which the decision to place a stent is left to the urologist's discretion. Our patient advisors asked for the study to be designed in this way.
- 3 Intraoperative randomization: To overcome the challenge of blinding surgeons to stent versus no stent before they start the case, patients are randomized in the operating room at the end of lithotripsy via a web-based randomization system [\[16\]](#).

- 4 HRQOL assessment: All patients complete validated questionnaires at multiple time points. By collecting longitudinal data, we gather insights into the trajectory of recovery and the impact of the intervention over time [\[17–20\]](#).
- 5 Ecological momentary assessment (EMA): EMA is a survey approach with repeated assessments over short periods. Patients are queried in real time via text messages in their natural environment and asked to evaluate their pain level, medication use, and impact on daily activities, which minimizes recall bias and captures within-subject variability [\[21\]](#).
- 6 Health care utilization: A hierarchical rank score that weighs the intensity of patient encounters is used to assess health care utilization, ranging from the least severe (phone calls to health care staff) to the most severe (critical care therapy) [\[22\]](#).
- 7 Mixed-methods study design: Patients and surgeons are interviewed and surveyed to gain a better understanding of attitudes and preferences regarding stenting, which has never been done before.
- 8 Real-world practice: The study involve 14 centers (academic and community) across the USA to capture a range of patient populations and health care environments. Most studies on stent omission have been conducted at expert centers.

### 4. Progress and aim

As of January 30, 2025, we have enrolled 457 patients, of whom 176 (38%) are in the randomized cohort.

During peer review, it was noted that successful completion of this scientifically rigorous study is likely to have a positive impact in the field of urology, and to help surgeons and patients make patient-driven informed health care decisions.

**Table 1 – Eligibility criteria for the SOUL clinical trial.**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
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| <b>Inclusion criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <ul style="list-style-type: none"> <li>• Age <math>\geq 18</math> yr</li> <li>• Unilateral ureteroscopy and lithotripsy</li> <li>• Renal and/or ureteral stone</li> <li>• Largest stone <math>\leq 1</math> cm in size</li> <li>• Independent cognitive function</li> <li>• English proficiency and access to communication for study questionnaires</li> </ul>                                                                                                                                                                                                                                                       |
| <b>Exclusion criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <ul style="list-style-type: none"> <li>• Prestented</li> <li>• Bilateral ureteroscopy</li> <li>• Anatomic abnormalities (eg, horseshoe kidney, crossed fused ectopia, pelvic kidney, urinary diversion)</li> <li>• Anatomic or functional solitary kidney</li> <li>• Planned secondary ureteroscopy</li> <li>• Use of ureteral access sheath</li> <li>• Ureteral dilation</li> <li>• Pregnancy</li> <li>• Comorbid pain syndromes</li> </ul>                                                                                                                                                                          |
| <b>Potential unanticipated complicating factors leading to ineligibility for randomization to stent vs no stent at the end of ureteroscopy (second-stage ineligibility)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <ul style="list-style-type: none"> <li>• Ureteral perforation</li> <li>• Unanticipated anatomic abnormality (eg, stricture or ureteropelvic junction obstruction)</li> <li>• Greater than expected bleeding</li> <li>• Ureteral dilation (<math>&gt;12</math> F)</li> <li>• Ureteral access sheath used</li> <li>• Failed ureteroscopy (unable to treat stone)</li> <li>• No lithotripsy performed (eg, no stone found)</li> <li>• Intraoperative decision to perform incomplete lithotripsy (eg, return for staged procedure)</li> <li>• Unable to complete case because of a medical or anesthetic event</li> </ul> |

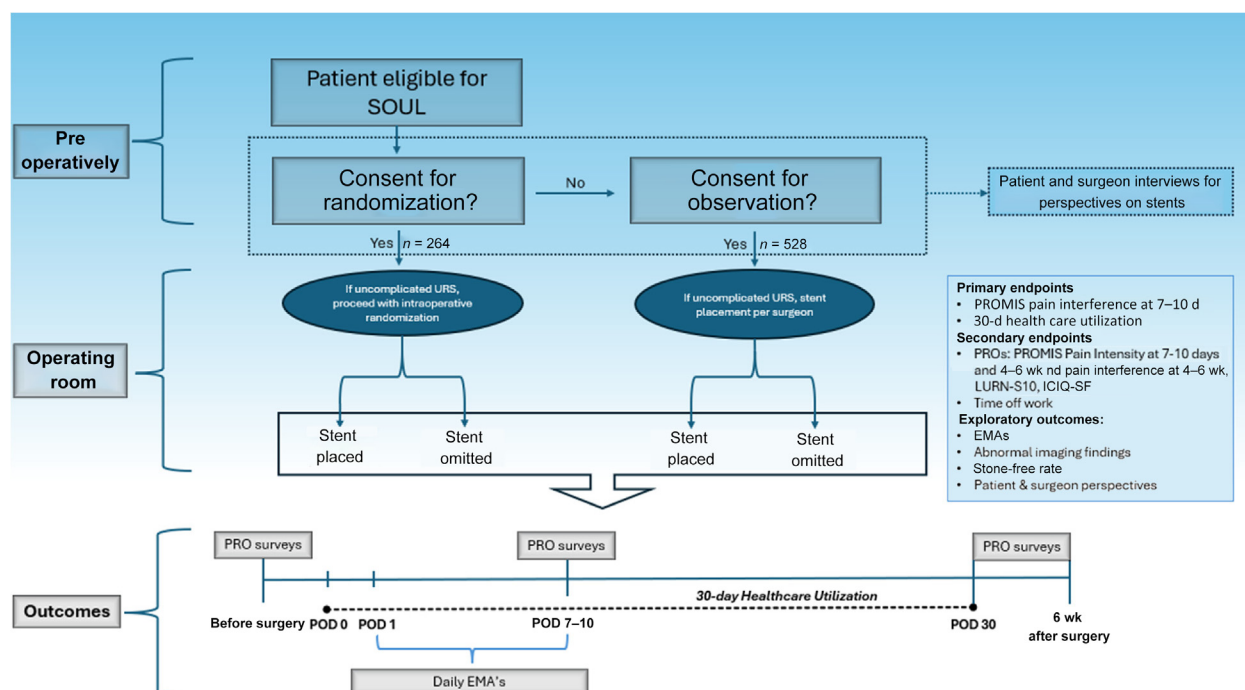


**Fig. 1 – Outline of the Stent Omission after Ureteroscopy and Lithotripsy (SOUL) combined randomized and observational clinical trial by the Michigan Urological Surgery Improvement Collaborative.** URS = ureteroscopy; PROMIS = Patient-Reported Outcomes Measurement Information System; LURN = Lower Urinary Tract Dysfunction Research Network Symptom Index; EMA = ecological momentary assessment; POD = postoperative day; PRO = patient-reported outcome; ICIQ-SF = International Consultation on Incontinence Questionnaire-Short Form.

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