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PRIMARY URETERIC STENT INSERTION UNDER LOCAL ANAESTHETIC OR SEDOANALGESIA IN NON-PREGNANCY – A SYSTEMATIC REVIEW

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Abstract

Background and Objective

To characterise the evidence surrounding local anaesthetic ureteric stent insertion (LAUSI) in contexts outside of pregnancy, a procedure typically performed under general anaesthetic (GAUSI), as it has never been the subject of a systematic review.

Materials and Methods

A systematic review of the Medline, EMBASE, PubMed, AMED, BNI, EMCARE, HMIC and PsycINFO databases was conducted to examine the published evidence in line with the Preferred Reporting Items of Systematic Review and Meta-analyses (PRISMA) guidelines surrounding the technique, patient demographics, setting, type of LA± sedoanalgesia used, cystoscopy and fluoroscopy usage, patient tolerability and pain, efficacy, complications and cost-effectiveness. Around 1,460 papers were systematically screened for inclusion.

Results

Seventeen studies were identified; one randomised controlled trials (RCT), four non-randomised comparative studies, and 12 case-series describing LAUSI. The 17 studies encompassed a total of some 1545 LAUSI. The clinical indications were similar to those for GAUSI. Successful LAUSI rate ranged from 71-98.9% in studies overall, with a pooled mean success rate of 89.3% overall (86.8% in LA only, 91.75% in LA ± sedoanalgesia). The tolerability of a LAUSI patient across 14 studies had a pooled mean rate of 91.8% (88.6% in LA only, 95% in LA ± sedoanalgesia). The procedure time was reported in seven studies, and it ranged from 5.35±0.87 to 65.0±27.5 minutes. The four comparative studies showed no difference in complication rates between LAUSI and GAUSI. All five studies reporting on cost-effectiveness showed LAUSI to be superior to GAUSI.

Conclusions

LAUSI is a safe, effective, and cost-effective alternative to GAUSI, which is under-utilised. Further research in the form of RCTs is required to formally establish its place and acceptability amongst urologists.

Keywords: *analgesia, local anaesthetic, sedation, systematic review, ureteral stent, ureteric obstruction, ureteric stent*

INTRODUCTION

Ureteric stent insertion is a necessary and fundamental skill for a urologist in the management of an obstructed urinary system, and remains in widespread use in sundry settings, including pre-open or post-open, endoscopic and robotic ureteric and renal surgery,[1–3] ureteric injury[4] or prophylactically prior to a non-urological surgery.[5] Cystoscopic ureteric stent insertion, which was first described in 1967 through the McCarthy panendoscope,[6] remains commonly used in current practice through a rigid cystoscope, typically necessitating general anaesthesia (GA) or regional anaesthesia in an operating room setting.

Similarly, the first flexible cystoscopy was described by Tsuchida and Sugawara in 1973.[7] This opened the doors to its use for ureteric stent insertion, first described by Clayman in 1986, at the bedside in mostly intubated critically unwell patients in intensive care.[8] Local anaesthetic ureteric stent insertion (LAUSI) and ureteric catheterisation under local anaesthetic (LA) and/or sedoanalgesia have since been described on several occasions,[8–10] particularly in pregnancy.[11–13] The benefits of avoiding a general anaesthetic in pregnancy due to the inherent risks of premature delivery, miscarriage and teratogenicity, has established LAUSI ± sedoanalgesia under ultrasound or minimal fluoroscopic guidance as an accepted technique in the management of refractory hydronephrosis or obstructive ureteric calculi.[14–16]

However, the general use of LAUSI outside of pregnancy is not widely practiced. The proponents of its use in outpatient or office-based settings point towards the avoidance of unnecessary admission, the risks of GA, benefits of saving time and cost, patient tolerance of the procedure and a few complications.[17,18] However, despite these excellent potential benefits, in the 30 years that have passed since the close of the 1980s, GA ureteric stent insertion (GAUSI) remains the standard in non-pregnancy, with many urologists anecdotally even being unaware of LAUSI as a possibility in this setting.

To our knowledge, a systematic review (SR) of the literature surrounding LAUSI with or without sedoanalgesia in non-pregnancy has not been published. The objective of this SR was to ascertain the evidence surrounding this techniques' use, efficacy, tolerability to patients, complications and cost-effectiveness.

MATERIALS AND METHODS

Search strategy

A comprehensive SR of published works was conducted according to the Preferred Reporting Items of Systematic Review and Meta-analyses (PRISMA).[19] Literature searches were performed systematically through the NHS HDAS interface of nine databases (Medline, EMBASE, PubMed, AMED, BNI, EMCARE, HMIC, PsycINFO) using the search terms: "([local anaesthetic OR sedation OR nitrous OR sedoanalgesia OR sedoanalgesia OR sedative OR benzodiazepine OR analgesia OR outpatient] AND [ureteric stent OR ureteral stent OR ureter OR primary ureteric stent insertion OR stent insertion OR JJ stent] [.ti,ab])" for papers published from inception up to August 2020. The full text of the articles were obtained and reviewed, and the search results were supplemented with hand searching of the reference lists. The search strategy was designed by one reviewer (JG), whilst two reviewers (JG and MQ) independently assessed titles and abstracts of all studies as part of the primary screening. Any disagreements were resolved by discussion with a senior author (SM) until a consensus was reached. All authors contributed to the writing of this manuscript.

Study selection

Randomised controlled trials (RCTs), non-randomised comparative studies (NRCSs) and case-series reporting the insertion of retrograde ureteric stents under LA, sedation or sedoanalgesia for any indication besides pregnancy, and in any clinical setting, with a minimum of five primary ureteric stent insertions were included in the study.

The studies that were published as full-text articles were included. The ureteric stent replacements or exchanges were excluded, though studies in which there was a proportion of primary ureteric stent insertion in the study population were considered on their merits. Where an institution published multiple series with overlapping surgical periods covering the same issue, the latest and largest of the studies were considered. All non-clinical, animal model studies, duplicates and conference abstracts were excluded.

The primary benefit outcomes were typically the immediate efficacy or success of LAUSI or correct positioning of the stent later or future intervention. The primary harm outcomes included intra-operative and post-operative complications, chiefly that of patient intolerance to the procedure due to pain, resulting in conversion to regional or general anaesthesia. Complications were reported in an ad hoc individual manner. The secondary outcomes included procedure time and cost analysis. Cost analysis was typically in a manner comparing LAUSI to GAUSI.

