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## Comparison of Urologist- vs Gastroenterologist-Directed Extracorporeal Shock Wave Lithotripsy for Pancreaticolithiasis

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### Abstract

**BACKGROUND & AIMS:** Extracorporeal shock wave lithotripsy (ESWL) for pancreaticolithiasis is most commonly performed by urologists. We investigated the effects of transitioning from urologist- to gastroenterologist-directed ESWL on case complexity, process measures, and duct clearance.

**METHODS:** We performed a retrospective study of patients who underwent ESWL for pancreaticolithiasis from 2014 through 2019 at a single center. We collected demographic, clinical, radiographic, and procedural data in duplicate and compared case complexity and process measures between the periods the procedure was performed by urologists (January 2014 through February 2017; 18 patients; 0.47 patients/month) vs gastroenterologists (March 2017 through December 2019; 61 patients; 1.79 patients/month). We also compared data on pancreatic duct stone characteristics and technical success (duct clearance, determined by imaging analysis).

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#### Conflicts of interest

This author discloses the following: Norman Scott is employed by a company that provides extracorporeal shock wave lithotripsy services to hospitals across the country. The other authors disclose no conflicts.

**RESULTS:** There were no differences in patient demographics, comorbidities, pancreatic stone morphology, or time from referral to ESWL during the period the procedure was performed by urologists vs gastroenterologists. Patients received a higher mean number of ESWL shocks per session during the gastroenterology period (4341) than during the urology period (3117) ( $P < .001$ ). A higher proportion of patients underwent same-session endoscopic retrograde cholangiopancreatography during the gastroenterology time period (66%) than the urology time period (6%) ( $P < .001$ ). A higher proportion of patients had partial or complete duct clearance during the gastroenterology period (71%) than during the urology period (44%) ( $P = .04$ ). During the urology period, a higher proportion of patients were hospitalized following ESWL, although there was no difference in captured adverse events between the periods.

**CONCLUSIONS:** Transition from urologist- to gastroenterologist-directed ESWL did not affect case complexity or wait times for ESWL. However, the transition did result in increased procedure volume, more shocks per ESWL session, and improved duct clearance.

### Keywords

ERCP; Chronic Pancreatitis; Pancreatic Stone

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Obstruction of the pancreatic duct by a stone may result in ductal hypertension, which could lead to acute pancreatitis, debilitating pain, and other complications, such as pseudocyst formation.<sup>1</sup> Opioid pain medications are frequently used but do not directly address the underlying problem and have an unfavorable safety profile. Endoscopic retrograde cholangiopancreatography (ERCP) permits ductal decompression; however, pancreatic stones are often refractory to this approach because of their size and structural characteristics. Extracorporeal shock wave lithotripsy (ESWL) was initially developed to treat urinary tract stones but was co-opted in the late 1980s as a method of addressing pancreaticolithiasis.

ESWL uses externally generated, fluoroscopically targeted sonic waves to fragment stones into smaller pieces. On the basis of observational data, ESWL with or without ERCP is associated with significantly higher rates of duct clearance, decreased duct diameter, better pain control and quality of life, and less opiate use.<sup>2,3</sup> Furthermore, compared with ERCP alone, ESWL seems to be associated with a decreased rate of hospitalization for chronic pancreatitis.<sup>4</sup> Therefore, ESWL is guideline-recommended for clearance of main pancreatic duct stones larger than 5 mm.<sup>5</sup>

Because of familiarity with, and access to the technology, ESWL for pancreaticolithiasis is most commonly performed by urologists in the United States. However, gastroenterologists specialize in the treatment of chronic pancreatitis, are able to combine ESWL with ERCP if necessary, and have more experience managing pancreatic complications of the procedure. For these reasons, and to mitigate the logistical challenges of coordinating care across specialties, gastroenterologists at a small number of centers in the United States perform ESWL for pancreaticolithiasis. In early 2017, our institution transitioned from urologist- to gastroenterologist-directed ESWL. Hypothesizing an expanded and improved capacity to care for this patient population, we aimed to evaluate the impact of this transition on case complexity, important process measures related to ESWL, and duct clearance.

