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Comparative Effectiveness of Shock Wave Lithotripsy and Ureteroscopy for Treating Patients with Kidney Stones

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Abstract

Context: Shock wave lithotripsy and ureteroscopy account for over 90% of procedural interventions for kidney stones, which affect 1 in 11 persons in the United States. Efficacy data for shock wave lithotripsy is over 20 years old. Advances in ureteroscopy, along with emerging evidence of reduced efficacy of modern lithotripters, has created uncertainty regarding the comparative effectiveness of these two treatment options.

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The institutional review board of the RAND Corporation determined that the study design was exempt from the requirement for review.

Objective: To compare the effectiveness of ureteroscopy and shock wave lithotripsy to remove or fragment urinary stones in a large private payer cohort.

Design, Setting, and Patients: We performed a retrospective cohort study of privately insured beneficiaries who had an emergency department visit for a kidney stone and subsequently underwent either shock wave lithotripsy or ureteroscopy. Using an instrumental variable approach to control for observed and unobserved differences between the two groups, we created a bivariate probit model to estimate the probability of repeat intervention following an initial procedure.

Main Outcome Measures: A second procedure (either shock wave lithotripsy or ureteroscopy) within 120 days of an initial intervention to fragment or remove a kidney stone.

Results: Following an acute care visit for a kidney stone, 25,914 (54%) underwent ureteroscopy and 21,937 (46%) underwent shock wave lithotripsy to fragment or remove the stone. After initial ureteroscopy, 4,852 (19%) of patients underwent an additional fragmentation or removal procedure, as compared with 5,186 (23.6%) of patients initially undergoing shock wave lithotripsy ($p < 0.001$). After adjusting for observed and unobserved variables, the estimated probability of repeat intervention was 11% following shock wave lithotripsy, and 0.3% following ureteroscopy.

Conclusions: Among privately insured beneficiaries requiring procedural intervention to remove a symptomatic stone, repeat intervention is more likely following shock wave lithotripsy. For the marginal patient, the probability of repeat intervention is substantially higher.

Introduction

Kidney stones impose a significant burden of disease in the United States. The prevalence of kidney stones has increased dramatically since 1976, a change which is likely driven by the obesity epidemic.[1,2] Stone disease now affects approximately 1 out of every 11 people, a prevalence similar to that of diabetes.[3] Up to 50% of stone formers will have a recurrence within 5 years.[4] Dietary and lifestyle factors contribute importantly to the risk of stone disease, and emerging physiologic data suggest that stone disease should be considered a metabolic disorder, punctuated by attacks of periodically formed, symptomatic kidney stones.

The costs to society of kidney stones are not insignificant. In terms of aggregate annual medical expenditures, kidney stones represent one of the most costly urologic conditions, with greater than $10 billion in expenditures in 2006 for treating patients with kidney stones.[5,6] Indirect costs, such as work loss and temporary disability, are also an important contribution to the disease burden, particularly as kidney stones impact a largely working age population.[7] Among the important cost drivers of kidney stone disease are procedural interventions to treat patients with symptomatic stones.

Fragmentation and removal of symptomatic stones relieves pain and prevents harm to renal function from chronic obstruction. Two dominant modalities exist for procedural intervention, namely shock wave lithotripsy (SWL) and ureteroscopy (URS). SWL is completely non-invasive, using high energy acoustic waves to fragment stones; URS is a minimally-invasive endoscopic technique that can access all parts of the ureter and renal collecting system, typically using a laser to fragment stones. Together, these two modalities represent over 90% of the procedures performed to remove renal and ureteral stones in the United States.[8] Both are considered first line options for the management of symptomatic stones, although SWL may be slightly less efficient than URS in published series.[9,10] More recently developed lithotripters appear to be less effective than the original HM3 device, which was used to generate most of the clinical trial data comparing ureteroscopy and SWL.[11,12] In addition, ureteroscopic technology has experienced important advances over the past decade.[13–15]

Reducing waste and avoiding retreatment are important levers in order to drive value in the provision of healthcare.[16,17] Prior analyses of clinical trial data suggest that one trade-off for the completely non-invasive nature of SWL is a greater need for retreatment.[9,10,18] In addition, claims data suggest that unadjusted retreatment rates for SWL can be up to triple that of ureteroscopy.[8] However, this analysis did not account for important clinical factors such as stone size, location, nor did it incorporate other potential confounders such as patient preferences.