Data extraction

The extracted data included the country and the date of the study, sample size, setting, method of local anaesthetic and/or sedoanalgesia, whether a flexible or rigid cystoscope and fluoroscopy was used, patient demographics and indication for stent insertion. The outcomes were also reported, including success rate, procedure time, pain score or assessment, complications and cost analysis. The primary outcome was mostly success rate of LA stent insertion. The data were collected from the study texts and tables, and the authors were not contacted about missing data.

Risk of bias assessment

The risk of bias assessments are summarised in Table 1. Two investigators (JG and MQ) independently assessed the risk of bias in the derived studies. For case-series, a modified version of a validated tool published by Murad et al.[20] based on modified criteria from the Newcastle-Ottawa Scale (NOS)[21], Pierson[22] and Bradford Hills[23] was used. This tool is used to evaluate case series and case reports under four domains (selection, ascertainment, causality and reporting), with eight leading explanatory questions with a yes/no answer to ascertain the risk of bias. The tool was modified to exclude questions 4, 5 and 6, which question if an alternative cause to the intervention may explain the observation, if a challenge/re-challenge phenomenon was undertaken and if there was a dose-response effect, respectively. They are irrelevant in the insertion of a ureteric stent, and as the authors of the tool describe, they are more relevant to cases of adverse drug events.[20]

For the NRCSs studies, the NOS[21] was used. The NOS is a qualitative tool that evaluates three categories, selection, comparability, and outcome, using a star system with a maximum score of nine stars. Selection is an assessment of the study cohort and the representation of the non-exposed cohort and is scored to a maximum of four stars. Comparability of the cohorts based on design or analysis may yield up to two stars. Outcomes are evaluated based on the method of assessment and the adequacy and length of follow up to three stars. The studies scoring seven or higher indicate a high-quality study.

The RCTs were assessed using the updated Cochrane risk of bias tool for randomised trials (RoB 2).[24] Risk of bias was assessed from the randomisation process, deviation from the intended interventions, missing outcome data, outcome measurement and in the selection of results. Risk of bias was judged in each domain as "low risk", "high risk" or showing "some concerns" following the published algorithm. A judgment of "high risk" in at least one domain or the judgment of "some concerns" in multiple domains would result in overall high risk of bias in the assessed study. A judgment of "some concerns" in at least one domain would result in overall some concerns of bias in the assessed study. A judgment of "low risk" in all domains would result in overall low risk of bias in the assessed study. In cases of discordance between

TABLE 1 Risk of Bias Assessments

Domains for Evaluating the Methodological Quality of Case Reports and Case Series									
	Selection	Ascertainment			Causality		Reporting		
	Leading Explanatory Questions								
	Question 1	Question 2	Question 3		Question 7		Question 8		
Adeyoju et al.[32]	Yes	Yes	Yes		No		Yes		
Andriole et al.[10]	No	Yes	Yes		Yes		Yes		
Birch et al.[35]	Yes	Yes	No		No		Yes		
Carrion et al.[38]	Yes	Yes	Yes		Yes		Yes		
Giannakopoulos et al.[30]	Yes	Yes	Yes		Yes		Yes		
Grasso et al.[36]	No	Yes	Yes		Yes		Yes		
Jeong et al.[33]	No	Yes	Yes		Yes		Yes		
Mark et al.[37]	No	Yes	Yes		Yes		Yes		
McFarlane et al.[18]	Yes	Yes	Yes		Yes		Yes		
Nourparvar et al.[34]	No	Yes	Yes		Yes		Yes		
Sigman et al.[31]	Yes	Yes	Yes		Yes		Yes		
Sinha et al.[17]	Yes	Yes	Yes		Yes		Yes		
	Nottingham-Ottawa Score (NOS)								
	Selection				Comparability	Outcome			
	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	Question 8	Total score/9
Carrouget et al.[28]	★	★	★	★	★	★	★	★	9
Doersch et al.[26]	★	★	★	★	★★	★	★	★	9
Gershman et al.[29]	★	★	—	★	★	★	★	★	8
Sivalingham et al.[27]	★	★	★	★	—	★	★	★	7
	Cochrane Tool for Assessing Risk of Bias in Randomised Trials (RoB 2)								
	Bias arising from randomisation process		Bias due to deviations from intended interventions	Bias due to missing outcomes data		Bias in measurement of outcome		Bias in selection of the reported results	Overall risk of bias
Hussein et al.[25]	Some concerns		Low risk of bias	Low risk of bias		Low risk of bias		Low risk of bias	Some concerns

the two reviewers, discussions with a senior author (SM) lead to consensus being reached.

Data analysis

Due to the scarcity of RCTs and NRSCs identified, a meta-analysis was not possible. The data was thus summarised in a narrative synthesis.

RESULTS

Search results

The search returned 1460 abstracts, and of those screened, 26 full-text studies were scrutinised for eligibility (Figure 1). The screening the reference lists of these eligible articles yielded a further 11 studies. A total of 1443 studies were excluded as they did not meet the inclusion criteria. Ultimately, 17 articles were eligible for final inclusion.

Study and patient characteristics

Of the 17 studies included, one was an RCT,[25] four were NRSCs,[26–29] and 12 were case-series describing LAUSI.[10,17,18,30-38] The 17 studies encompassed a total of some 1545 LAUSI. The RCT[25] randomised a cohort of primary LAUSI into two groups, and allowed to observe their procedure; its primary endpoint was comparison of pain score. This outcome was the basis of our risk of bias assessment, and it does not affect the analysis for the endpoints of the SR. The four NRSCs[26–29] compared cohorts (or a proportion thereof) of patients undergoing LAUSI ± sedoanalgesia and GAUSI. The studies are summarised in Table 2.

Indications for LA stent insertion, patient demographics and study setting

Indications for LAUSI were diverse across studies, reflecting the similarly variable clinical indications for GAUSI. The largest series of 429 primary LAUSI (within a cohort of 565 primary LAUSI and stent exchange) by Doesrch et al.[26] had urolithiasis as the main indication (67.2%), followed by malignancy (14.9%) and ureteric stricture (6.5%). Sigman[31] reported a series of 97 primary LAUSI±IV sedation in renal allograft transplant hydronephrosis. Other indications from studies dating back to the 1990s[11,32,37] included LAUSI prior to extracorporeal shock wave lithotripsy. The patient demographics were similarly varied across identified studies.

