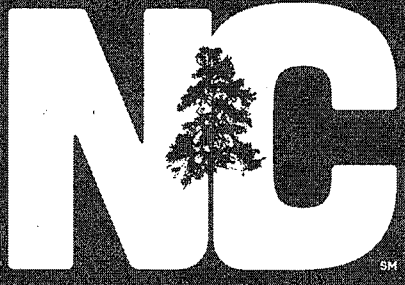
EXHIBIT A

2017

STATE HEALTH COORDINATING COUNCIL

PROPOSED STATE MEDICAL FACILITIES PLAN



Health Service Regulation
HEALTH AND HUMAN SERVICES

North Carolina Department of Health and Human Services
Division of Health Service Regulation

LITHOTRIPSY

Introduction
Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure with which this section will concern itself.

A lithotripter is a device that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient's abdomen and the shock waves are focused on the stone, which is shattered by the force.

A lithotripter's service area is the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state.

Lithotripter Utilization
Lithotripter utilization can be reasonably estimated by the incidence of urinary stone disease. Urinary stone disease, or urolithiasis, is a disease in which urinary tract stones or calculi are formed. The annual incidence of urinary stone disease is approximately 16 per 10,000 population[1]. Not all cases of urinary stone disease would be appropriately treated by lithotripsy. It has been estimated that 85 to 90 percent of kidney stone patients, when surgery is indicated, can be treated successfully by ESWL treatment. The annual treatment capacity of a lithotripter has been estimated to be 1,000 to 1,500 cases.

The number of lithotripsy procedures reported in North Carolina for the period of 2014-2015 was 10,019 procedures. There were 14 lithotripsy units operated by eight providers and one lithotripter approved in the 2016 State Medical Facilities Plan, but not yet operational. Procedures were provided by a fixed unit at one facility, and by 13 mobile units operated by seven providers. Given the 14 lithotripsy units, the average number of procedures per lithotripter for the 2014-2015 fiscal year is 716.

Access
Due to the mobility of lithotripter services, and the subsequent number of sites from which the service is provided, it may be concluded that geographic access is available to the maximum economically feasible extent.

Lithotripsy Need Determination Methodology
North Carolina uses a methodology based on the incidence of urinary stone disease. The need is linked to the estimate of urinary stone disease cases and is based on the assumption that 90 percent could be treated by ESWL.

The standard methodology used for determining need for lithotripters is calculated as follows:

Step 1: Divide the July 1, 2017 estimated population of the state, available from the North Carolina Office of State Budget and Management, by 10,000 and multiply the result by 16, which is the estimated incidence of urinary stone disease per 10,000 population.

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[1] Pahiri, J.J. & Razack, A.A. (2001) "Chapter 9: Nephrolithiasis". In Clinical Manual of Urology, by Philip M. Hanno, Alan J. Wein, S. Bruce Malkowicz. McGraw-Hill Professional Publisher.

Step 2: Multiply the result from Step 1 by 90 percent to get the number of patients in the state who have the potential to be treated by lithotripsy in one year.

Step 3: Divide the result of Step 2 by 1,000, which is the low range of the annual treatment capacity of a lithotripter, and round to the nearest whole number.

Step 4: Sum the number of existing lithotripters in the state, lithotripters not yet operational but for which a certificate of need has been awarded, and lithotripter need determinations from previous years for which a certificate of need has yet to be awarded.

Step 5: Subtract the result of Step 4 from the result of Step 3 to calculate the number of additional lithotripters needed in the state.

Lithotripsy Services in North Carolina

There are eight providers that offer lithotripsy services in North Carolina. On the following pages, Table 9A and Table 9B provide information on the number of procedures as well as the location of the facilities served by these eight providers.

