# Virtual reality for pain management during extracorporeal lithotripsy: A randomized pilot study

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## ABSTRACT

**Introduction:** Virtual reality (VR) creates an immersive environment that may alleviate pain and improve tolerance of extracorporeal shockwave lithotripsy (SWL). This randomized pilot trial evaluated feasibility and explored the effects of a pre-procedural VR session on pain, anxiety, and opioid use during SWL.

**Methods:** Thirty patients undergoing their first SWL for kidney stones were randomized (2:1 minimization) to VR or control. The VR group received 20 minutes of audiovisual stimulation via headset before SWL, while controls rested quietly in a calm room. Pain during SWL was

**KEY MESSAGES**

- Pain management during SWL remains a challenge, as current pharmacologic approaches can be insufficient or carry side effects.
- VR given before SWL significantly reduced pain intensity during SWL without causing adverse effects.
- Patients who experienced VR were more willing to undergo repeat SWL, suggesting improved comfort, satisfaction, and treatment adherence.
- VR offers a safe, non-pharmacologic, and patient-centered approach that aligns with current efforts to reduce opioid use and enhance procedural experiences.

measured using a verbal rating scale, anxiety with the State-Trait Anxiety Inventory (STAI), and fentanyl consumption was recorded.
**Results:** The study took place between November 2022 and May 2024, with an eligibility rate of 25.8% (69/267) and a recruitment rate of 43% (30/69). Eighteen patients were allocated to VR and 12 to control (mean age 57, range 21−82). All patients completed the VR session except for one, who interrupted the session after experiencing mild distress. SWL pain intensity was significantly lower in the VR group (3.8/10 vs. 5.9/10, p=0.043). No differences were found in STAI scores and opioid consumption. Principal limitations of the study include its small sample size and selection bias.
**Conclusions:** The implementation of an adequately powered randomized controlled trial may face low recruitment rates if restricted to first SWL experience. VR showed promising outcomes for SWL-induced pain, although opioid consumption and anxiety were not reduced. Future studies with larger sample sizes are required to confirm these preliminary findings.

## INTRODUCTION

Urolithiasis is common in urology, affecting 10–12% of men and 7–8% of women [1, 2]. Extracorporeal shock wave lithotripsy (SWL) remains a first-line treatment for ureteral or kidney stones despite advances in endoscopic and laser technologies. SWL can be performed outpatient with or without sedation, making it convenient and appealing to patients [3].

Despite its benefits, SWL often causes pain and anxiety, frequently requiring sedatives or opioids [4], which carry risks of dependence and side effects. Managing pain during SWL remains challenging, highlighting the need for innovative approaches. Virtual reality (VR) offers immersive distraction to reduce pain [5]. VR pain management relies on distraction theory and may stimulate endogenous opioid release [6]. By engaging various sensory modalities and creating an immersive experience, VR diverts attention away from pain, therefore reducing its perception [7]. VR has shown efficacy in various settings, including colonoscopy, postoperative care, burn management, experimental pain, as well as in medical inpatient wards for acute pain and anxiety management, but it's use in the context of SWL remains limited and understudied [5,8,9]. To date, only two small studies have explored the use of VR during SWL for pain management. Candela et al. [10] included only 30 patients and did not incorporate a control group, limiting internal validity and precluding definitive conclusions regarding the independent effect of VR on pain outcomes. Weynants et al. [11] reported encouraging results; however, patients were included regardless of prior SWL exposure, and the VR group contained a significantly

higher proportion of SWL-naïve patients. Given that prior exposure to SWL may influence pain perception, anxiety, and expectation, this imbalance introduces a potential source of bias and complicates interpretation of the observed effect. These limitations highlight the need for a controlled and methodologically rigorous evaluation of VR for SWL naïve patients, which guided the design of our randomized study. This pilot trial thrives to address these gaps, assess feasibility and estimate effect size, paving the way for a larger, well-powered randomized controlled trial.

The primary objective was to evaluate the feasibility of the study using VR before SWL for pain management. The secondary objectives were to assess VR's tolerability and its effect on pain and anxiety.

