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Use of ultra-low dose computed tomography versus abdominal plain film for assessment of stone-free rates after shock-wave lithotripsy: implications on emergency room visits, surgical procedures, and cost-effectiveness

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ORIGINAL PAPER

Use of ultra-low dose computed tomography versus abdominal plain film for assessment of stone-free rates after shock-wave lithotripsy: implications on emergency room visits, surgical procedures, and cost-effectiveness

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Abstract

The aims of this investigation were: (1) to compare residual stone-fragment (RSF) detection rates of ultra-low dose computed tomography (ULD-CT) and abdominal plain film (KUB) in urolithiasis patients undergoing shock-wave lithotripsy (SWL), and (2) to evaluate the downstream sequelae of utilizing these two disparate imaging pathways of differing diagnostic fidelity. A retrospective chart-review of patients undergoing SWL at two high-volume surgical centers was undertaken (2013–2016). RSF diagnostic rates of ULD-CT and KUB were assessed, and the impact of imaging modality used on subsequent emergency room (ER) visits, unplanned procedures, and cost-effectiveness was investigated. Adjusted analyses examined association between imaging modality used and outcomes, and Markov decision-tree analysis was performed to identify a cost advantageous scenario for ULD-CT over KUB. Of 417 patients studied, 57 (13.7%) underwent ULD-CT while the remaining 360 underwent KUB. The RSF rates were 36.8% and 22.8% in the ULD-CT and KUB groups, respectively ($p = 0.019$). A 5.6% and 18% of the patients deemed stone-free on ULD-CT and KUB, respectively, returned to the ER ($p = 0.040$). Similarly, 2.8% and 15.1% needed an unplanned surgery ($p = 0.027$). These findings were confirmed on multivariable analyses, Odds ratios CT-ULD versus KUB: 0.19 and 0.10, respectively, $p < 0.05$. With regards to cost-effectiveness, at low ULD-CT charges, the ULD-CT follow-up pathway was economically more favorable, but with increasing ULD-CT charges, the KUB follow-up pathway superseded. ULD-CT seems to provide a more 'true' estimate of stone-free status, and in consequence mitigates unwanted emergency and operating room visits by reducing untimely stent removals and false patient reassurances. Further, at low ULD-CT costs, it may also be economically more favorable.

Keywords Urolithiasis · Urinary stone · Computed tomography · X-ray · Extracorporeal shock-wave lithotripsy

Introduction

Shock-wave lithotripsy (SWL) is an outpatient procedure of low morbidity that offers stone-free rates of 60–90% in patients with non-lower pole renal stone burden of ≤ 2 cm or lower pole renal stone burden of ≤ 1 cm [2, 12, 19]. The American Urological Association and the European Association of Urology guidelines on urinary stone disease list SWL as a first-line treatment option for these patients [3, 4, 20].

Following SWL treatment, the patients are allowed a period of 4–6 weeks to pass the stone fragments. At this point, the patients are re-imaged to assess stone clearance. Traditionally this has been performed via an abdominal plain

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film, also known as a kidney ureter bladder X-ray (KUB). However, it is well-recognized that a KUB has limited sensitivity in detecting stones—approximately 60% [7, 9]. This poor accuracy may lead to untimely removal of an indwelling ureteral stent (if such was used prior or during the SWL treatment) and/or false patient reassurance, which can lead to a negative patient outcome. Despite the relatively poor accuracy, the KUB has remained in use as it is associated with low radiation exposure (~ 0.7 mSv). For comparison, a standard abdominal computed tomography (CT) scan with contrast is associated with a radiation exposure of 10 mSv [7, 9]. This is not a trivial dose, as malignancies have been documented at ionizing radiation doses of 100 mSv [5, 18], and the patients with stone disease are typically young and often have frequent radiation encounters, either for diagnostic or therapeutic reasons. Thus, imaging modalities that offer low radiation doses are critical in management of these patients.

In efforts to reduce radiation exposure, low dose, and more recently, ultra-low dose imaging protocols have been developed. A low dose CT is typically associated with a radiation exposure of ~ 3 mSv, while an ultra-low dose CT (ULD-CT) is associated with an exposure of ~ 0.5 to 1 mSv [10, 13–16]. Both protocols have excellent and equivalent diagnostic accuracies—approximately 95% [13, 16]. An ULD-CT protocol thus seems to be an ideal imaging method for stone disease patients as it combines the benefit of computed tomography's excellent sensitivity, while maintaining a low radiation exposure.