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2015 data as reported on the "2016 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Carolina Lithotripsy, 9825 Spectrum Drive Bldg 3, Austin, TX 78717-2; Machines #1137 (11/15/2000); #01179 (12/15/2011)

Areas Generally Served: Eastern North Carolina

Facility and Location	*Procedures*
Cape Fear Valley Medical Center, Fayetteville, NC	143
CarolinaEast Medical Center, New Bern, NC	89
Carteret General Hospital, Morehead City, NC	40
Columbus Regional Healthcare, Whiteville, NC	18
Duke Raleigh Hospital, Raleigh, NC	3
Firsthealth Moore Regional Hospital, Pinehurst, NC	173
Firsthealth Richmond Memorial, Rockingham, NC	15
Halifax Regional Medical, Roanoake Rapids, NC	48
Johnston Health, Smithfield, NC	86
Lenoir Memorial Hospital, Kinston, NC	25
New Hanover Regional Medical Center, Wilmington, NC	189
Novant Brunswick Medical Center, Bolivia, NC	31
Onslow Memorial Hospital, Jacksonville, NC	7
Rex Hospital, Raleigh, NC	27
Rex Surgery Center of Cary, Cary, NC	65
Southeastern Regional Medical Center, Lumberton, NC	47
Vidant Beaufort Hospital, Washington, NC	37
Vidant Medical Center, Greenville, NC	142
WakeMed Raleigh Campus, Raleigh, NC	64
Wayne Memorial Hospital, Goldsboro, NC	23
Wilson Medical Center, Wilson, NC	34
Total Procedures:	**1,306**
Average Number of Procedures per Lithotripter	**653**

Provider: Catawba Valley Medical Center, 810 Fairgrove Church Road, SE, Hickory, NC 28602-2; Machines #1355 (11/2010); TC-2051 (03/2001)

Areas Generally Served: Western and Central North Carolina

Facility and Location	*Procedures*
Catawba Valley Medical Center, Hickory, NC	221
Frye Regional Medical Center, Hickory, NC	57
Rutherford Regional Medical Center, Rutherfordton, NC	62
Scotland Memorial Hospital, Laurinburg, NC	66
Total Procedures:	**406**
Average Number of Procedures per Lithotripter	**203**

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2015 data as reported on the "2016 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Fayetteville Lithotripters Limited Partnership-South Carolina II, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1; SID OR-197 (01/17/2011)

Areas Generally Served: Western North Carolina and South Carolina

Facility and Location	*Procedures*
Charles George VA Medical Ctr, Asheville, NC	30
Harris Regional Hospital, Sylva, NC	114
Haywood Regional Medical Center, Clyde, NC	143
Margaret R Pardee Memorial Hospital, Hendersonville, NC	80
Park Ridge Health, Hendersonville, NC	61
St. Luke's Hospital, Columbus, NC	10
The McDowell Hospital, Marion, NC	23
Transylvania Regional Hospital, Brevard, NC	34
Oconee Medical Center, Seneca, SC	63
Total Procedures:	**558**
Average Number of Procedures per Lithotripter	**558**

Provider: Fayetteville Lithotripters Limited Partnership-Virginia I, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1; SID OR-519 (11/9/2013)

Areas Generally Served: Eastern North Carolina and Virginia

Facility and Location	*Procedures*
Sentara Albemarle Medical Center, Elizabeth City, NC	33
The Outer Banks Hospital, Nags Head, NC	7
Vidant Chowan Hospital, Edenton, NC	32
Mary Immaculate Hospital, Newport News, VA	159
Mary Washington Hospital, Portsmouth, VA	3
Rappahannock General Hospital, Kilmarnock, VA	3
Riverside Doctors Surgical, Williamsburg, VA	3
Riverside Tappahannock Hospital, Tappahannock, VA	10
Southside Community Hospital, Farmville, VA	2
Southside Regional Medical Center, Petersburg, VA	9
Spotsylvania Regional Medical Center, Fredricksburg, VA	3
Total Procedures:	**264**
Average Number of Procedures per Lithotripter	**264**

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2015 data as reported on the "2016 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Piedmont Stone Center, PLLC, 1907 S Hawthorne Road, Winston-Salem, NC 27103-