Thirteen of the 17 studies[17,18,25–27,29–33,36,37] described primary LAUSI±IV sedation in an outpatient setting (including office-based, clinic room or cystoscopy/endoscopy/lithotripsy suite), two[28,35] in the operating room, one[34] at the patients' bedside in the emergency department and one[10] was unclear.

Type of LA used, sedoanalgesia, cystoscopy type and use of fluoroscopy

Sixteen of the 17 studies[17,18,25–38] used a lidocaine/lignocaine gel urethrally as LA, one study[10] did not explicitly specify what they used. The lidocaine gel was either 1% or 2%. Of these 16 studies, nine used lidocaine gel alone, while five[18,28,29,35,36] used LA in combination with sedoanalgesia (typically a benzodiazepine administered orally or intravenously), two with lidocaine gel and a further lidocaine solution intravesically[28,38] and one[31] study had subgroups using both LA alone and LA with sedoanalgesia.

A flexible cystoscope alone ranging in calibre from 15-18F was used in nine studies[10,17,18,30,32,34,36–38], a rigid cystoscope from 17.5-22F in four studies[25,28,33,35] and a combination based on patient sex or surgeon preference in the four remaining studies[26,27,29,31] which tended to favour flexible cystoscopy for males and rigid cystoscopy for females.

Fluoroscopy was used for all LAUSI in 10 studies[10,18,26–31,33,38] not used at all in six[17,32,34–37] and used variably based on surgeon preference in one[25] study.

Primary endpoint-efficacy of LA stent insertion

A successful stent insertion, defined as immediate successful placement under LA was directly reported within 13 studies[17,18,26–32,34,36–38], with data presented in Figure 2. Successful LAUSI rates ranged from 71-98.9% in studies overall, with a pooled mean success rate of 89.3% overall (86.8% in LA only studies, 91.75% in LA ± sedoanalgesia).

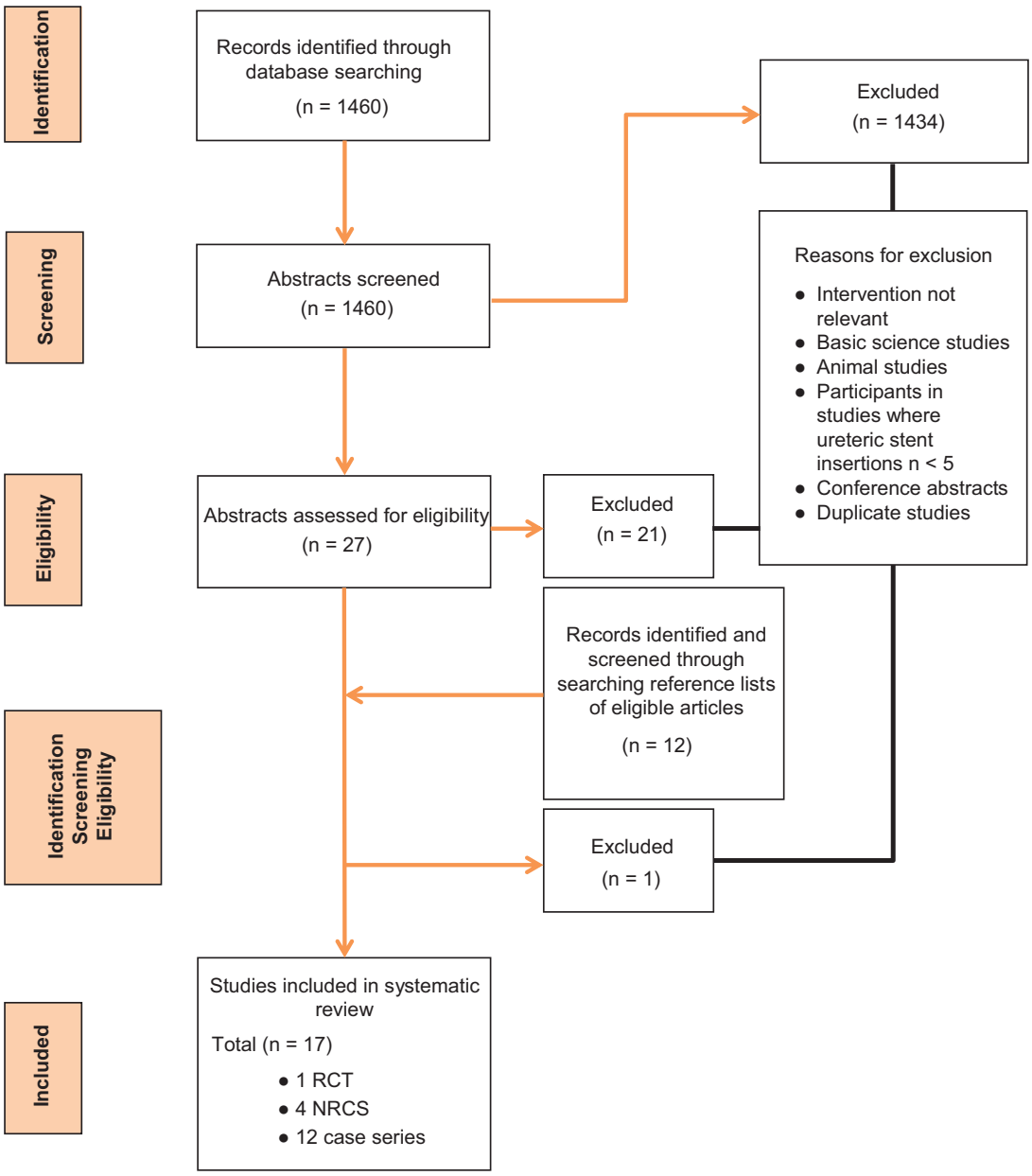

FIGURE 1. PRISMA Diagram.

Twelve of these 13 studies reported an overall success rate of 83.3-98.9%. Failure was typically described as being due to an inability to cannulate the ureteric orifice, or passage of a wire or stent up an obstructed ureter.

Tolerability and pain

Patient tolerability to LAUSI was variably reported and is presented in Figure 3. For the purposes of this review, tolerability was defined as (i) the rate at which LAUSI was not terminated due

TABLE 2 Included studies.