We undertook the current project to study the utility of ULD-CT versus KUB as the follow-up imaging in patientsreceiving SWL for upper urinary tract stones. We sought to compare the stone-free rates in these patients as detected by KUB versus ULD-CT, and evaluate the implications of imaging modality used on emergency department visits, unplanned and planned procedures, and overall cost-effectiveness. We hypothesized that the ULD-CT use would be associated with more accurate stone-free estimates (at equivalent radiation exposure as a KUB) and in consequence reduced unplanned care episodes, but there will be a higher overall healthcare cost.

Patients and methods

Study population and study time-period

We performed a retrospective review of electronic medical charts of patients with upper urinary tract stones who had undergone SWL at one of two high-volume surgical centers—Henry Ford Hospital, Detroit, MI or Wyandotte Hospital, Wyandotte, MI (January 2013 to December 2016). Both hospitals utilized Epic medical software to maintain patient records (Epic Systems Corporation, WI). Patients included in this study were selected for SWL per standard guidelines [3, 4, 20]. Briefly, patients who had an upper urinary tract stone burden of < 2 cm were given the choice of SWL or ureteroscopy, and outcomes of each technique were explained in light of the location of the stone, total stone burden, patient habitus, and stone density. Patients with a BMI > 40 kg/m^2 were not offered SWL. Patients with untreated cardiac arrythmia, active abdominal aortic aneurysm > 4.5 cm, and/or on anticoagulation other than Aspirin-81 were also not offered SWL. Patients who ultimately decided to proceed with SWL were included in this study ($n = 487$). The study was approved by the IRB of the Henry Ford Health System (IRB number #12450).

SWL technique and follow-up

A Dornier Lithotripter SII System, which is an electromagnetic lithotripter, was used for SWL. A negative urinalysis or urine culture was mandatory in every patient before treatment. All procedures were performed on an outpatient basis and under intravenous anesthesia. Patients with renal or renal pelvic stones received 2500 [median (IQR): 2360 (2210–2750)] shocks to the afflicting stone while patients with proximal ureteral stones received 2500–3500 [median (IQR): 2780 (2100–2990)] shocks, under fluoroscopic and/or ultrasound guidance. An indwelling ureteral stent at the time of SWL was placed for a stone burden > 1.5 cm or bilateral urolithiasis. Patients with pre-SWL indwelling ureteral stent had received it for treatment of a prior acute renal colic episode. All patients were followed-up for 4–6 months from the date of surgery. A minimum follow-up of 3 months from the date of follow-up imaging was necessary to be included in the study. Patients with insufficient follow-up ($n = 49$) or those who required a surgical intervention prior to imaging (i.e. the time-interval from the SWL treatment but prior to imaging, $n = 21$) were excluded. Our final sample size consisted of 417 patients.

Covariates

For each patient, the following clinical parameters were noted: age, gender, body mass index, renal function, comorbidities, use of medications that commonly affect stone formation such as hydrochlorothiazide, furosemide and anti-epileptics, and whether the patient had a history of recurrent urinary tract infections. Stone and treatment characteristics collected included the treatment side, stone location (renal or proximal ureter), skin-to-stone distance, stone density in Hounsfield units on the CT scan, diameter of the largest/targeted stone, whether the patient received a ureteral stent during/before the procedure, and whether the patient received antibiotics during the procedure, and alpha-blockers at discharge.

The nature of follow-up imaging used was recorded and the patients were stratified according to it into two groups: Those undergoing KUB ($n = 360$) and those receiving ULD-CT ($n = 57$). The imaging type ordered was based on surgeons' discretion, however, the main factor ultimately governing the kind of imaging the patient underwent was insurance authorization, as an ULD-CT was requested in 196 patients, but it was approved in only 57 patients.