Given that both technologies are well established, and only incrementally evolving, it is unlikely that new randomized clinical trials comparing the two will occur. In addition, creating a large registry of ureteroscopy and SWL procedures, along with data regarding patient preferences, in order to understand comparative effectiveness of these technologies would be time-consuming and expensive. Therefore, we performed an administrative claims-based analysis using econometric techniques to compare repeat interventions among patients initially treated with either SWL or ureteroscopy, and control for important unmeasured confounders such as stone size, location, and patient preferences. Use of appropriate econometric techniques, such as instrumental variable analysis, seeks to balance both observed and unobserved confounders among treatment groups, by using naturally occurring variation in observational data.[19–21] Through use of a bivariate probit model in a large cross-section of commercially-insured beneficiaries, we sought to compare the effectiveness of shock wave lithotripsy versus ureteroscopy in the treatment of patients with urinary stones.

Methods

Data Source

To identify patients who were likely to have a symptomatic stone, we used data from the Marketscan Commercial Claims and Encounters dataset to select beneficiaries with an emergency department or urgent care center clinical encounter (the ‘index encounter’) for a kidney or ureteral stone between 2003 and 2010. The Marketscan data includes encounter level health claims for clinical services and pharmacy claims. Although they are not nationally representative, these data represent a convenience sample of commercially insured beneficiaries in the United States. The institutional review board of the RAND Corporation determined that the study was exempt from the requirement for review.

Study Cohort

We further restricted our cohort of patients receiving emergent or urgent care to those who had no claim for any clinic visit or procedure for urinary stones within12 months prior to the index encounter, and who had at least 8 months of continuous enrollment following the index encounter. Finally, we limited our cohort to those beneficiaries who underwent ureteroscopy or shock wave lithotripsy within 4 months of the index encounter. These exclusion criteria resulted in a study sample of 47,851 patients who underwent treatment to remove or fragment a presumably symptomatic urinary stone.

Treatment Identification and Patient Covariates

We identified procedures for treating patients with kidney or ureteral stones using Common Procedural Terminology codes (eTable 11).[8] We created a binary treatment variable for shock wave lithotripsy or ureteroscopy.

Demographic characteristics for each patient were identified from Marketscan data. These included age and sex; patient race is not included in this dataset. Year of treatment was included in order to address secular trends in practice during the 9 year study period. Pre-existing co-morbid conditions were summarized by calculating the Charlson index using claims submitted within 365 days prior to the index encounter. Geographic variation in the epidemiology of stone disease exists, as well as variation in practice patterns. Therefore, we included census region as reported in the Marketscan data.

Outcome Measures

The primary outcome was a second procedure to remove or fragment stones within 120 days of the initial intervention. We elected a window of 120 days to capture potential second procedures performed outside the global period for these procedures.Either a second ureteroscopy or second shock wave lithotripsy was considered an outcome event, regardless of which initial procedure the patient underwent.

Statistical Analysis

We used the chi-square test and t-test, as appropriate, to compare patient-level covariates between procedures. The χ^2 test was also used to compare the proportion of patients undergoing a second procedure between SWL and ureteroscopy.