Machines 4; 01138 (03/26/2002); 01175 (04/10/2003); 01171 (04/24/2003); 1925 (12/26/2006)

Areas Generally Served: Western and Central North Carolina and Virginia

Facility and Location	*Procedures*
Alamance Regional Medical Center, Burlington, NC	175
Annie Penn Hospital, Reidsville, NC	33
Carolinas HealthCare System-Blue Ridge, Valdese, NC	184
Davis Regional Medical Center, Statesville, NC	54
High Point Regional Health System, High Point, NC	417
Hugh Chatham Memorial Hospital, Elkin, NC	149
Iredell Memorial Hospital, Statesville, NC	118
Lexington Medical Center, Lexington, NC	50
Maria Parham Medical Center, Henderson, NC	64
Morehead Memorial Hospital, Eden, NC	217
Northern Hospital of Surry County, Mount Airy, NC	51
Novant Health Forsyth Medical Center, Winston-Salem, NC	98
Novant Health Rowan Medical Center, Salisbury, NC	220
Novant Health Thomasville Medical Center, Thomasville, NC	49
Piedmont Stone Center, Winston-Salem, NC	780
Randolph Hospital, Asheboro, NC	138
Wake Forest Baptist Medical Center, Winston-Salem, NC	81
Watauga Medical Center, Boone, NC	132
Wesley Long Hospital, Greensboro, NC	315
Wilkes Regional Medical Center, North Wilkesboro, NC	89
Yadkin Valley Community Hospital, Yadkinville, NC	20
Carilion New River Valley Medical Center, Christiansburg,, VA	19
Lynchburg General Hospital, Lynchburg, VA	251
Martha Jefferson Hospital, Charlottesville, VA	203
Memorial Hospital of Martinsville, Martinsville, VA	124
Montgomery Regional Hospital, Blacksburg, VA	26
Piedmont Day Surgery Center, Danville, VA	39
Twin County Regional Hospital, Galax, VA	84
Total Procedures:	**4,180**
Average Number of Procedures per Lithotripter	**1,045**

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2015 data as reported on the "2016 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Stone Institute of the Carolinas, LLC, 215 S Main Street, Suite 201, Davidson, NC 28036-

Machines 2; 2053 (10/2006); 1048 & 01384 (01/2001)

Areas Generally Served: Western and Central North Carolina

Facility and Location	*Procedures*
Carolinas HealthCare System - Cleveland, Shelby, NC	146
Carolinas HealthCare System - Huntersville, Huntersville, NC	112
Carolinas HealthCare System - Lincoln, Lincolnton, NC	59
Carolinas HealthCare System - Northeast, Concord, NC	238
Carolinas HealthCare System - Pineville, Charlotte, NC	199
Carolinas HealthCare System - Union, Monroe, NC	106
Carolinas HealthCare System - University, Charlotte, NC	225
Carolinas Medical Center, Charlotte, NC	123
Caromont Regional Medical Center, Gastonia, NC	160
Lake Norman Regional Medical Center, Mooresville, NC	155
Novant Health Matthews Medical Center, Matthews, NC	175
Novant Health Presbyterian Medical Center, Charlotte, NC	96
Piedmont Medical Center, Rock Hill, SC	195
Total Procedures:	**1,989**
Average Number of Procedures per Lithotripter	**995**

Provider: Triangle Lithotripsy Corp, 7003 Chadwick Dr #321, Brentwood, TN 37027-

Machines 1; 10142940 (04/01/2010)

Areas Generally Served: East Central North Carolina

Facility and Location	*Procedures*
Central Carolina Hospital, Sanford, NC	54
Durham Regional Hospital, Durham, NC	8
James E Davis Ambulatory Surgery, Durham, NC	60
Nash General Hospital, Rocky Mount, NC	122
North Carolina Specialty Hospital, Durham, NC	68
Rex Hospital, Raleigh, NC	219
Rex Surgery Center, Cary, NC	306
Sampson Regional Medical Center, Clinton, NC	7
WakeMed, Raleigh, NC	154
Wayne Memorial Hospital, Goldsboro, NC	59
Total Procedures:	**1,057**
Average Number of Procedures per Lithotripter	**1,057**