Authors, study design, nationality and year	Sample size and information	Patient demographics	Indications	Outcomes	Comments
Adeyoju et al. Case series, UK 1999[32]	n = 6 ureteric stent insertions and 14 retrograde ureteric catheters under LA Flexible cystoscope 16.6F. No fluoroscopy, plain X-ray subsequently Outpatient setting LA - Lignocaine gel urethrally and 100 mg PR diclofenac	Age range – 23y – 86y Sex – Male 35% ASA grade not reported	For the 6 ureteric stent insertions: 2 prior to ESWL, 2 small symptomatic proximal ureteric calculi, 1 symptomatic PUJO, 1 prior to balloon stenting of ureter Retrograde ureteric catheters for frank or non-visible haematuria, or suspicious/ inadequately imaged system on IVU	Successful in 5/6 ureteric stents and 12/14 retrograde ureteric catheters 15% failure rate (3 cases): inability to visualise U.O. due to turbid urine, previous resection or large prostatic median lobe Mean duration 11 mins Tolerability – 82.4% no pain and happy to undergo procedure again, 17.6% painful and would prefer a GA Cost analysis not performed	Authors commented the two procedures suitable for the outpatient/day case situation, well-tolerated and accepted by most patients.
Andriole et al. Case series, USA, 1984[10]	n = 31 primary ureteric stent insertions as part of a larger group (n= 87) of stent insertions Cystoscope type not noted Fluoroscopy used Setting not clearly described LA type not specified	Not recorded	**Total cohort (n = 87)** Cancer – 41.4% Stones – 10.3% PUJ obstruction – 3.4% Ureteral stricture – 3.4% RPF – 3.4% VUJ obstruction – 2.3% Endometriosis – 1.1% Adjunct to genitourinary surgery – 17.2% Upper urinary tract fistulas – 11.5% Hydronephrosis uncertain origin – 5.7%	60.7% of endoscopic stent insertions were done under local anaesthetic. Patient tolerability is not reported. Inaccurate stent insertion was noted in only one case (unclear if LA or GA) at open surgery subsequently Cost analysis is not performed.	This early paper in which JJ ureteric stents were becoming newly used shows even from the outset LA was favoured above GA.

(*Continues*)

TABLE 2 *Continued*

Authors, study design, nationality and year	Sample size and information	Patient demographics	Indications	Outcomes	Comments
Birch et al. Case series, UK, 1990[35]	n =14 stent insertions Rigid cystoscope, 17.5F. Fluoroscopy not reported Operating room setting LA – 2% lidocaine gel urethrally, sometimes additional 4% ligonacaine spray topically to perineum and IM benzodiazepine	Not recorded	Not recorded	Not recorded	Of the 1020 urological procedures done over a two year period under sedoanalgesia, 14 ureteric stents were inserted. Results of these not commented on.
Carrion et al. Case series, Spain, 2018 (38)	n = 33 LAUSI in 37 patients Flexible cystoscopy 15.5F, fluoroscopy used for 95% (43/45 cases) except in pregnancy Office-based setting LA – 2% lidocaine 10 ml urethrally and 2% lidocaine 50 ml solution left in bladder for 5 mins	Mean age – 58.6y Sex – Male 27%	Stone – 37.8% Extrinsic compression – 28.9% Surgery ureteral localisation – 22.2% PUJO – 2.2% Urinary fistula – 4.4% Ureteral stricture – 4.4%	Successful insertion – 89% No procedure terminated due to pain. Complications (Clavien-Dindo, %) I – 15.6 II – 0 IIIa – 2.2 IIIb, IV, V – 0 No significant differences found on univariate analysis between patient demographics, prostate volume or stent indication between successful and failed attempts. Average cost, office-based vs OR – €640 vs €2500	Authors concluded that LAUSI can be safely and effectively performed under local anaesthesia in the office cystoscopy room freeing up procedure operating room time, reducing costs and minimising side effects of GA.

Carrouget et al. Non-randomised comparative study, France, 2014	n = 18 LAUSI vs. n = 18 GAUSI Rigid cystoscopy 21F, fluoroscopy used Operating room setting LA – 1% lidocaine gel, intravesical instillation of 1% lidocaine (60 ml) and 14% bicarbonate (60 ml) + 0.25 mg alprazolam + 1 g paracetamol	**LAUSI** Age (y) – 58.5±27.5 Pre-operative pain (VAS) – 2.57 [1-7] Intraluminal	**LAUSI** Intraluminal obstacle (n, %) – 12, 50 Extraluminal obstacle (n, %) – 6, 50 No significant difference between LAUSI and GAUSI groups (p=1) **LAUSI vs GAUSI** Pregnancy (%) - 27.7 vs 0, p=0.045	**LAUSI vs GAUSI** Successful placement under LAUSI – 17/18, 94.4% Operative time (mins) – 24.4±13.28 vs 18.5±6.5, p=0.099 Operating room time (mins) – 52.65±22.9 vs 65±31.5, p=0.193 Intraoperative pain (VAS) – 5.9±2.9 vs 2±2.6, p<0.0001 Tolerability 9/18 (50%) would not undergo procedure LAUSI Patient satisfaction 11 (61.1%) vs 15 (83.3%), p=0.264 Post-operative analgesic Level I – 100% vs 100%, p=1 Level II – 33.3% vs 5.5%, p=0.228 Level III – 11.1% vs 5.5%, p=1 Post-operative complications (Clavien-Dindo) II – 22.2% vs 5.5%, p=0.338 IV – 5.5% vs 0, p=1	LAUSI was deemed feasible under LA, but 50% of patients reported they would prefer not to undergo it under LA in the future. No difference was seen in patient satisfaction, operative time or post-operative complications.
Doersch et al. Non-randomised comparative	n = 429 Compared 565 ureteric stent procedures (76% primary insertions)	**LAUSI (primary and stent replacement)**	**LA stents** Stone – 67.2% Malignancy – 14.9% Stricture – 6.5% UPJO – 4.4%	**LAUSI±N_2O vs. GAUSI** Failure (1.1% vs. 0.56%) Procedure time (10 mins vs. 12 mins, p<0.01)	Ureteric stent placement under LA/LA±N_2O was significantly quicker than under GA, and

(*Continues*)