Endpoints

A patient was deemed stone-free if radiography, via KUB or ULD-CT, failed to identify a remaining stone or stone fragment at the site of treatment. The assessment was performed at 4–6 weeks after surgery by an attending radiologist. To assess whether follow-up imaging modality has an impact on further healthcare needs of these patients, co-primary endpoints comprising emergency department (ED) visits, unplanned ureteral stent procedures, and planned lithotripsy procedures (second SWL or ureteroscopy) were assessed. The former two outcomes were assessed in patients who were deemed stone-free, with the underlying rationale that if these patients were truly stone-free, they should not need any further care with regards to the treated stone. An unplanned ureteral stent procedure was defined as a need for ureteral stent on the treated side within 3 months of being deemed stone-free. Return to emergency room was defined as an ED visit related to genitourinary symptoms including hematuria, dysuria, flank pain on the treated side, fevers/chills or nausea/vomiting within 3 months of being deemed stone-free. The time frame of the assessment was limited to 3 months from follow-up imaging based on clinical practice patterns, and a prior study which suggested that beyond 3 months these patients can have a new renal colic episode [17]. The need for planned procedures was only assessed in patients that were not deemed stone-free. We performed this analysis to ascertain if patients undergoing ULD-CT were receiving disproportionally more secondary procedures "overtreatment" or not.

Charges for ULD-CT and KUB

For cost-effectiveness analysis, charge estimates were obtained via online search of publicly available government repositories, namely Centers for Medicare and Medicaid Service (CMS) reimbursement guide [8], Agency for care Research and Quality (AHRQ) emergency room services expenses [1] and online cost calculators (https://www.fairhealthconsumer.org/). The charges were estimated at: 1. ULD-CT, median 1191$ (range $38–$2000), 2. KUB, median 161$ (range $74–$208), 3. Median charges of a typical emergency room visit with imaging and labs: 1265$ + 1191$ + 55$ = 2511$, 4. Medicare reimbursement for the year 2018 for ureteroscopy: 3483$, and 5. Medicare reimbursement for the year 2018 for ureteral stent placement: 2541$.

Statistical analyses

Descriptive statistics of categorical variables focused on frequencies and proportions. Medians and interquartile ranges (IQR) were reported for continuously coded variables. Chi-squared and Mann–Whitney *U* tests were used to compare proportions and medians, respectively.

Parsimonious multivariable logistic regression analyses studied the impact of imaging modality on outcomes. The models adjusted only for the variables significant in the univariable analysis ($p < 0.05$) [6]. For cost-effectiveness analysis, a simple Markov decision-tree analysis was performed in order to determine the relative cost-effectiveness of ULD-CT versus KUB "pathway". Given a range of potential outcomes after the initial imaging including ED visits and unplanned or planned surgeries, along with the variances in associated rates and costs of each of these outcomes, the overall expected cost of each pathway could be determined for a specific set cost of the initial intervention. Different initial costs of ULD-CT and KUB were thus examined to analyze the differences in expected overall pathway costs. Three separate cost-average pathways (low-charge, intermediate-charge, and high-charge) were generated.

All statistical analyses were performed using the R statistical package (R Foundation for Statistical Computing, Vienna, Austria), considering a statistical significance at $p < 0.05$.

Results

Baseline characteristics

Of the 417 SWL patients studied, 57 (13.7%) underwent ULD-CT while the remaining 360 (86.3%) underwent KUB for follow-up imaging. Baseline characteristics of all patients, stratified by the type of follow-up imaging modality utilized, are detailed in Table 1. Compared to patients who underwent KUB, patients who underwent ULD-CT were more likely to have diabetes mellitus (38.6% vs 16.4%, $p < 0.001$), were more likely to be taking hydrochlorothiazide (19.3% vs 7.8%, $p = 0.006$), and were less likely to have antibiotics prescribed at the time

Table 1 Baseline characteristics in patients undergoing shock-wave lithotripsy for upper urinary tract calculi, stratified by the type of follow-up imaging modality utilized; $n=417$ patients (January 2013 to December 2016)