## METHODS

### Study design and population

We designed a randomized controlled pilot study including adult patients with radiopaque kidney stones undergoing SWL for the first time from November 2022 to May 2024 at Sherbrooke University Hospital (CIUSSS de l'Estrie-CHUS, QC, Canada). A sample size of 30 patients was chosen pragmatically, based on typical pilot study ranges, to assess feasibility and gather preliminary data for future trials. Patient charts were reviewed for eligibility the week before their SWL. Indication for SWL was given in accordance with European Association of Urology guidelines [3]. Patients were excluded from the study if they had previously received SWL, had ureteral stones, were unable to speak French, had fentanyl intolerance, or had significant hearing or sight impairments. Ureteral stones were excluded to minimize cohort heterogeneity and ensure technical comparability. It allowed shock wave delivery to be consistently performed at the lumbar fossa, reducing anatomical and technical variability across cases. Patients were also excluded if they had chronic pain, defined as pain persisting for at least three months and requiring regular analgesic medication regardless of underlying etiology, or a neurocognitive disorder, defined as a clinically significant impairment in one or more cognitive domains interfering with comprehension or participation in the study.

Patients were contacted by phone a week before the intervention. Interested patients received the consent form by mail. On the intervention day, the study was re-explained, and all gave written consent.

Randomization was performed using centralized computer-based allocation through MinimPy software with a 2:1 allocation ratio (VR:control) [12],[13]. Minimization was applied to balance groups according to sex, which was the only prespecified balancing variable (weight 1.0). Allocation was performed by a research assistant in a separate room using the software interface. Due to the nature of the intervention, participants were not blinded; however, treating staff and referring physicians remained

unaware of group allocation, thereby maintaining allocation concealment at the clinical care level. This study was approved by the local ethical committee (project 2022-4604).

On the intervention day, patients completed the State-Trait Anxiety Inventory (STAI) before being seated alone in a quiet room, with or without VR. Patients received SWL directly afterwards. After SWL patients were re-administered the STAI and their subjective experiences were assessed.

**Virtual reality care**

Patients in the VR group wore a Meta Quest 2™ VR headset equipped with sound diffusion and a screen providing visual stimuli which has specifically been designed for reducing anxiety and the feeling of pain. The VR intervention consisted of a standardized 20-minute, non-interactive application designed to reduce anxiety and pain perception through combined visual and auditory therapeutic sequences, including binaural beats, verbal hypnotic suggestions, nature sounds, attentional redirection, and alternating bilateral visual stimulation. Participants passively viewed immersive natural landscapes and were instructed during specific sequences to visually track a moving object without head movement. The application was not customizable, and all participants received identical content. The VR session was administered immediately prior to SWL whenever feasible, with a maximum delay of approximately 25 minutes before shock wave initiation. Control participants rested quietly in a calm room for 20 minutes without access to music, smartphones, or other devices. A research staff member remained present during this period with minimal interaction. In our study, VR was delivered before SWL for two reasons: the VR system displayed landscapes from a standing position, which is incompatible with the supine SWL position (risking nausea and discomfort), and patient–technician communication to assess pain levels would have frequently interrupted VR, reducing its effectiveness as a distraction. In addition, this standardized pre-procedural administration helped ensure consistent exposure across participants and minimized procedural variability. Administering VR just before SWL was considered appropriate because this approach relaxes and distracts the patient and may trigger endorphin release, providing a prolonged analgesic effect. [6,7]. In other words, VR delivered before SWL could attenuate pain by reducing anticipatory anxiety and by priming central pain modulation pathways before nociceptive stimulation occurs.

**Shockwave lithotripsy session**

Technicians performing the SWL sessions were blinded to randomization. They adhered to a standardized ramping protocol [14]. Each session consisted of 3000 pulses over 50 minutes at a frequency of 1 Hz with the patient lying supine. The energy level of the SWL began at a low setting (30% power) and was increased by 20% every 500 pulses (approximately every 8 minutes) to reach 70% at 1000 pulses. Then, the power was increased based on the patient's comfort level. A Sonolith i-sys lithotripter (EDAP TMS,

France) was used for SWL. During the SWL treatment, intravenous analgesia with fentanyl (50 ug per dose) was administered by the SWL technician upon patient request, up to a maximum cumulative dose of 150 µg.