Total Mobile Procedures: **9,760**

Table 9B: Fixed Lithotripsy Providers and Locations Served

(From 2015 data as reported on the "2016 Hospital License Renewal Application")

Provider: Mission Hospital, Inc./Mission, 509 Biltmore Ave., Asheville, NC 28801

Machines: 1 08/2000

Area Served:

Facility and Location	*Procedures*
WNC Stone Center, Asheville, NC	259
Total Number of Procedures:	**259**
Average Number of Procedures per Lithotripter:	259

Table 9C: Mobile and Fixed Lithotripsy

(Total Procedures/Units Reported)

Total Procedures Reported	Units Reported	Average Procedures Per Unit
10,019	14	716

2016 Need Determination for one lithotripter brings the state total to 15.

Table 9D: Lithotripter Need Determination

(Proposed for Certificate of Need Review Commencing in 2017)

It is determined that the service areas listed in the table below need additional lithotripters as specified.

Lithotripters	Lithotripter Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
It is determined that there is no need for additional lithotripters anywhere else in the state and no other reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).

EXHIBIT B

Contemporary Surgical Trends in the Management of Upper Tract Calculi

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Abbreviations and Acronyms

ABU = American Board of Urology

PCNL = percutaneous nephrolithotomy

SWL = shock wave lithotripsy

URS = ureteroscopy

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Study received Northwestern University Feinberg School of Medicine institutional review board approval.

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For another article on a related topic see page 1030.

Purpose: Upper tract nephrolithiasis is a common surgical condition that is treated with multiple surgical techniques, including shock wave lithotripsy, ureteroscopy and percutaneous nephrolithotomy. We analyzed case logs submitted to the ABU by candidates for initial certification and recertification to help elucidate the trends in management of upper tract urinary calculi.

Materials and Methods: Annualized case logs from 2003 to 2012 were analyzed. We used logistic regression models to assess how surgeon specific attributes affected the way that upper tract stones were treated. Cases were identified by the CPT code of the corresponding procedure.

Results: A total of 6,620 urologists in 3 certification groups recorded case logs, including 2,275 for initial certification, 2,381 for first recertification and 1,964 for second recertification. A total of 441,162 procedures were logged, of which 54.2% were ureteroscopy, 41.3% were shock wave lithotripsy and 4.5% were percutaneous nephrolithotomy. From 2003 to 2013 there was an increase in ureteroscopy from 40.9% to 59.6% and a corresponding decrease in shock wave lithotripsy from 54% to 36.3%. For new urologists ureteroscopy increased from 47.6% to 70.9% of all stones cases logged and for senior clinicians ureteroscopy increased from 40% to 55%. Endourologists performed a significantly higher proportion of percutaneous nephrolithotomies than nonendourologists (10.6% vs 3.69%, $p < 0.0001$) and a significantly smaller proportion of shock wave lithotripsies (34.2% vs 42.2%, $p = 0.001$).

Conclusions: Junior and senior clinicians showed a dramatic adoption of endoscopic techniques. Treatment of upper tract calculi is an evolving field and provider specific attributes affect how these stones are treated.

Key Words: urolithiasis; physician's practice patterns; ureteroscopy; lithotripsy; nephrostomy, percutaneous

In the last 30 years the management of urinary tract stone disease has undergone tremendous changes prompted by the adoption of new technological and treatment advances.[1–4] In the current era open surgery has been almost entirely replaced by the minimally invasive techniques of URS, extracorporeal SWL and PCNL. As more treatment modalities become available to treat upper tract calculi, there is a corollary increase in the complexity of decision making in the management of these stones. Urologists are often faced with surgical scenarios in which several treatment modalities may be acceptable. Several studies

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have confirmed that there is considerable variation in the practice patterns of urologists today.[5–7] The advent of this increasingly complex clinical decision making led us to investigate contemporary surgical trends in upper tract stone management.