## Methods

### Design and Study Sample

This was a retrospective cohort study of all patients who underwent ESWL for pancreaticolithiasis at the Medical University of South Carolina (MUSC) from January 1, 2014 to December 31, 2019. The study was approved by our institutional review board. Although ESWL has been performed at MUSC since 2004, we restricted our analysis to the specified study period because significant personnel, documentation, and operational changes in the gastroenterology (GI)/pancreaticobiliary practice in 2014 and antecedent changes in ESWL practice would have confounded a more longitudinal comparison of outcomes. The prior ESWL experience at MUSC was previously reported.<sup>6</sup>

Patients were considered eligible if they underwent ESWL at MUSC for pancreaticolithiasis during the study period and had sufficient medical records to abstract >70% of prespecified data points. Study subjects were identified using internal patient registries maintained by the Department of Urology and Division of Gastroenterology and Hepatology. To ensure complete capture of potentially eligible patients, our institutional clinical data warehouse was queried using diagnosis and procedural codes for chronic pancreatitis, pancreaticolithiasis, and ESWL, but no additional subjects were identified.

All patients underwent ESWL by the same technician (NS) using the same electromagnetic lithotripter throughout the study period. All cases were performed under fluoroscopic guidance.

### Data Collection

Eligible patients' medical records were manually reviewed in independent fashion by 2 investigators (ILJ and KAB). Discrepancies in abstracted data between reviewers were resolved by consensus. Variables collected included: demographics; chronic pancreatitis disease characteristics (eg, etiology, duration); presence of diabetes mellitus; insulin dependence, opioid, anticoagulant, and antiplatelet medication use; number, size, and location of main pancreatic duct stones; prior endoscopic or surgical interventions; timing and number of ESWL sessions; number of shocks delivered during each session; number and timing of ERCP after initial ESWL; imaging findings after ESWL; hospitalization; and adverse events related to ESWL and ERCP.

### Study Outcomes

The outcomes of interest in this study pertained primarily to case complexity and process measures related to ESWL. We also explored pancreatic duct stone characteristics on follow-up imaging to assess technical success (ie, duct clearance). A rigorous analysis of clinical outcome measures was not considered feasible in this single-center, retrospective study because of the complexity of studying pain and other outcomes in this patient population, insurmountable confounding, and a small sample size.

Our main objectives were to determine: whether gastroenterologists were willing to take on more challenging ESWL cases than urologists, expressed as complexity of medical illness

and/or chronic pancreatitis stone burden; and whether gastroenterologist-directed ESWL resulted in improved care processes, expressed as higher throughput, shorter time between referral and ESWL, more shocks per session, shorter time between ESWL and ERCP, and less hospitalization. In an exploratory analysis, we compared technical success between the urology- and GI-directed periods. Secondary markers of duct clearance used to assess technical success in this study were: (1) reduced ductal dilation, (2) reduced size of largest stone, (3) new ability to advance a wire and stent past the site of previous obstruction, or (4) improved outflow of contrast from the pancreatic duct during pancreatogram.

### Statistical Analysis

For the analysis of our outcomes of interest, differences between the urology and GI periods were analyzed using the Student t test for continuous variables and the chi-square test for proportions, with a final 2-sided  $P < .05$  indicating statistical significance. Analyses were performed using the Stata version 12.0 statistical package (Stata Corp, College Station, TX).

All authors had access to the study data and reviewed and approved the final manuscript.

### Results

Over the study period, 79 patients underwent ESWL at MUSC. Eighteen patients were treated by the urology service between January 2014 and February 2017, whereas 61 patients were treated by the GI service between March 2017 and December 2019, amounting to 0.47 patients/month in the urology period versus 1.79 patients/month in the GI period. Three patients (16.7%) in the urology period underwent a second ESWL session compared with 6 patients (9.8%) in the GI period.