**Variables and data collection**

Patients' baseline characteristics included gender, age and stone laterality, diameter and location. Size and location of the stones were determined using a computerized tomography scan or X-ray. Stone size was defined by its maximum diameter. Patients' anxiety was evaluated using the STAI, a 40-item self-assessment questionnaire with validated psychometric properties in French-speaking populations, administered before and after the SWL. Only the state portion (STAI-Y1) of the State–Trait Anxiety Inventory was used to assess anxiety before and after SWL. Scores (range 20–80) were obtained by summing up the 20 items, with higher scores indicating greater anxiety. Change in STAI (ΔSTAI) was calculated as post-SWL score minus pre-SWL score. The trait portion (STAI-Y2) was not analyzed, as the objective was to measure situational anxiety related to the procedure.

At the beginning and every 500 pulses during SWL, we assessed the SWL power (%) as well as pain intensity and unpleasantness using a verbal rating scale (VRS) ranging from 0 (no pain) to 10 (worst possible pain) [15]. The average VRS score was then calculated as the mean of all recorded time points. Every dose of intravenous sedative received was documented (Fentanyl 50 µg). After SWL, patients answered four standardized questions rated using a 5-point Likert scale assessing anxiety, willingness to repeat SWL, willingness to use VR again, and preference for VR during future SWL (1 = least favorable response, 5 = most favorable response) [16]. All data was gathered using a REDCap database.

**Statistical analyses**

Feasibility was evaluated through recruitment and eligibility rates as well as protocol adherence[17]. Predefined thresholds were established a priori to evaluate feasibility: eligibility was considered acceptable if ≥50% of screened patients were eligible, recruitment was considered acceptable if ≥60% of eligible patients consented to participate, and protocol adherence was deemed satisfactory if ≥90% of patients completed the intervention as planned. These thresholds allowed us to objectively assess whether the study was practical and could be scaled for a larger trial[18].

We analyzed preliminary evidence of VR's effect on pain. As a pilot study, formal sample size and power calculations were not performed. Analyses are exploratory and descriptive, with results presented as means and standard deviations or confidence intervals to provide preliminary estimates for future studies. Frequencies and percentages were used for categorical variables, while means and standard deviations were used for continuous variables. Baseline numerical data and clinical outcomes were compared

using independent sample t-test whereas baseline categorical data was compared using chi-square test. Exploratory subgroup analyses on pain intensity were performed using independent-samples t-tests by age (≤50 vs. >50) and gender (male vs. female). These analyses are descriptive, with small cell sizes, and no causal conclusions should be drawn. The significance threshold was set at $p<0.05$. Primary objectives were analyzed in the intention-to-treat population, while secondary analyses were conducted in the per-protocol population.

## RESULTS

Of the 267 patients who received SWL between November 2022 and May 2024, 69 (25.8%; 95% CI: 20.5%-31.1%) were eligible for the study. A total of 132 patients (66.6%) were excluded due to prior SWL treatment, and 50 (25.3%) because they had a ureteral stone. Other reasons for exclusion included neurocognitive disorders, chronic pain syndromes, and hearing or sight impairments (n=16, 8.1%). The recruitment rate was 44.9% (31/69 eligible SWL patients; 95% CI: 33.2%-56.6%). Among the eligible patients, 27 (39.1%) declined to participate, and 7 (10.1%) could not be reached. Four (5.8%) of the patients that were initially recruited were later excluded on the day of the procedure for various reasons: urinary tract infection, inability to visualize the stone, last-minute withdrawal after reading the consent form, refusal to receive opioids. These last-minute exclusions explain why our groups did not maintain the planned 2:1 ratio. A total of 31 patients were enrolled in the study, with 30 patients included in the per-protocol population: 18 (60%) in the VR group and 12 (40%) in the control group (Figure I).

Table I presents the baseline patient characteristics. No significant differences were observed between the two groups.

The use of VR did not compromise SWL treatments or prolong the procedure time. Protocol adherence was achieved in 30 out of 31 patients (96.8%; 95% CI: 90.6%-100%). Indeed, one patient experienced distress during the intervention and discontinued the VR session after 5 minutes. This patient was excluded from the per-protocol population. The outcomes for our secondary endpoints are detailed in Table II.