TABLE 2 *Continued*

Authors, study design, nationality and year	Sample size and information	Patient demographics	Indications	Outcomes	Comments
study, USA 2018 and 2019[26,41]	in clinic using local anaesthetic ± nitrous oxide gas vs. 179 stent procedures (79.2% primary insertions, p=0.36) in operating room Flexible cystoscope, 16F in males, rigid cystoscope 22F in females Fluoroscopy used Office based vs. operating room setting. LA – lidocaine jelly urethrally	Median age – 57y [18y – 95y] Sex – Male 41% Charlson Comorbidity Index (3 [0-14]) No clinically significant difference in the above vs. GA group.	RPF – 2.5% Other – 5.3% No clinically significant difference in the above vs. GA group.	Complications (4.1% vs. 7.8%, p=0.99) Unplanned admission to hospital post-stent (3.0 vs. 9.5%) Cost analysis is not performed.	was not any different in complication rate. Tolerability is not directly evaluated.
Gershman et al. Non-randomised comparative study, USA, 2013[29]	n = 24 primary LAUSI in "renal units" with comparison of similar cohort n= 10 GAUSI Flexible cystoscope, in males, flexible or rigid cystoscope in females. Fluoroscopy used Office based setting LA 1% lidocaine gel urethrally, some patients also receiving oral lorazepam	Mean age – 62.2y Mean stone diameter in primary stent insertion – 5.8 mm (3–8.8)	**Indications for primary LAUSI or exchange** Malignant extrinsic ureteric compression – 37.0% Ureteric stone – 32.6% PUJ obstruction – 13.0% Benign extrinsic ureteric compression – 10.9% Ureteric stricture – 4.3% Hydronephrosis – 2.2%	No procedures terminated due to patient pain. **Success rate** Primary LAUSI – 95.8% (23/24) (1 case [4.2%] failure due to ureteric stone at site of stricture] Ureteric catheterisation with retrograde pyelography or BCG instillation – 100% **LAUSI (n=20) vs. GAUSI (n=10)** Procedure time (mins) – 65.0±27.5 vs 45.1±17.6, p=0.048	The authors commented: Office-based procedures associated with a nearly three-fold reduction in total hospital time as a result of reduced perioperative waiting times. Ureteral stent placement, ureteral stent exchange, and ureteral catheterization can be performed safely and effectively in

				Periprocedure time (mins) – 32.9±28.6 vs 226.4 ±21.6, p<0.001 Total hospital time (mins) – 106.2±31.2 vs 275.0 ±33.5, p<0.001 **Complications** No complications. **Cost analysis, LAUSI vs. GAUSI** Primary ureteric stent insertion - $599 vs $2306	the office in both men and women. This avoids general anaesthesia and provides significant savings of time and cost for both patients and the healthcare system.
Giannakopoulos et al. Case series, Greece, 2008[30]	n = 59 primary stent placements in 54 patients Flexible cystoscope 15F, fluoroscopy used Outpatient endoscope suite setting LA consisted of 2% lidocaine gel urethrally	Sex – Male 51.9%	Renal stones – 32.2% Ureteric stones – 16.9% Benign stricture – 10.2% Prolonged urine leak after PCNL – 8.5% PUJ obstruction – 6.8% RPF – 6.8% Unexplained hydronephrosis – 5.1%	Successful attempts – 91.5% Mean operative time – 6.6 mins [3.5-23] Mean fluoroscopy time – 1.1 mins (0.6-17.3) Procedure tolerability: Acceptable (87%), uncomfortable (9.3%), painful (3.7%) Comment that in their national health system, any cost benefit would be minimal, but no further analysis.	Only two male patients rated the procedure painful. The authors concluded the procedure is safe and effective and easily tolerated by the vast majority of patients.
Grasso et al. Case series, USA, 1990[36]	n = 32 stent insertions prior to ESWL Flexible cystoscopies (15-18F), no fluoroscopy Lithotripsy suite outpatient setting LA – 2% lidocaine gel and IV sedation (type not specified)	Sex – Male 37.5%	All stents prior to ESWL	Success rate – 84.3% Procedure time not reported. Initial failures with open-ended ureteric catheters inserted same sitting – 15.6% Cost effectiveness not reported.	No conversion to GA required. No fluoroscopy used, so 3 stents retrograde migration on removal 1-3 weeks post-operatively. The authors noted the use of fluoroscopy would improve accuracy.

(*Continues*)

TABLE 2 *Continued*

Authors, study design, nationality and year	Sample size and information	Patient demographics	Indications	Outcomes	Comments
Hussein et al. Randomised controlled trial, Iraq/Malaysia, 2013[25]	n = 80 primary ureteric stent insertions, randomised into two groups, one allowed to observe on video monitor the stent insertion , or not allowed to observe Rigid cystoscope, 20F, fluoroscopy used sometimes Day case operating room setting LA – 2% lidocaine urethrally	Sex – Male 100% Mean age – 38.83y	Ureteric stones – 75.5% Renal stones – 26.25% Anuria – 16.3%	Mean duration of procedure (mins) – 5.35±0.87 No significant difference in duration between groups. **Pain** No pain (VAS scale = 0) - 17.5% Mild pain (VAS scale = 1–3) -33.8% Moderate pain (VAS scale = 4–7) - 35.0% Severe pain (VAS scale = 8–10) - 13.8% Mean pain score between groups, observed vs non-observed (VAS) - 1.40 ± 1.932 vs 6.43 ± 1.752, p=0.000 Post-procedure mean systolic blood pressure between groups, observed vs non-observed - 126.63 ± 15.590 vs 135.90 ± 20.348, p=0.025 Cost analysis not reported.	In the group allowed to observe their stent insertion they had significantly lower pain score and post-operative systolic blood pressure.
Jeong et al. Case series, Korea, 2005[33]	n = 127 primary ureteric stent insertions Rigid cystoscope (22F), fluoroscopy was used Outpatient setting Lidocaine 2% gel urethrally in males, non in females.	Mean age – 52.6y Sex – 43% male Subjective pain tolerance – yes, 64%	Relief of urinary obstruction due to renal stones, ureter stones, post-operative complications after pelvic surgery, and pelvic cavity mass, etc. or pre-stenting prior to aid ureteric identification in surgery.	Mean pain score – 4.48±2.07, no different between sexes Patients feeling analgesia premedication required – 36% Success and cost-effectiveness of stents not reported.	Although performed with a rigid cystoscope, the procedure was generally well tolerated – 36% of patients felt additional analgesia would have been required. Females did not receive any analgesia as standard urethrally.