Patient and process characteristics are listed in Table 1. Sufficient medical records were available for all identified study subjects. One pediatric patient was included in the study sample. There were no differences between the 2 periods in: age, sex, Charlson Comorbidity Index, prior interventions, number of main pancreatic duct stones, and diameter of the largest stone. A larger proportion of patients in the urology period used opioid pain medications at the time of referral ( $P = .024$ ), perhaps reflecting secular trends in narcotic medication use.

Most patients in both groups underwent computed tomography scan (81% vs 67%, GI vs urology;  $P = .23$ ). Fewer patients in the GI period underwent magnetic resonance imaging (36% vs 67%, GI vs urology;  $P = .02$ ). Approximately one-half of patients in both groups underwent endoscopic ultrasound. In total, 16/61 patients (26%) in the GI period underwent both computed tomography and magnetic resonance imaging compared with 9/18 (50%) in the urology period ( $P = .06$ ). Most patients in both groups (89% urology vs 79% GI) underwent a prior ERCP; most of these patients had pancreatic sphincterotomy and attempted stent placement (83% urology 83% vs 73% GI) (Table 2). These differences were not statistically significant.

There was no difference in referral time to ESWL (41.3 days vs 49 days;  $P = .4$ ).

Patients in the GI period underwent a higher mean number of ESWL shocks per session (4341 vs 3117;  $P < .001$ ). In the exploratory analysis, more patients in the GI period experienced partial or complete duct clearance (71% vs 44%;  $P = .04$ ).

In the GI period, 66% of patients underwent ERCP immediately following ESWL during the same anesthesia session compared with 6% in the urology period ( $P < .001$ ). Ninety-four percent of patients in the urology period, by intent, came back for ERCP on a different day. More patients in the urology period were hospitalized after ESWL (100% vs 15%;  $P < .001$ ). This occurred because patients in the urology period were admitted for post-procedure observation by protocol.

The proportion of patients who were identified in follow-up to have experienced an adverse event requiring medical attention was similar between the 2 periods (urology, 16.7% vs 21.7%;  $P = .65$ ). The most common adverse events were pancreatitis (including 3 cases of post-ESWL alone pancreatitis) and pain requiring hospitalization. One patient in the GI-directed group developed cholangitis after ESWL alone.

## Discussion

Our institution was 1 of the first in the United States to adopt ESWL for pancreaticolithiasis. Although the early procedures were performed by a urologist, the program itself was the result of forward-thinking interdisciplinary collaboration that helped many patients and contributed to important discoveries in the field, representing a great example of cooperative progress. Following the lead of our international colleagues, more widespread adoption of ESWL by gastroenterologists in the United States seems logical and perhaps inevitable, but objective data on the benefits of such a transition are lacking.

Gastroenterologist-directed ESWL has several potential advantages that encouraged our practice to make the change. First, there are challenges associated with interdepartmental coordination of care between the 2 services that practice in 2 different physical locations at our institution, which might impede the timely delivery of treatment. A paper by Weigel et al<sup>7</sup> describes these logistical difficulties, in particular the coordination of efforts for multiple procedures among anesthesia, GI, and urology. Second, our anecdotal observation has been that urologists tend to use a more conservative approach to ESWL based on an increased risk of bleeding in the highly vascular genitourinary tract. Third, gastroenterologists' familiarity with the disease process and the capabilities and limitations of ERCP may allow a more tailored (and perhaps effective) ESWL approach. Fourth, familiarity with ERCP-related adverse events may allow more efficient rescue from serious ESWL-associated complications. Lastly, the ability to perform same-session intra-ESWL pancreatography (via ERCP or endoscopic ultrasound-guided injection) may allow improved targeting of radiolucent stones.

Considering that any perceived benefits must be balanced against the structural, logistical, and regulatory challenges of establishing an ESWL practice in the endoscopy unit, additional data are necessary to inform decisions about more widespread adoption of

GI-directed ESWL in the United States. Our experience at MUSC represents a unique opportunity to begin exploring the impact of such a transition.