An important consideration in any observational analysis is the potential for estimation bias due to unmeasured variables that can confound the results, and therefore limit causal inference. In particular, if unobserved factors that affect the treatment decision also affect the outcomes, standard estimates of treatment effects might be biased. For example, the size and location of urinary stones are important determinants both of treatments (SWL versus ureteroscopy) and outcomes.[9] Thus, treatment effects may be biased by the lack of equivalence of the unobserved factors. Previous claims-based comparisons of SWL and ureteroscopy have failed to address this potential confounding.[8] We adopt an alternative approach in which we specify and estimate a simultaneous equations model that addresses this concern. Our approach, which is analogous to instrumental variable analysis, employs an econometric technique designed to balance the effect of both measured and unmeasured confounders among treatment groups,[19] and if specified correctly, allows for causal inference of treatment effects.

The validity of our approach is contingent upon the availability of instrumental variables that satisfy two conditions: (1) they are strongly correlated with treatment decisions, and (2) conditional on other observable factors, they are only related to the outcome (in our case, a second intervention to remove stones) through their influence on treatments.[19,21]

We identified three potential instruments for the analysis. We hypothesized that distance to a hospital with SWL versus ureteroscopy capability will influence patients' probability of receiving one of the treatment and that this is the only mechanism by which distance to hospital with SWL versus ureteroscopy capability will influence a second procedure within 120 days of the initial intervention. Similar distances have been used effectively in several other instrumental variable analyses.[20,22] We hypothesized that per capita density of urologists and surgeons would reflect both the availability of surgical services at the local area level, as well as the intensity of potential competition among providers, and that these factors would influence the probability of the patients receiving one of the treatments (eMethods, eTable2).

Given that the regression coefficients of probit models are not intuitive to interpret, we then calculated model-derived probabilities of repeat treatment for ease of interpretation. As a sensitivity analysis, we constructed separate models for patients treated from 2002 – 2005, and from 2006 – 2010. Statistical testing was 2-sided, with Type 1 error rate set at 5%. Analyses were performed using SAS version 9.2 and Stata version 11.0.

Results

The cohort included 47,851 subjects who underwent an initial procedure for fragmentation/ removal of a urinary stone. Among these subjects, 25,914 (54%) underwent ureteroscopy and 21,937 (46%) underwent shock wave lithotripsy as the first procedure. The subjects undergoing SWL were slightly older than those undergoing URS (Table 1). Females were more likely to undergo URS as the first procedure (41% vs. 38%, $p < 0.001$). Minor regional variation in the use of the two procedures existed. The majority of patients had a Charlson comorbidity score of 0.

Within 120 days of the initial procedure, approximately 1 in 5 subjects underwent an additional procedure to remove or fragment urinary stones (10,038/47,851; 21.0%). Those undergoing initial SWL were more likely to undergo a second procedure than those undergoing initial ureteroscopy (Table 2). The relative risk of a second procedure following SWL was approximately 25% higher than after URS (RR 1.26, $p<0.001$). On multivariable analysis ("naïve model"), differences in the proportion of subjects undergoing additional fragmentation or removal procedures persisted after adjusting for observable confounders such as age, sex and geographic region. Adjustment for these potential confounders did not substantively change the predicted probability of additional treatments (Table 2).

We then used a two-equation bivariate probit model to adjust for both observed and unobserved potential confounders. Likelihood ratio test of the two equation model demonstrated that the results were statistically significant (P <0.001). The two-equation model substantially reduced the predicted probability of additional treatments for both SWL and URS (Table 2). Controlling for observed and unobserved potential confounders, the predicted probability of an additional procedure for the marginal patient undergoing SWL was 11.0%. In contrast, again controlling for observed and unobserved potential confounders, the predicted probability of an additional procedure for the marginal patient undergoing URS was 0.3%.

Comment

In this novel analysis, we use an econometric approach to compare the effectiveness of shock wave lithotripsy and ureteroscopy. Our findings demonstrate that, on an unadjusted basis and after adjusting for observable potential confounders, the relative risk of an additional stone fragmentation or removal procedure is approximately 25% higher following SWL as compared with ureteroscopy. After using a bivariate probit model to address unobserved potential confounders (e.g., stone size), the probability of additional procedures decreases for both SWL and URS, but the marginal patient undergoing SWL is substantially more likely to experience an additional procedure to remove a previously treated stone, as compared with the same patient undergoing ureteroscopy.