Beginning in 2003 the ABU initiated the practice of requiring detailed electronic surgical operative logs for all candidates at initial certification as well as at each subsequent recertification.[8] These case logs serve as a unique source of the documented clinical practices of American urologists. We used these ABU surgical case logs to determine the current practice patterns of upper tract calculi treatment of urologists in the United States.

MATERIALS AND METHODS

The ABU was started in 1934 to serve as a surgical specialty board to improve standards, promote competency and encourage education in the practice of urology. Urologists may be granted certification by the ABU by completing basic training, thereby demonstrating they have attained the level of knowledge and expertise required for the care of patients with urological disease. If certified before 1985, recertification is not mandatory but for all urologists certified after 1985 mandatory recertification must be performed every 10 years.

A significant portion of certification is the completion of surgical operative logs describing a consecutive 6-month period before application submission. These logs characterize patient demographics, including age and gender, and surgeon characteristics, including age, certification group and clinical practice location. In addition, surgeons report self-appointed subspecialization in 1 of 5 areas (endourology, oncology, pediatrics, andrology and female urology). Diagnoses are logged according to ICD-9 code and surgical procedures are coded using CPT codes.

We analyzed annualized case logs from 2003 to 2012 for trends and used logistic regression models to assess how surgeon specific attributes affected the treatment of upper tract stones. Cases were identified using CPT codes as the search criteria. They included SWL (50590), URS (52336—URS with removal of stone, 52337—URS with lithotripsy, 52352—cystourethroscopy with URS and/or pyeloscopy/with removal or manipulation of calculus and 52353—cystourethroscopy with URS and/or pyeloscopy, laser lithotripsy) and PCNL (50080—stone burden less than 2 cm and 50081—stone burden greater than 2 cm). The Northwestern University Feinberg School of Medicine institutional review board granted this study exempt status.

We determined trends in the surgical management of upper tract urinary calculi among urologists who submitted case logs for ABU certification. We hypothesized that younger urologists (candidates) would be more likely to manage stones endoscopically than older (recertifying) urologists. In addition, we hypothesized that surgeons who specialized in endourology would perform an increased number of PCNLs relative to nonendourologists. Finally, we assessed surgeon and practice characteristics associated with nephrolithiasis surgery. Results were considered statistically significant at 2-sided $\alpha < 0.05$. We used multivariate logistic regression when appropriate to evaluate surgeon factors and practice factors associated with nephrolithiasis surgery.

RESULTS

A total of 6,620 urologists recorded case logs during this 9-year period from 2003 to 2012. A total of 2,275 urologists with a mean age of 34 years comprised the candidate certification cohort. In the 2 recertification cohorts we identified 2,381 and 1,964 individuals with a mean age of 43 and 53 years, respectively.

A total of 441,162 total procedures for upper tract urinary calculi were performed, of which 54.2% were URS, 41.3% were SWL and 4.5% were PCNL (see table). We observed an overall increase in URS from 40.9% of all stone procedures in 2003 to 59.6% in 2012 (fig. 1). There was a corresponding decrease in SWL from 54% to 36.3%. PCNL remained stable, accounting for 4% to 5% of all surgeries during this period ($p = 0.81$, fig. 1). New urologists showed an increase in URS during this period from 47.6% to 70.9%, representing a 23% increase. More senior surgeons (those undergoing first or second recertification) similarly showed an increase in URS from 40% in 2003 to 55% in 2012, representing a 15% increase (fig. 2).

Figure 3 shows differences in treatment modality use by endourology specialists vs nonendourologists. Endourologists performed a significantly higher proportion of PCNL than nonendourologists (10.6% vs 3.69%, OR 2.87, $p < 0.0001$) and a significantly smaller proportion of SWL (34.2% vs 42.2%, OR 0.8102 $p = 0.001$).