We found that ESWL cases, in terms of medical complexity and disease burden, did not differ between periods. We had hypothesized that ESWL availability in the endoscopy unit would allow us to take on more challenging cases that would have previously been deemed ineligible for treatment (medical complexity) or prematurely referred for surgical drainage (disease burden); however, this was not our observation.

We found that the frequency with which ESWL is performed at our institution more than tripled as a result of the transition, allowing us to treat more patients that may have remained otherwise untreated, sent to other tertiary centers, or referred for surgery. We believe that several factors may have contributed to this growth in volume, including increased availability of ESWL (ie, more dedicated pancreatic ESWL sessions), a more efficient preprocedural care pathway (ie, no need to coordinate with another service), and perhaps an increased number of referrals (eg, from other regional academic centers) once it became known that ESWL was offered by our group. Although the increase in volume may be perceived favorably by patients and does bolster endoscopic volume (with its associated reputational and financial incentives), it is important to consider that 1 potential downside of ESWL availability is the overuse of endotherapy in patients who are more likely to benefit from definitive surgery, which is associated with superior long-term outcomes.<sup>8,9</sup> In these cases, repeated ERCPs, each with its attendant risks, increase resource use and may have a negative impact on eventual surgical candidacy and islet cell yield in the event of a total pancreatectomy with islet autotransplant. Ongoing research elucidating the patient characteristics that predict favorable endoscopic versus surgical outcomes will better inform decision-making in this area, which remains nuanced and largely influenced by patients' perception that the endoscopic approach is less invasive.

A major incentive for the transition to GI-directed ESWL was a projected reduction in procedure wait times; however, we did not observe a difference between the 2 periods because of increased case volume in the gastroenterologist-directed period. In principle, wait times could be reduced by increasing ESWL capacity; however, because we perform ESWL in an ERCP suite, this must be balanced against reduced ERCP capacity. Several centers in the United States perform ESWL in another area before moving the patient to endoscopy for ERCP; however, this requires significant coordination between the 2 procedure areas and anesthesia services. Additionally, performing ESWL in the ERCP suite permits the acquisition of a pancreatogram via standard ERCP or endoscopic ultrasound-guided injection, which we have found very helpful in the targeting of radiolucent stones in a handful of cases.

We did find that more shocks were delivered per ESWL session in the GI-directed period, which we attribute to urologists' adherence to protocols aimed to protect the more sensitive genitourinary system. In the exploratory analysis, we did observe increased duct clearance after ESWL in the GI period, although this finding should be interpreted cautiously because the criteria we used for technical success were somewhat subjective and adjudicated by authors who are gastroenterologists. This increased duct clearance may have been caused by



the higher number of shocks, although our study was not able to identify the exact reason for the improvement. Furthermore, patients were much more likely to undergo same-session ERCP in the gastroenterologist-directed period which may also explain why duct clearance was more likely on follow-up imaging in this group. We performed ERCP immediately following ESWL in most cases; however, data supporting this practice are lacking. Indeed, a randomized study suggested equivalent outcomes without concurrent ERCP, and this practice is endorsed by European professional society guidelines.<sup>5,10</sup> Additional multicenter studies on the optimal number of shocks (standardized to the potency of the ESWL generator) and the role of concurrent ERCP are needed.

We identified no major difference in adverse events between the 2 periods, but a significant reduction in post-procedure hospitalization when ESWL was directed by a gastroenterologist. Compared with our urology colleagues who routinely admitted ESWL patients for overnight observation, gastroenterologists had a higher level of comfort performing pancreaticobiliary interventions on an outpatient basis as is common practice for ERCP. This is an important benefit of GI-directed ESWL, and on the basis of our experience and that of others, centers that use urologist-directed ESWL should consider same-day discharge of uncomplicated cases.