Patient characteristics	KUB group; $n=360$	ULD-CT group; $n=57$	p value
Age in year, median (IQR)	57 (45–61)	62 (44–72)	0.073
Females, n (%)	128 (35.6)	22 (38.6)	0.657
Body mass index in kg/m^2, median (IQR)	28.5 (26.5–31.7)	27.0 (25.2–36.3)	0.977
Preoperative creatinine in mg/dl, median (IQR)	1.03 (0.79–1.25)	0.73 (0.67–1.09)	0.922
Comorbidities, n (%)			
Diabetes mellitus	59 (16.4)	22 (38.6)	<0.001
Hypertension	167 (46.4)	33 (57.9)	0.106
Asthma	22 (6.1)	2 (3.5)	0.433
COPD	33 (9.2)	7 (12.3)	0.458
Coronary artery disease	47 (13.1)	4 (7.0)	0.196
Atrial fibrillation	2 (0.6)	1 (1.8)	0.320
Medications that affect stone formation, n (%)			
Hydrochlorothiazide	28 (7.8)	11 (19.3)	0.006
Furosemide	11 (3.1)	2 (3.5)	0.855
Anti-epileptics	0 (0)	0 (0)	0.999
History of recurrent UTIs, n (%)	42 (11.7)	2 (3.5)	0.062
Stone characteristics			
Treated side [right (remaining left)], n (%)	162 (45.0)	25 (43.9)	0.872
Stone location [renal (remaining proximal ureter)], n (%)	265 (73.6)	43 (75.4)	0.831
Multiple stones on the treated side, n (%)	37 (10.3)	4 (7.0)	0.442
Skin to stone distance in cm, median (IQR)	13.5 (10.7–14.6)	12.1 (10.7–12.9)	0.439
Stone density in Hounsfield units, median (IQR)	678.4 (574.1–908.2)	714.4 (554.3–971.2)	0.342
Diameter of largest/treated stone in mm, median (IQR)	8.0 (6–12.5)	7.0 (6.3–9.5)	0.413
Stent (in place or placed during the procedure), n (%)	165 (46.0)	20 (35.1)	0.125
Antibiotics used during the procedure, n (%)	312 (86.7)	35 (61.4)	<0.001
Alpha-blockers prescribed at discharge, n (%)	229 (63.6)	35 (61.4)	0.748

49 patients were lost to follow-up and were not included in the analysis

Of note, we could only assess the Hounsfield units for the stones for the patients that had a preoperative

CT [$n=281$ for the KUB group, and all patients ($n=57$) in the ULD-CT group had a preoperative CT]

KUB kidney ureter bladder X-ray (also called abdominal plain film), *ULD-CT* ultra-low dose computed tomography scan, *UTI* urinary tract infection, *IQR* interquartile range

of surgical procedure (61.4% vs 86.7%, $p<0.001$). Otherwise the groups were well-matched.

Stone-free rates and univariable outcomes

The stone-free rates were 63.2% ($n=36$ of 57) and 77.2% ($n=278$ of 360) in the ULD-CT and KUB groups, respectively ($p=0.019$; Fig. 1a).

A 5.6% ($n=2$ of 36) of the patients deemed stone-free on ULD-CT, and an 18% ($n=50$ of 278) of patients deemed stone-free on KUB returned to the ED within 3 months ($p=0.040$) (Fig. 1b). Similarly, 2.8% ($n=1$ of 36) of the patients in the ULD-CT group, compared to 15.1% ($n=42$ of 278) of patients in the KUB group needed an unplanned surgery ($p=0.027$) within 3 months of the follow-up imaging (Fig. 1b).

Of those patients deemed not stone-free, 19.0% ($n=4$ of 21) underwent a planned follow-up lithotripsy procedure in the ULD-CT group, compared to 14.6% ($n=12$ of 82) in the KUB group (Fig. 1c). This difference was not statistically significant, $p=0.418$.