Pain intensity was significantly lower in the VR group, averaging a VRS score of 3.83/10 (95% CI: 2.73-4.93) compared to 5.92/10 (95% CI: 4.95-6.90) in the control group ($p=0.04$). There were no statistical differences in pain unpleasantness between the two groups (4/10 vs. 5.42/10, $p=0.10$). No differences were observed in the ΔSTAI scores between both groups ($p=0.13$). The average SWL power was not significantly different, with a mean of 68.9% for the VR group and 67.2% for the control group ($p=0.67$). Analgesic use was similar in both groups, averaging 1.4 doses ($p=0.75$) of intravenous fentanyl.

Regarding the patient's subjective experiences, 67% (12/18) reported reduced anxiety with VR and 72% (13/18) expressed willingness to receive VR treatment again.

Moreover, 94% (17/18) of patients in the VR group would undergo SWL again compared to 67% (8/12) in the control group (p=0.05) (Table II).

In the subgroup analysis, focusing on pain intensity (VRS score), patients aged 50 years or younger who received VR reported lower pain intensity compared to the control group (p=0.03). The results of the subgroup analysis are summarized in Table III.

## DISCUSSION

The study aimed to determine the feasibility, tolerability, and patient-reported effect on pain and anxiety of VR before SWL. The study showed that a randomized controlled trial would be feasible, despite facing challenges with eligibility and recruitment. Our predefined eligibility threshold (≥50%) was not met, as only 25.8% of patients were eligible. Similarly, the predefined recruitment rate (≥60%) was not achieved, with only 44.9% consenting to enrollment. The major eligibility challenge was the exclusion of patients with prior SWL treatment, since inclusion required SWL-naïve participants. To facilitate eligibility, given the high recurrence of kidney stones, patients in future trials could be stratified by prior SWL status, with planned subgroup analyses to account for its potential impact [19]. Concerning the recruitment rate, some early patient refusals were related to limited awareness that SWL may cause discomfort, leading to surprise when approached for a pain-reduction intervention. Improved pre-procedural counseling regarding expected pain may enhance patient acceptance in future applications. From a practical standpoint, implementation of VR in the clinical setting was feasible and well-integrated into workflow. Minor staff turnover occurred during the study period but did not significantly affect implementation.

The prespecified protocol adherence threshold (≥90%) was achieved, with 96.8% of patients receiving the intervention according to protocol. Indeed, the protocol proved to be safe and well tolerated, as only one patient experienced mild, transient distress leading to early discontinuation of the VR session without interruption of the SWL procedure.

After the 20-minute VR session, a statistically and clinically significant reduction in pain intensity was observed without seeing an effect on anxiety symptoms or opioid use. Moreover, the exploratory subgroup analyses indicated a larger reduction in VRS score for patients aged 50 or younger, suggesting that younger patients might derive greater benefit from VR intervention. However, given the small cell sizes, these findings need to be confirmed in a larger study. The majority of patients would use VR again during SWL. Moreover, more VR patients expressed willingness to undergo SWL again compared to controls. The reduction in pain perception observed with VR may partly account for the greater willingness of patients in the VR group to undergo the procedure again. This is important because, if there is a stone recurrence, VR use may increase willingness to choose SWL again rather than delay treatment and risk more invasive surgery.

Distraction through visual or audio stimulation can reduce pain perception during SWL. Two 2021 meta-analyses showed audiovisual and music interventions significantly

lowered pain and anxiety [20,21]. Two 2023 studies investigated VR for pain management during SWL. Candela et al. conducted a 30-patients pilot study recording a median VRS score of 4/10 [10]. Similarly, our study recorded an average VRS score of 3.8/10 for the VR group. However, their patients were treated exclusively with VR during SWL, whereas ours received VR before SWL and could receive additional analgesic treatment if needed. Weynants et al. conducted a larger prospective randomized controlled trial involving 166 patients using VR during SWL [11]. They recorded an average VRS score for pain intensity of 4.0/10 for the VR group, which aligns with our results. Additionally, similar to our findings, they observed comparable comfort levels (pain unpleasantness) between the two groups, and their subgroup analysis showed that VR was more effective for women and younger patients. However, they reported higher delivered energy in the VR group, whereas our results showed similar SWL power. Consistent with prior studies, our findings suggest VR can reduce pain without significant side effects.