Additional statistical analysis was done to assess differences in stone surgery based on clinical practice location as defined by state. Although the Southeast logged the highest number of total stone surgeries, there was no statistically significant difference in stone surgery type when stratified by the population of each region in the United States. Although small individual differences existed among states, a consistent trend was noted toward increased URS in each geographic region.

Procedures by cohort from 2003 to 2012

	No. SWL	No. PCNL	No. URS	Total No.
New certification	40,850	8,784	92,026	141,660
1st Recertification	76,074	6,730	84,650	167,454
2nd Recertification	66,534	3,396	62,118	132,048
Totals	183,458	18,910	238,794	441,162

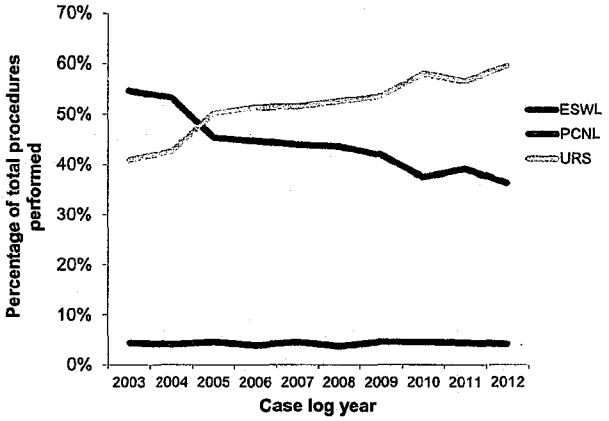

Figure 1. Change in stone treatment modality with time of all certifying urologists. *ESWL*, extracorporeal SWL.

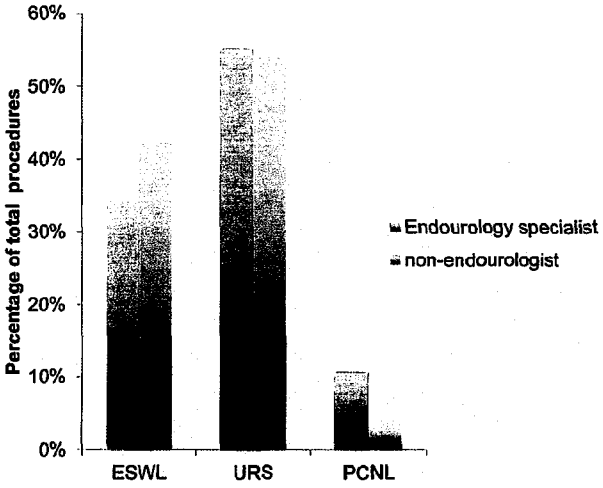

Figure 3. Treatment modality differences among specialists. Endourologists performed higher proportion of PCNL than nonendourologists (11% vs 3.7%, p <0.0001). *ESWL*, extracorporeal SWL.

DISCUSSION

Nephrolithiasis is a common and costly disease in the United States and its treatment remains a cornerstone of urology practice. Recent estimates demonstrate that approximately 9% of the adult American population is diagnosed with urolithiasis in a lifetime.[9] However, only a few randomized, controlled trials have been performed to determine the efficacy of the various treatment options for renal stones.[9,10] Because stone disease represents a tremendous health care burden, it is important to understand surgical practice patterns and how trends in surgical care are changing with time. Only a few studies have been done to examine the surgical trends of all 3 modalities for stone treatment.[4,11–13] Unfortunately most available studies are retrospective in nature and relied on limited national sampling databases or recall biased voluntary surveys. ABU case logs more accurately represent the practice patterns of all urologists in the United States. They avoid the referral bias of studies completed at academic institutions, which may be skewed toward more complex stone cases.[9] Since we used ABU data, our study relied on independently reviewed and approved certification case logs.