Multivariable adjusted outcomes

Using ULD-CT for follow-up was associated with significantly reduced odds of ED visits and unplanned procedures in multivariable analyses, with odds ratios (OR) of 0.19

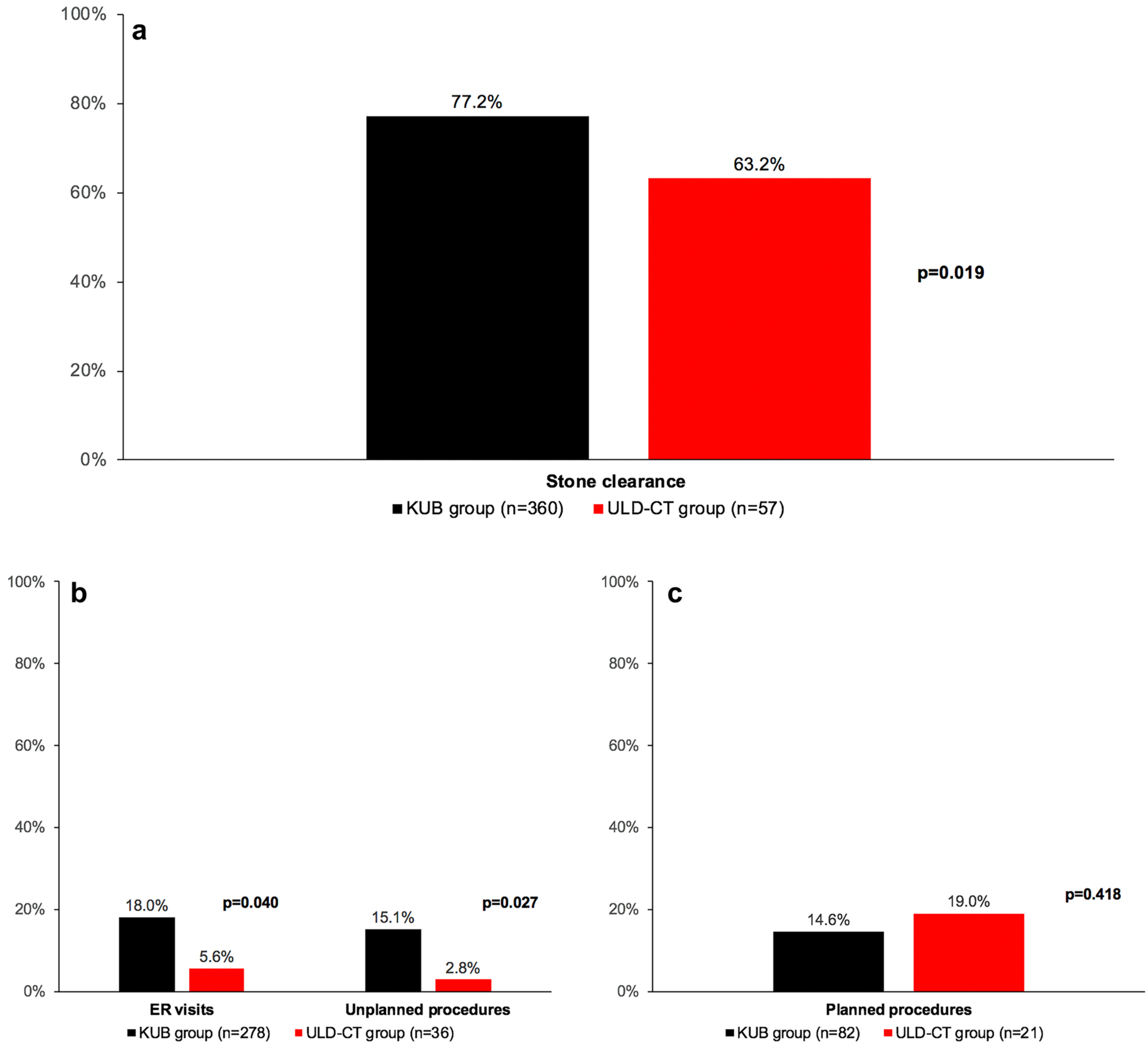


Fig. 1 Bar-plots depicting the stone-free rates **a**, the rates of emergency room (ER) visits and unplanned procedures among the patients that were deemed stone-free **b**, and the rate of planned procedures among the patients that were NOT deemed stone-free **c**—the study groups were ultra-low dose computed tomography (ULD-CT) and kidney ureter bladder X-ray (KUB)

(95% CI 0.04–0.92, $p=0.039$) and 0.10 (95% CI 0.01–0.79, $p=0.030$), respectively (Table 2A).

There were no differences in the odds of planned procedures in patients that were not deemed stone-free, OR 1.73 (95% CI 0.44–6.81, $p=0.434$; Table 2B).