The findings of this study must be interpreted in the context of several limitations. First, the sample size was small, limiting the precision of point estimates and our ability to detect anything but large differences between study groups. This limitation was exacerbated by missing data (<10% of data points) that reduced the functional sample size for a few of the end points. Second, the retrospective nature of the study in combination with small numbers made it impossible to address confounding and thus comparisons between study groups are not adjusted. Third, capture of adverse events was most likely incomplete because many patients present to local hospitals when they develop symptoms after ESWL or ERCP. Lastly, the study design and quality of data did not allow comparison of patient-centered outcomes, which are ultimately most important in defining the value of gastroenterologist-directed ESWL in clinical practice.

In conclusion, within the limitations of this observational study, a transition from urologist- to gastroenterologist-directed ESWL resulted in increased ESWL volume and fraction of same-day ERCP. It also resulted in the delivery of a higher number of shocks and possibly increased duct clearance without an increase in the complication rate. However, the impact of these findings on clinical outcomes remains unclear. The transition did not lead to a change in case complexity or a reduction in wait times, but did reduce the frequency of post-procedure hospitalization. These findings may help inform decision-making at other centers in the United States that are considering a transition to gastroenterologist-directed ESWL.

### Abbreviations used in this paper:

<b>ERCP</b>	endoscopic retrograde cholangiopancreatography
<b>ESWL</b>	extracorporeal shock wave lithotripsy

**GI** gastroenterology  
**MUSC** Medical University of South Carolina

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## What You Need to Know

### Background

Extracorporeal shock wave lithotripsy (ESWL) for pancreatic duct stones is most commonly performed by urologists. This study investigated the effects of transitioning from urologist- to gastroenterologist-directed ESWL on case complexity, process measures, and duct clearance.

### Findings

The transition to gastroenterologist-directed ESWL increased procedure. Patients who were treated by a gastroenterologist had more shocks per session and a higher percentage had same-session ERCP, but a lower percentage were hospitalized after the procedure. Duct clearance on follow-up imaging appeared to be more common after GI-directed ESWL.

### Implications for patient care

These findings, from a single center, may be informative to other institutions that are considering a transition to gastroenterologist-directed ESWL.

**Table 1.** Comparison of Cases and Process Measures Between Urologist- and Gastroenterologist-Directed ESWL

Variable	Urologist-directed	Gastroenterologist-directed	P value
Number of pts (rate)	18 (0.47/mo)	61 (1.79/mo)	
Mean patient age, <i>y</i> (SD)	58.6 (13.5)	57.6 (13.1)	.77
Female sex, <i>n</i> (%)	8 (44)	25 (41)	.79
Prior intervention, % of pts	89	80	.40
Charlson Index (SD)	2.61 (1.82)	3.26 (2.82)	.36
Opiate use, % of pts	78	46	.017
Mean number of pancreatic stones (SD)	1.78 (1)	1.75 (0.94)	.91
Mean diameter of largest stone, <i>mm</i> (SD)	9.4 (4.29)	11.6 (6.20)	.22
Time from referral to ESWL, <i>d</i> (SD)	41.3 (28.4)	49.0 (35.2)	.40
Mean shocks/session (SD)	3117 (567)	4341 (663)	<.001
Same day ESWL and ERCP, % of pts	5.6	65.6	<.001
Post-procedure hospitalization, % of pts	100	14.8	<.001
Captured adverse events, % of pts	16.7	21.7	.65

ERCP, endoscopic retrograde cholangiopancreatography; ESWL, extracorporeal shock wave lithotripsy; pts, patients; SD, standard deviation.

**Table 2.** Comparison of Prior Interventions Between Urologist- and Gastroenterologist-Directed ESWL

Intervention, n (% of pts)	Urologist-directed	Gastroenterologist-directed	P value
ERCP	16 (88.9)	51 (83.6)	.59
Sphincterotomy	15 (83.3)	44 (73.3)	.39
Stent placement	12 (66.7)	30 (49.1)	.19
Electrohydraulic lithotripsy	0	3 (4.9)	
Surgical procedure <sup>a</sup>	1 (5.6)	3 (4.9)	

ERCP, endoscopic retrograde cholangiopancreatography; ESWL, extracorporeal shock wave lithotripsy; pts, patients.

<sup>a</sup>Includes Whipple procedure and distal pancreatectomy.