Mark et al., Case series, New Zealand 1990[37]	n = 34 attempted primary LAUSI prior to ESWL Flexible cystoscope, no fluoroscopy Outpatient setting LA – 2% lignocaine gel	Median age – 60y Sex – Male 73.3%	Prior to ESWL	Success rate – 88.2% All the failures 4/32 (12.5%) failed due to feed stent over guidewire in distal ureter – 3 failed subsequently under GA in theatre, the last not attempted. Complications: 12.5% (n = 3) returned with renal colic within 24 hrs, 2 managed with simple analgesia, 1 requiring admission. Stent migration – 8.3% Estimated cost saving vs day-case GA – NZ$120.00 per patient	This simple, safe and reliable technique for insertion and removal of double pigtail ureteric stents under local anaesthesia increases the role of the flexible cystoscope in urological practice and complements the Out-patient Lithotripsy Service.
McFarlane et al., Case series, UK 2001[18]	n = 723 ureteric procedures, around 225 primary ureteric stent insertions using lidocaine gel ± IV sedoanalgesia Other procedures were cystoscopy alone, retrograde ureterogram, stent change and stent removal	**All ureteric procedures** Mean age - 60.6 [16-93] Sex - Male 53%	**Stent placement and retrograde pyelography** Stone disease – 23% Malignant ureteric obstruction – 22% Unexplained hydronephrosis – 21% Haematuria – 13% Benign ureteric strictures – 10%	**Stent placement and retrograde pyelography** Tolerability (94% of patients found them acceptable, 4% uncomfortable, 2% painful) **Reason for failure (% of total)** Failure to cannulate ureteric orifice – 7 Unable to pass guidewire past stone/stricture – 1.8	Number of primary stent insertions not clear from paper. 89% of all procedures (not just stent insertions) were successful. In 2.5% of patient unable to pass a wire or stent past a ureteric stricture or stone causing obstruction.

(*Continues*)

TABLE 2 *Continued*

Authors, study design, nationality and year	Sample size and information	Patient demographics	Indications	Outcomes	Comments
	Flexible cystoscopy, fluoroscopy used Interventional radiology suite, outpatient setting Lignocaine gel urethrally and diazemuls and pethidine additionally in some cases		Autosomal dominant polycystic kidney disease – 3% Filling defect on IVU – 2% Hydronephrosis of pregnancy – 1% Risk of contrast allergy – 1% Ureteric trauma – 1% Unexplained loin pain – 1% Other – 3%	Unable to push stent past stone/stricture – 0.7 Panic attack – 0.1 **Failure by indication (% of total)** Malignant ureteric obstruction – 28 Stone disease – 9 Unexplained hydronephrosis – 6 **Complications** 21 patients Cost analysis and procedure time not explored.	The authors concluded that retrograde ureterography and ureteric stent placement may be satisfactorily undertaken with the patient under sedoanalgesia on an outpatient basis, reducing costs, hospital admissions, general anaesthetic use, demands on theatre time and complication rates.
Nourparvar et al. Case series, USA, 2016[34]	n = 30 primary ureteric stent insertions for urolithiasis under LA from a total cohort of 42 Flexible cystoscope, no fluoroscopy Bedside in the emergency department LA – 1% lidocaine gel urethrally	Mean age – 51.3y Sex – Male 48% Mean stone size – 8.3 mm Ureteric stone location: proximal (71%), distal (29%)	Emergency admissions with symptomatic ureteric calculi Pain – 59% Infection – 14% Nausea/vomiting – 2% Immunocompromised – 2%	Successful stent placement – 71% No immediate complications, no cases terminated due to discomfort Cost benefit LA stent vs GA - $11000 vs $25000 Procedure time not reported.	Statistical analysis did not reveal any significant predictors of successful stent placement. The authors reported that bedside ureteral stent placement was well tolerated, safe and efficacious, thus expediting upper tract decompression in the setting of obstructed renal units in greater than 70% of patients

Sigman et al. Case series, USA, 1999[31]	n = 97 n=24 LAUSI, n = 57 LAUSI+ IV sedation, n = 5 under GA Flexible and rigid cystoscopies and semi-rigid ureteroscopes of variety of calibres Fluoroscopy used Cystoscopy suite outpatient setting LA was 2% lidocaine gel urethrally, IV sedation with midazolam and fentanyl	Sex – 56.7% male	Renal allograft transplant hydronephrosis All patients found to have hydronephrosis on USS. 63% proven to have ureteric obstruction on MAG-3 renogram, 26% equivocal results, 11% worsening AKI despite Foley urethral catheter, adequate hydration and no allograft rejection on biopsy.	88% of cases managed successfully with retrograde stenting, of whom 28% LA alone, 67% LA + IV sedation. Of these 5% required GA or regional anaesthesia. 12% failed and underwent open surgical exploration: 83% of whom had ureteral necrosis and the remaining allograft rupture. Cost analysis and procedure time is not explored.	Authors commented that retrograde stenting of the hydronephrotic renal allograft can be achieved with a high success rate and minimal morbidity, usually without general or regional anaesthesia. If the ureter cannot be managed in a retrograde fashion, a high index of suspicion for a serious allograft complication should exist.
Sinha et al. Case series, South Africa 2018[17]	n = 276 ureteric stents and n= 40 ureteric catheter insertions Flexible cystoscope, no fluoroscopy Outpatient setting LA 2% lidocaine gel urethrally	Sex – male 50.9% Median age – Males 48y, females 45y	Obstruction due to ureteric stone complicated by non-resolving pain, failure of medical expulsive therapy, urinary tract infection or renal failure. Also, before PCNL or for retrograde pyelography	Total success rate 85.4% (stent 85.5%, ureteric catheter 85.0%) Complication rate overall 3.8% **Success vs failed attempts** Pain score <5 – 87.5% vs 12.5% >5 – 72.7% vs 27.3% (p=0.02) Median time (mins) 10 vs 20, p<0.0001 Difficulties encountered (%) – 13.7 vs 82.6, p<0.0001	Patients with a greater pain score (>5) experiences significantly greater proportion of failure, with successful procedures also being significantly shorter. Authors noted the procedure was easily mastered and technically

(*Continues*)