Cost-effectiveness analysis

Significant variation was noted in online-reported ULD-CT charges ($382 to $2000). Comparatively, charges for KUB varied from $74 to $208. Figure 2 provides the details on the probabilities, and charges of each unplanned or planned encounter, and thereby the overall cost-effectiveness of the ULD-CT versus KUB pathway for a set initial intervention cost. At low ULD-CT ($382) and KUB ($74) charges, the ULD-CT follow-up pathway was economically more favorable, but with increasing ULD-CT charges, the KUB follow-up pathway superseded economically.

Table 2 (A) Multivariable adjusted odds of experiencing an unplanned emergency room visit or an unplanned surgery within 3 months in patients deemed stone-free after shock-wave lithotripsy via ultra-low dose computed tomography scan [reference: kidney ureter bladder X-ray (KUB)]; $n = 314$ patients (January 2013 to December 2016) (B) Multivariable adjusted odds of undergoing a planned surgery within 3 months in patients deemed to be NOT stone-free after shock-wave lithotripsy via ultra-low dose computed tomography scan [reference: kidney ureter bladder X-ray (KUB)]); $n = 103$ patients (January 2013 to December 2016)

Outcomes	ULD-CT vs KUB (ref.)		
	Odds	95% confidence interval	*p* value
(A)			
Unplanned emergency room visit	0.19	0.04–0.92	0.039
Unplanned surgery	0.10	0.01–0.79	0.030
(B)			
Planned surgery	1.73	0.44–6.81	0.434

The logistic regression models adjusted for all variable with $p < 0.05$ in univariable analysis—diabetes mellitus, Hydrochlorothiazide prescription and use of antibiotics during the procedure

KUB kidney ureter bladder X-ray (also called abdominal plain film), *ULD-CT* ultra-low dose computed tomography scan

Discussion

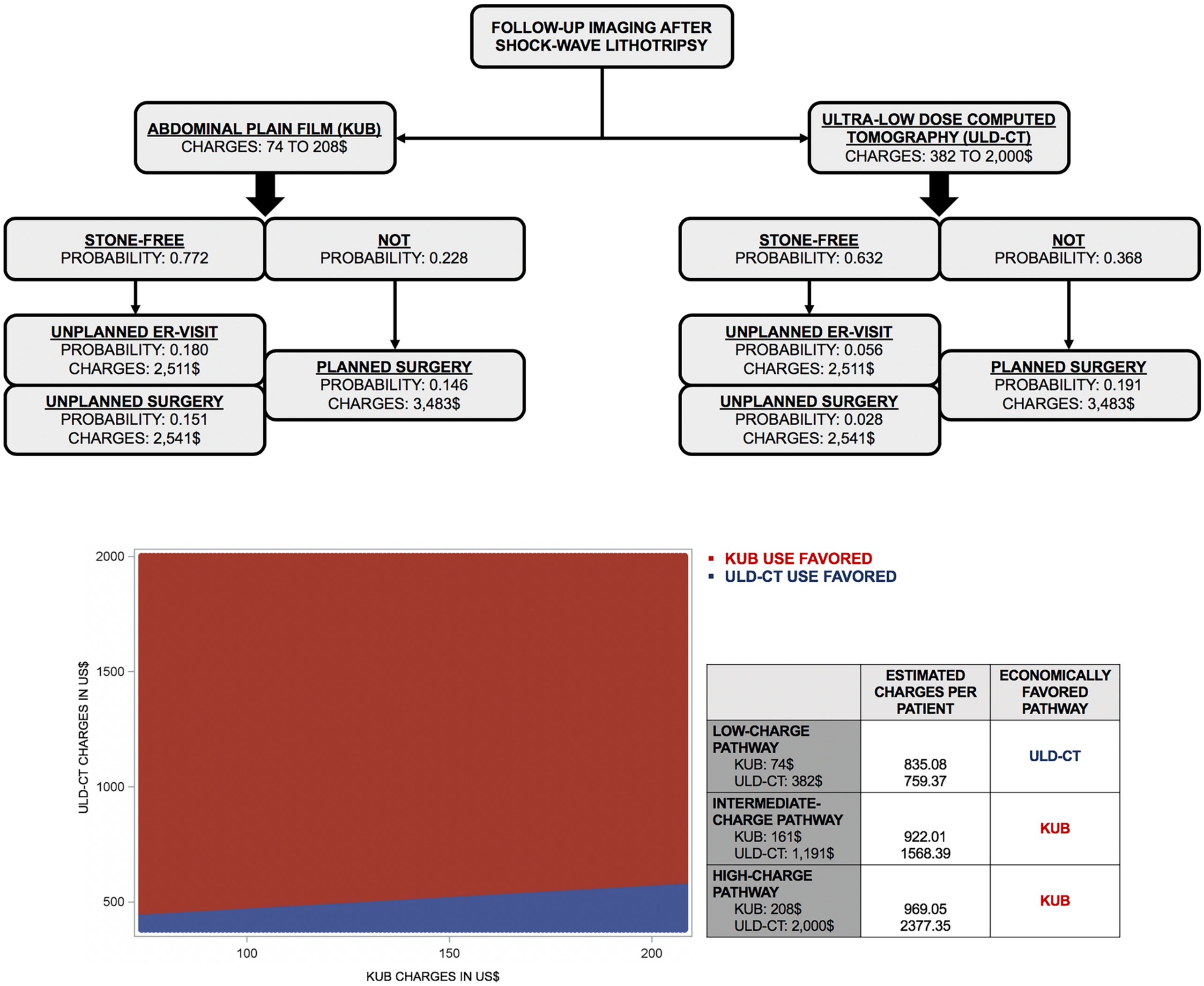
SWL accounts for roughly 40% [17] of the 125,000 ambulatory stone surgical procedures performed in the United States annually, see Tables 9–19 and 9–20 in the cited reference [11]. Follow-up assessment of the stone-free status in these patients has remained virtually unchanged for the past 20 years, despite extraordinary advances in imaging. We undertook this study to determine the benefits, if any, of utilizing ULD-CT, over KUB, in the follow-up of SWL treated patients.