The efficacy of SWL and ureteroscopy for fragmenting and removing urinary stones is well-established.[9,23] For ureteral stones, SWL and ureteroscopy both are considered first-line therapy.[9] However, for ureteral stones >10 mm in size, ureteroscopic fragmentation generally results in higher stone-free rates with fewer procedures.[9,24–26] For renal stones ≤ 10 mm, SWL and ureteroscopy have similar efficacy in clinical trials.[27]

In contrast to abundant efficacy data, the comparative effectiveness of SWL and ureteroscopy outside of controlled clinical trials is poorly documented. One claims-based cost analysis suggested that the mean number of procedures per patient is slightly higher for SWL (1.22 versus 1.12 for ureteroscopy).[7] Prior work from the Urologic Diseases in America project examined practice patterns for stone fragmentation and removal procedures among unselected Medicare beneficiaries.[8] In a longitudinal cohort, 38% of Medicare beneficiaries undergoing SWL had an additional stone fragmentation or removal procedure within 120 days, as compared with 12% of those undergoing ureteroscopy. Importantly, neither of these analyses adjusted for important covariates such as stone size and location, nor did they focus on patients with symptomatic stones, as opposed to patients potentially treated for incidentally detected stones.

Our findings suggest that, for the marginal patient with a symptomatic stone amenable to either SWL or ureteroscopy, first line treatment with shock wave lithotripsy would result in approximately 11% of patients undergoing an additional stone removal procedure. By comparison, the model results suggest that the same patient undergoing ureteroscopy faces less than a 1% chance of an additional stone removal procedure. Importantly, our analytic approach should control for both observable factors, such as patient sex, and factors that we could not observe in our analysis, such as patient obesity, the size and location of the targeted stone, or ureteral stent placement (Table 3). This approach strengthens the causal inference of our findings.[19]

The contrast between efficacy data and comparative effectiveness data for these technologies is noteworthy. Some of this difference could be due to evolving technical capabilities of the two procedures. Much of the efficacy data for SWL was generated using the original Dornier HM3 lithotripter. Newer lithotripter models have smaller focal zones and deliver shockwaves at faster rates, which is believed to *decrease* the efficiency of stone fragmentation.[11] At the same time, substantial technical progress has been made with endoscopic technology, which has improved the capability of ureteroscopy.[13–15] Technical limitations of modern lithotripters have stimulated intense interest in new, more efficient designs.[28,29] Our findings provide additional support for the importance of engineering research to improve the technical capabilities of SWL.

Our findings have important implications for counseling patients regarding treatment options. Kidney stones affect approximately 9% of the United States population,[1] and up to half of patients who develop a kidney stone will experience recurrence within 5 years.[4] Many of these patients will undergo procedures to fragment or remove stones. A substantial proportion of patients undergoing SWL will require a second procedure to fragment or remove stones. However, SWL may be preferred by some patients because it is a completely non-invasive procedure.[25] Given this tradeoff, physicians should formally assess patient-centered outcomes and preferences, and ideally develop a tool to facilitate shared decision-making for those patients who require procedural intervention.

These findings also have important policy implications regarding payment structures for healthcare delivery. Under the current fee-for-service structure, the intervention most likely to require additional treatments (SWL) is reimbursed at a higher rate than the technology most likely to remove a stone in a single session (ureteroscopy).[30] Even when surgeon fees are limited by a global payment period, substantial ancillary costs (i.e., anesthesia and facility payments) still pertain. This misaligned economic structure would seem to exacerbate the costs of treating patients with kidney stones. Not only are these costs growing rapidly, but kidney stones are one of the most costly urologic conditions from the perspective of aggregate healthcare expenditures.[5,6] Shifting towards a payment structure based on an episode of care would more closely align payer and provider incentives, and potentially reduce the overall costs of treating patients with kidney stones.