This study has many strengths. It is among the first to assess VR before lithotripsy. Both approaches—administering VR before or during SWL—are feasible and may offer clinical benefit. However, from a practical standpoint, delivering VR prior to SWL may be technically easier to implement, as it avoids interference with patient positioning and procedural communication during treatment. In this context, documenting the effect of pre-procedural VR, as performed in the present study, remains clinically and scientifically relevant, as it reflects a pragmatic and potentially more easily generalizable approach to routine practice. The randomized controlled design provides a strong level of evidence and was conducted within a clinical setting, enhancing its external validity and future applicability. The SWL technicians were blinded to randomization and followed a standardized ramping protocol.

Limitations include the small sample size and voluntary enrollment, introducing potential selection bias. Blinding was not possible for patients, and outcome assessors were aware of group allocation, raising the potential for reporting and observer bias, particularly given the subjective nature of pain outcomes. A Hawthorne effect related to study participation cannot be excluded. From a methodological standpoint, given the pilot nature and small sample size, the study may have been underpowered for certain outcomes, increasing the risk of type II error. Conversely, the use of multiple statistical comparisons may increase the risk of type I error.

## CONCLUSIONS

This pilot study provides interesting insights into the potential benefits of incorporating VR into pain management protocols for SWL. A randomized controlled trial would face challenges with eligibility and recruitment if restricting inclusion to SWL-naïve patients. To address this, a multicentric study, inclusion of ureteral stones, and inclusion of patients with prior SWL experience should be considered. The results showed promising

outcomes of VR given before SWL on pain perception during SWL, although analgesics doses and anxiety were not reduced. Further studies are needed to confirm these results.

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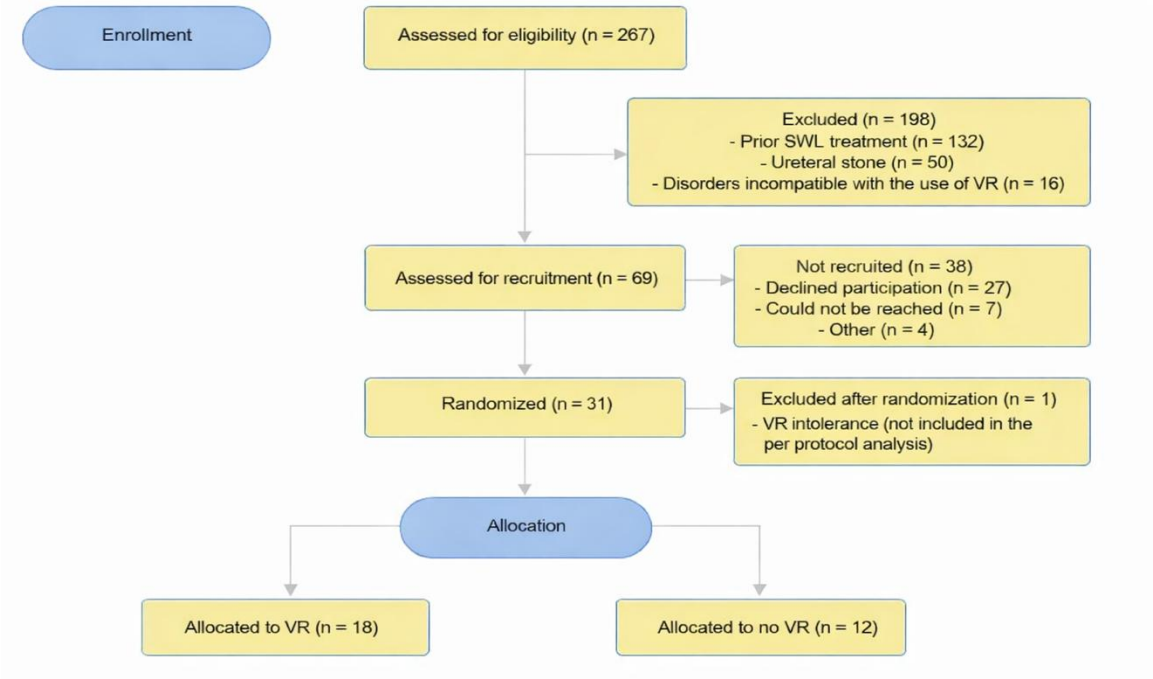
## FIGURES AND TABLES