The key finding of our study is the demonstration of the ULD-CT's ability in reducing the burden of post-imaging unplanned healthcare encounters in SWL patients. Specifically, we showed that the rates of ED visits within 3 months of the imaging assessment were 5.6% and 18.0% for the patients undergoing ULD-CT versus KUB ($p = 0.040$), respectively. Similarly, the rates of unplanned surgery in these patients were 2.8% and 15.1% ($p = 0.027$), respectively. It must be emphasized here that the assessment period for these outcomes was 3 months from the date of postoperative imaging, and not from surgery. Thus we did not capture any adverse events that may have occurred between the time of surgery and the time of postoperative imaging—this peculiarity of our study design throws into sharp relief the divide that exists in terms of adverse events between the two postoperative imaging pathways. These differences are likely due to the fact that patients undergoing ULD-CT are more accurately diagnosed with residual stone fragments versus not, and counseled and managed accordingly, avoiding false patient reassurance, untimely removal of ureteral stents, or halting of medical expulsive therapy. These data, to the best of our knowledge, have not been published before, and have important clinical implications.

From a patient care perspective, use of ULD-CT for follow-up is undeniably superior as it leads to reduced unplanned care encounters and procedural morbidity. It is equally important to look at these data from a healthcare-economic perspective. If ULD-CT was to be adopted widely, would it lessen the financial burden of the healthcare? The answer is yes and no. No, because in the present culture and at present costs for imaging, adoption of ULD-CT will only increase the financial toxicity. However, if reforms were made at the administrative health policy levels to curb and monotonize the costs of ULD-CT across hospitals, then the answer could be yes. In line with this, our Markov decision-tree analysis demonstrated that at low-charge for ULD-CT, this follow-up pathway was economically more superior to the KUB follow-up pathway. Efforts to promote utilization of ULD-CT following SWL is an actionable change, if sought after diligently by healthcare leaders and policy makers, and represents a pragmatic opportunity to both improve patient outcomes and deliver cost-effective care.