Our results should be considered in the context of several limitations. The study population was young, generally healthy and privately insured. Thus, our results may not generalize to older populations (e.g., Medicare) or others without private insurance. The claims-based nature of the analysis prevents direct examination of the influence of important clinical factors such as obesity, stone size and location. Similarly, we are unable to incorporate patient preferences for SWL or URS into our investigation. However, assuming that the instrumental variables function appropriately, our analytic approach should balance these and other unobserved confounders. Finally, the study findings pertain to the "marginal" patient, rather than the outcomes of treatment for the average patient. Clinical experience likely represents an average picture of patient outcomes. Thus, even when expressed as probability for repeat treatment, the findings may not be intuitive from a clinical perspective. Conceptually, patients undergoing either URS or SWL for stones comprise three groups: those who always undergo ureteroscopy (i.e., a 6 millimeter distal ureteral stone), those who always undergo SWL (i.e., a 10 millimeter intermittently symptomatic renal stone, treated by a specialist in SWL), and those who might undergo either procedure. Average outcome (e.g., clinical experience) likely represents the comparison of all patients undergoing URS versus all of those undergoing SWL. In contrast, the 'marginal patient' represents the comparison of only those subjects who might undergo either procedure.[31]

These limitations notwithstanding, our findings retain significant validity and have important policy implications. Observed differences in comparative effectiveness suggest that further exploration of additional outcomes (i.e., unplanned post-procedural care, complication rates, costs) will inform comparison of outcomes for these procedures. Formal assessment of patient preferences, incorporating potential trade-offs in the nature and outcomes of these procedures, could potentially reduce decisional conflict and improve patient satisfaction. Finally, efforts to improve the efficiency of modern lithotripters should continue to be supported.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Characteristics of Study Cohort

Characteristics	Ureteroscopy (N = 25914)	Shock Wave Lithotripsy (N = 21937)	*P* Value
Age (yrs, mean ± SD)	42.5 ± 11.8	43.5 ± 11.1	<0.001
Female, No. (%)	10715 (41)	8252 (38)	<0.001
Charlson Score, No. (%)			
0	23030 (89)	19520 (89)	
1	2430 (9)	2063 (9)	0.50
≥ 2	454 (2)	354 (2)	
Region, No. (%)			
Northeast	1427 (6)	1530 (7)	
North Central	8221 (32)	6048 (28)	<0.001
South	12993 (50)	11326 (52)	
West	3273 (13)	3032 (14)	
Year, No. (%)			
2003	1264 (5)	1127 (5)	
2004	1866 (7)	1674 (8)	
2005	2160 (8)	1931 (9)	
2006	2218 (9)	1937 (9)	<0.001
2007	3614 (14)	3179 (14)	
2008	4254 (16)	3665 (17)	
2009	5324 (21)	4335 (20)	
2010	5214 (20)	4089 (19)	

Table 2.

Estimated probability of second procedure, by adjustment method.

	Retreatment Probability (%, 95% CI)	
Effect	**SWL**	**URS**
Unadjusted	23.6 (23.1 – 24.2)	18.7 (18.3 – 19.2)
Naïve Model (adjust for observed confounders*)	23.64 (23.59 – 23.69)	18.72 (18.68 – 18.76)
Bivariate Probit Model (adjust for observed* and unobserved confounders)	11.0 (10.9 – 11.1)	0.327 (0.325 – 0.329)

*Adjusted for age, sex, Charlson score, region and year

Table 3.

Examples of observed and unobserved potential confounders of treatment outcomes for ureteroscopy or shock wave lithotripsy addressed using bivariate probit model.

Observed	Unobserved
Age	Race
Sex	Stone size/location
So-morbid conditions	Ureteral stent placement
Geographic region	Bilateral stone
	Patient preference