TABLE 2 *Continued*

Authors, study design, nationality and year	Sample size and information	Patient demographics	Indications	Outcomes	Comments
				Stone blockage (%) – 8.1 vs. 44.7, p=0.0005 Stent blockage (%) – 13.5 vs 0%, p=0.03 Patient difficulty (%) – 18.9 vs 2.6, p=0.03 Cost benefit – save 2.6 million ZAR as day case compared to a day of inpatient stay, rising to 3.3 million for 3 days of stay.	simple, and represents savings in cost, time and human resources in their setting.
Sivalingam et al. Non-randomised comparative study, USA, 2013[27]	n = 119 total stent insertions, n = 46 under LA, n = 73 under GA All primary stent insertions for symptomatic obstructive ureteric calculi Rigid 21F or flexible 15F cystoscope for females, and flexible cytoscope for men. Fluoroscopy used Office vs operating room setting LA – 1% lidocaine gel urethrally.	Mean age LA group (52.5y) – no significant difference to GA group. No significant gender difference.	**LA group** Pain – 57%, fever/pyuria – 28% **GA group** Pain – 33%, fever/pyuria – 55%, p=0.005	**LA vs GA** Stent placed within 12 hrs (%) – 54 vs 58 Interval to definitive stone removal (d) – 35 vs 33 Failure to successful stent placement (%) – 8.7 vs 1.3%, p=NS Procedure terminated due to pain – 1 vs 0, p>0.05 Complications – 0 vs 0 Cost analysis (total cost per encounter $) – 7770 vs 30,060	No significant difference in failure rate of stent placement in LA vs GA group. Only one patient cancelled due to pain.

GA: general anaesthetic, GAUSI: general anaesthetic ureteric stent insertion, LA: local anaesthetic, LAUSI: local anaesthetic ureteric stent insertion

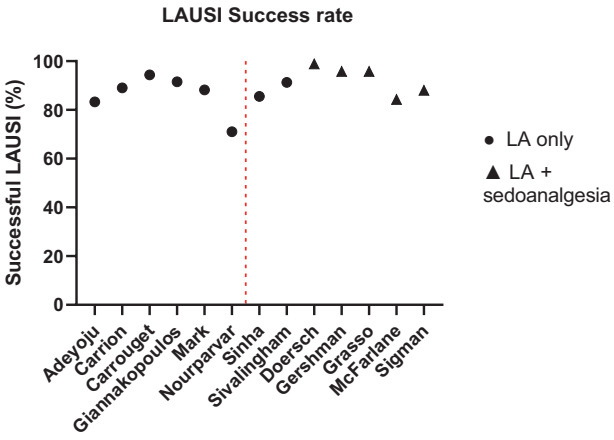

FIGURE 2. Success rate of local anaesthetic ureteric stent insertion.

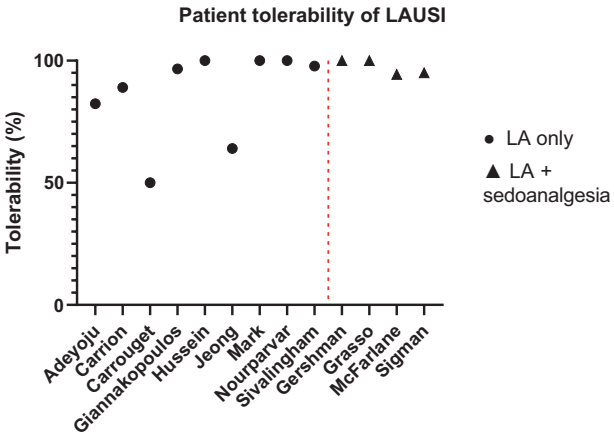

FIGURE 3. Patient tolerability of local anaesthetic ureteric stent insertion.

to patient intolerance (typically due to pain), either directly reported or inferred, or through (ii) direct surveying of patients asking if they would undergo the procedure under LA once again. The LAUSI patient tolerability ranged from 50-100% across 14 studies[18,25,27–29,31–34,36–38] with a pooled mean rate of 91.8% (88.6% in LA only studies, 95% in LA ± sedoanalgesia).

Four studies examined patient pain during LAUSI using a pain score, all LA only. Hussein et al.[25] in their RCT of a total of 80 LAUSI patients randomised them into two groups of 40, permitting one group to observe their cystoscopy live on screen, and the other to not to determine if this affected pain scores. Those able to watch their cystoscopy had significantly lower visual analog scale (VAS) pain scores from 10 (1.40 ± 1.932 vs 6.43 ± 1.752, p=0.000), and the mean pain score was 3.91 ± 3.12. Jeong et al. in their series of 127 LAUSI using a 22F rigid cystoscope found a mean pain score of 4.48±2.07.[33] Giannakopoulos reported a mean pain score of 3.91 ± 3.12 in 59 LAUSI in 54 patients, with 87% deeming the procedure acceptable, 9.3% uncomfortable, and two male patients (3.7%) deeming it painful.[30] Carrouget et al.[28] in their NRCS compared 18 LAUSI to 18 GAUSI, and found that intraoperative VAS pain scores were significantly higher in the LA group (5.9±2.9 vs 2.0±2.6, p<0.0001), and a post-operative survey found LAUSI to be more associated with pain and discomfort than GAUSI (p=0.012 and p=0.018), though this did not affect their satisfaction with the procedure ("satisfied" 61.1% vs 83.3%, p=0.264 and "very satisfied" 55% vs 16.6%, p=0.264). Sinha et al.[17] in their large cohort of 276 LAUSI and 40 ureteric catheter insertions found that 86.7% had a pain score ≤5, and that those with a pain score of >5 experienced a significantly greater proportion of failure than patients reporting a pain score of ≤5 (27.3% vs 12.5%, p=0.02).

Procedure time, complications, and cost-effectiveness

The procedure time was reported in seven studies[25,26,28-30,32] and ranged from 5.35±0.87 to 65.0±27.5 minutes. Adeyoju et al. in their series of six patients in an outpatient setting without the use of fluoroscopy reported a median procedure time of 11 mins.[32] Giannakopoulos et al.'s series of 59 LAUSI in the outpatient endoscopy suite using fluoroscopy reported a mean operative time of 6.6 (3.5-23) mins.[30] Hussein et al.'s RCT of 80 LAUSI in a day-case operating room setting with variable fluoroscopy use, reported a mean operative time of 5.35±0.87 mins.[25]

In Carrouget's NRCS (18 LAUSI vs 18 GAUSI), performed in the operating room with

fluoroscopy, reported no difference in operative time (24.4±13.28 vs 18.5±6.5 mins, p=0.099) or total operating room time ((52.65±22.9 vs 65±31.5 mins, p=0.193) between groups. In Gershman's NRCS[29] (20 LAUSI vs. 10 GAUSI) however, though LAUSI had a significantly greater procedure time (65.0±27.5 vs 45.1±17.6 mins, p=0.048), periprocedure time (i.e., waiting time) and total hospital time were significantly lower (32.9±28.6 vs 226.4±21.6 mins, p<0.001, and 106.2±31.2 vs 275.0±33.5 mins, p<0.001 respectively).