Our study also answers the question: what are the 'true' stone-free rates in patients undergoing SWL? We found that the stone-free rates in patients undergoing ULD-CT were lower, at 63.2%, versus 77.2% for the KUB group, which is not a surprising finding, given the known superior accuracy of ULD-CT in detection of renal and ureteral calculi, reported to be close to 95% [13, 16]. On the other hand, the diagnostic accuracy of a KUB is reported to be about 60% [7, 9]. Thus, the stone-free rates observed in the ULD-CT group are likely to be a closer estimation of the 'true' stone-free rates, and should be used when counseling patients regarding the efficacy of SWL.

Our study is not without limitations. First, it is retrospective in nature and thus limited by its inherent design. However, the data collected were mined from a high-fidelity electronic database, namely Epic, and there were no fields of interest (excepting evidence of abnormal renal anatomy) which had missing data for the patients eligible for the study. Second, the use of alpha-blockers, antibiotics and ureteral stenting prior to or during the SWL was not standardized. This is bound to affect outcomes, however, in general the providers followed the guidelines laid down by the American Urological Association [3, 4], as noted in the methods section. Third, only 57 out of the 417 patients underwent ULD-CT, leading to a rather small-sized experimental group. This was due to several reasons: (1) difficulty in obtaining insurance authorization for the ULD-CT imaging due to the paucity of data on this subject—it is difficult to bring about a change in 20 years of reimbursement and practice patterns



	ESTIMATED CHARGES PER PATIENT	ECONOMICALLY FAVORED PATHWAY
LOW-CHARGE PATHWAY KUB: 74$ ULD-CT: 382$	835.08 759.37	ULD-CT
INTERMEDIATE-CHARGE PATHWAY KUB: 161$ ULD-CT: 1,191$	922.01 1568.39	KUB
HIGH-CHARGE PATHWAY KUB: 208$ ULD-CT: 2,000$	969.05 2377.35	KUB

Fig. 2 A simple Markov decision-tree analysis evaluating the cost-effectiveness of the ULD-CT versus KUB pathway—the study groups were ultra-low dose computed tomography (ULD-CT) and kidney ureter bladder X-ray (KUB)

without substantial data, and (2) hesitancy on consultant radiologists' part to perform the ULD-CT due to reduced resolution of soft tissues and the associated risk of missing related pathologies and the medico-legal ramifications of such. Although the limited sample size in the current study is a limitation, it does speak to the timeliness and importance of undertaking this study for future patients. Fourth, 79 patients out of the 360 in the KUB study group did not undergo a preoperative CT scan. Hence, for these patients we were not able to calculate the skin-to-stone distance and stone density in Hounsfield units. In these cases, surrogate markers such as BMI and the ease of stone visibility on the KUB (a rough indicator of stone hardness) guided the clinician's judgment to enroll the patient for SWL. Lastly, it is possible that certain patients may have had complications but did not present to our institution for management, and thus the rate of adverse events post-imaging may be underestimated. This, however, we assume would affect both groups equally, and would not be an unequal source of bias on the study findings. Our study is the first of its kind and should be viewed as an exploratory study. It is often difficult to undertake prospective studies without preliminary data to support them (from retrospective studies). Our limitations listed here thus represent areas for improvement for a future prospective study.

Conclusions

In conclusion, ULD-CT provides a more 'true' estimate of stone-free status after SWL, and in consequence mitigates unwanted emergency and operating room visits. Further, at low ULD-CT costs, it may also be economically more favorable. Prospective studies are warranted to evaluate this question further, and if findings hold true, a health policy level change in curbing ULD-CT costs may be needed. The utilization of ULD-CT following SWL thus represents a unique opportunity to both improve patient outcomes and deliver cost-conscious care.

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Author contributions Literature: AS, PW, AB, JB, JK, CH, BE, RL, DAL. Study design: AS. Data collection: AS, CH, BE. Data analysis: AS, JK. Data interpretation: AS, DAL. Writing: AS, PW, AB, JB, JK, CH, BE, RL, DAL. Supervision: AS, DAL.

Availability of data and material Available on request.

Code availability Available on request.

Declarations

Conflict of interest None of the authors have any relevant disclosures, and none of the authors have any financial or non-financial interests that may be relevant to the submitted work.

Ethics approval (include appropriate approvals or waivers) The study was approved by the IRB of the Henry Ford Health System (IRB number #12450).

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