**Figure 1.**




| **Table 1. Baseline characteristics** | | | | |
|---|---|---|---|---|
| | **VR** | **No VR** | **Total** | **p** |
| Patient no (%) | 18 (60.0) | 12 (40.0) | 30 | – |
| Mean age (SD) | 57.9 (15.8) | 54.9 (18.4) | 56.7 (16.6) | 0.634 |
| Gender, n (%) | | | | |
| Male | 9 (50.0) | 5 (41.7) | 14 (46.7) | 0.773 |
| Female | 9 (50.0) | 7 (58.3) | 16 (53.3) | |
| Stone laterality, n (%) | | | | |
| Left | 8 (44.4) | 9 (75.0) | 17 (56.7) | 0.522 |
| Right | 10 (55.6) | 3 (25.0) | 13 (43.3) | |
| Stone location, n (%) | | | | |
| Upper pole | 1 (5.5) | 2 (16.7) | 3 (10.0) | |
| Middle pole | 5 (27.8) | 4 (33.3) | 9 (30.0) | 0.700 |
| Lower pole | 3 (16.7) | 2 (16.7) | 5 (16.7) | |
| Renal pelvis | 9 (50.0) | 4 (33.3) | 13 (43.3) | |
| Mean stone diameter, mm (SD) | 8.0 (2.8) | 7.8 (3.0) | 7.9 (2.8) | 0.818 |

SD: standard deviation; VR: virtual reality.

| **Table 2. Secondary outcomes: side effects, anxiety, pain, and patient-reported outcomes** | | | |
|---|---|---|---|
| | VR | No VR | p |
| VR side effects, n (%) | | | |
| Yes | 0 (0.0) | 0 (0.0) | 0.406 |
| No | 18 (100.0) | 12 (100.0) | |
| Anxiety control | | | |
| STAI Y1 pre-SWL (SD) | 28.06 (7.34) | 34.58 (8.82) | 0.036 |
| STAI Y1 post-SWL (SD) | 23.89 (4.86) | 26.08 (5.65) | 0.266 |
| ΔSTAI Y1 (SD) | -4.17 (6.52) | -8.50 (8.83) | 0.133 |
| Average SWL power, % (SD) | 68.9 (11.0) | 67.2 (10.1) | 0.669 |
| Pain control | | | |
| Analgesic doses (95% CI)[a] | 1.4 (0.95-1.85) | 1.4 (0.99-1.81) | 0.753 |
| Average pain intensity, VRS (95% CI)[b] | 3.83 (2.73-4.93) | 5.92 (4.95-6.90) | 0.043 |
| Average pain unpleasantness, VRS (95% CI)[c] | 4.00 (3.07-4.93) | 5.42 (4.49-6.35) | 0.096 |
| Subjective outcomes, n (%) | | | |
| Would receive SWL again | 17 (94.4) | 8 (66.7) | 0.046 |
| Thought VR reduced their stress | 12 (66.7) | 3 (25.0) | 0.025 |
| Would receive VR again | 13 (72.2) | N/A | – |
| Would like VR during SWL | 11 (61.1) | 5 (41.7) | 0.296 |

[a]One dose=Fentanyl 50 mcg IV. [b]Pain intensity was evaluated with a VRS score (0=no pain, 10=worst possible pain). [c]Pain unpleasantness was evaluated with a VRS score (0=not bothersome, 10=worst possible unpleasantness). STAI: State-Trait Anxiety Inventory; SWL: shockwave lithotripsy; VR: virtual reality.

| **Table 3. Subgroup analyses on average pain intensity[a]** | | | |
|---|---|---|---|
| | **VR** | **No VR** | **p** |
| Age ≤50 years old (SD) | 3.0 (3.2) | 7.2 (1.8) | 0.032 |
| Age >50 years old (SD) | 4.2 (2.9) | 5.8 (2.7) | 0.166 |
| Female gender (SD) | 3.8 (2.8) | 6.4 (2.4) | 0.078 |
| Male gender (SD) | 3.8 (3.3) | 5.2 (2.9) | 0.436 |

[a]Pain intensity was evaluated with a VRS score (0=no pain, 10=worst possible pain)
SD: standard deviation; VR: virtual reality.