The four comparative studies showed no significant differences in complication rates between LAUSI and GAUSI. Carrouget et al. (18 LAUSI vs 18 GAUSI) showed no difference in Clavien-Dindo (CD) II (22.2% vs 5.55%, p=0.338) or IV (5.5% vs 0.0%, p=1) complications. Similarly, Doersch et al.'s comparative study of 565 clinic stents (including 429 LAUSI) vs OR stents showed no difference in complication rate (4.1% vs 7.8%, p=0.99). No complications occurred in either group (46 LAUSI or 73 GAUSI) in Sivalingham et al.'s study[27] or in Gershmann et al.'s (24 LAUSI).[29]

Five studies reported a cost-analysis of LAUSI.[27,29,34,37,38] The three US-based studies reported or estimated cost saving in favour of LAUSI vs GAUSI (Gershmann et al.[29] $599 vs $2306, Sivalingham et al.[27] $7770 vs 30,060, Nourparvar et al.[34] $11,000 vs 25,000). Carrion et al.[38] in Spain estimated, with the exclusion of emergency department charges and pre-operative tests, an average cost of €640 vs €2500 per encounter in favour of LAUSI. Mark et al.[37] in New Zealand reported a total cost saving of NZ $120.

DISCUSSION

Flexible cystoscopy has been a staple of urological diagnosis since it was first performed by Tsuchida and Sugawara 1973,[7] and is a fundamental endourological skill that all urologists are trained in. It has since evolved from being a mere diagnostic tool to a therapeutic one in the outpatient setting, being used first in cystodiathermy[39] and now increasingly for laser fulguration of bladder lesions.[40] Its use in obstructive uropathy was first described in a series by Clayman and Kramolowsky in 1986[8] who successfully inserted 7.1F pigtail ureteric catheters in three of five critically ill patients on ITU. Its expansion continued in the 1980s and 1990s, with ureteric catheters and stents being inserted under LA with or without sedoanalgesia.[10,35,36] In the current era, LAUSI is perhaps more widely recognised and utilised in the management of refractory ureteric colic in pregnancy due to the uncertainty surrounding the safety of soluble anaesthetic gases, in addition to the other challenges of tracheal intubation and aortocaval compression by the gravid uterus.[14–16] Its more general use in the non-pregnancy setting has however only sporadically been reported in the literature, and has never been studied in a direct RCT against GAUSI, despite its clear potential benefits in the avoidance of a general anaesthetic, reduced procedure time and cost effectiveness. This is to our knowledge the only systematic review to date of the literature surrounding LAUSI.

The present review has shown that LAUSI is an effective technique, with successful immediate stent placement in the range of 71-98.9% in reported studies. Twelve of the thirteen studies placed this range higher at 83.3-98.9%; the one study by Nourparvar et al.[34] reporting a success rate of 71%. This was a study of 42 attempted LAUSI performed at the bedside in the emergency department without the use of fluoroscopy for patients presenting with acute ureteric calculi causing obstruction without sepsis. Of the 12 failed cases, nine failed due to a failure of wire advancement past an impacted stone, one of which could not be placed even under GAUSI, and two due to premature stent deployment in the proximal ureter. These were identified immediately on the post-procedure XR-KUB, and the authors note, occurred early in their centre's experience of LAUSI.

It is undeniable that a significant learning curve exists, as with any new procedure, for LAUSI. The ability to insert ureteric stents through a flexible cystoscope without direct visualisation,

using fluoroscopic free-hand techniques for final stent deployment, or doing away with fluoroscopy altogether is not a skill that most general urologists routinely encounter, nor their nursing teams. Sinha et *al.*[17] in their series of 276 LAUSI and 40 ureteric catheters used procedure time as a proxy for measure of mastery; there was a statistically significant halving of procedure time from 12 to 6 mins ($p = 0.0007$) from the first ten cases performed to completion of ≥30 completed. McFarlane et al.'s[18] series of 723 outpatient LA ± sedoanalgesia endourological procedures, including approximately 225 LAUSI similarly showed improvement in success rate with increasing experience. This may well go some way to explaining the difficulties encountered in small series such as Carrouget et al.[28]

LAUSI was in general well tolerated across studies, with a pooled mean rate of 91.8% (88.6% in LA only studies, 95% in LA ± sedoanalgesia), though the heterogeneity of definitions of tolerability and pain scores, in addition to modes of LA and sedoanalgesia make it difficult to be conclusive and identify an optimal regimen or setup. No comparative study identified LAUSI as having a significantly higher complication rate than GAUSI, and a general survey of complication outcomes in reported case series revealed no alarming complications outside of that which could be expected for GAUSI, rendering it a safe technique. LAUSI also seems to have a major cost-saving benefit versus GAUSI in reported studies, which stands to reason when considering the alleviated costs of an operating theatre, anaesthetist, and hospital bed for admission.

Limitations of this review include the paucity of studies surrounding LAUSI, typically involving small patient numbers, in addition to the quality of the studies, being predominantly non-comparative studies and case series. A meta-analysis could not be conducted due to the heterogeneity of involved studies and outcomes. No prospective RCT directly comparing LAUSI to GAUSI has yet been conducted, which we strongly recommend be undertaken.

CONCLUSION

Despite the above limitations, the available published evidence strongly suggests that LAUSI offers a safe, efficacious technique and is generally well-tolerated and accepted by patients, with clear potential cost-saving benefits to patients and institutions when performed in outpatient settings. This well-established, yet under-utilised intervention may be a valuable weapon in the armamentarium of any urologist, and further research in the form of RCTs should be conducted to allow formal recommendations to be established for its use and place in the armamentarium of the urologist, as well as exploring the reasons it has seemingly been under-utilised until now.

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