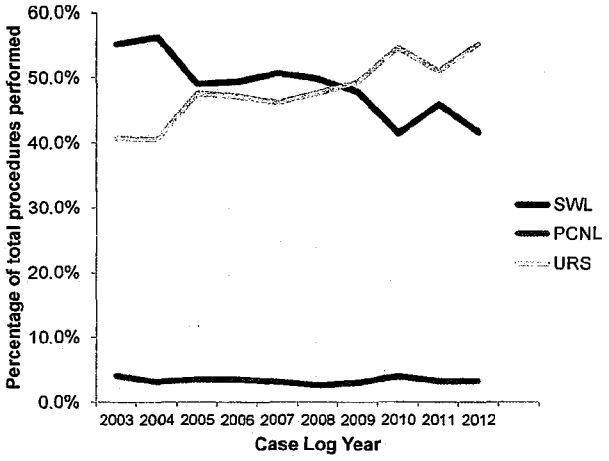

Figure 2. Change in treatment modality with time of senior urologists for first and second recertification.

Our findings demonstrate that the treatment of upper tract calculi continues to evolve and provider specific attributes continue to affect stone treatment. Our study confirms the findings of previous studies showing that younger urologists have adopted endoscopic techniques at a high frequency.[14] To our knowledge this is the first study to show that senior urologists are also adopting endoscopic techniques at a rapid pace and now perform URS at a higher frequency than SWL. It is now clear that junior and senior clinicians show a dramatic increase in the adoption of these endoscopic treatment modalities for upper tract stones with a subsequent decrease in SWL. This is in contrast to a number of previous studies in which SWL was the most commonly performed procedure and URS predominated only in the junior urologist cohort.[13,14]

Modern ureteroscopic technology is the product of the last 2 decades. This development has favored urologists in the initial certification cohort who trained more recently in endoscopic techniques. Interestingly it appears that the newer technology was adopted by all cohorts in our study. There are

several theories why surgeons of all generations now perform endoscopic procedures at increased frequency, including technological improvements resulting in decreased costs, and surgeon comfort and ease of use as well as improved surgical outcomes, such as stone-free and retreatment rates, compared to SWL.[15,16]

During the last 15 years there has been an increasingly widespread dispersion of technologies such as flexible URS, resulting in improved cost-effectiveness, which may account for the increased use.[17] For example, factors such as the improved durability of newer scopes[18] as well as the superior efficiency and cost-effectiveness of URS for stones up to and greater than 1 cm compared to SWL may partially account for these practice pattern changes.[19]

Furthermore, several studies confirmed higher URS surgical cure and stone-free rates compared to SWL, which might drive this change in adoption.[3–7] For example, Wu at el assessed the treatment of proximal ureteral stones and found a significantly improved stone-free rate after URS compared to SWL (92% vs 61%).[20] In addition, in a recent study Scales et al found that compared to SWL URS is associated with significantly fewer repeat treatments.[21] These findings confirm those of previous studies demonstrating that SWL has a 20% to 30% re-treatment rate and associated patient discomfort due to fragment passage.[21]

Despite the introduction of newer SWL technologies with modifications to improve SWL efficacy[22] we observed a decrease in SWL in our study. Is it possible that these newer machines have more potential problems than first generation devices, resulting in decreased use? Further research is needed to determine whether this preference for ureteroscopic techniques is due to the inferiority of SWL in completely treating the stone burden at a single session. Recent data on newer technologies, such as large focus shock wave sources, are promising since these methods may provide increased efficacy with minimal trauma.[22,23] Improved pulverization and fewer re-treatments using these newer technologies may lead to the resurgence of SWL.

PCNL use remained stable from 2003 to 2012. Although we have seen technological advances with improvements in stone fragmentation and decreased complications using PCNL,[4,24,25] it is likely that PCNL is being reserved for larger or complex stone burdens and its overall increased morbidity may limit any expanded application. Not surprisingly these cases are performed at a much higher rate by endourologists who specialize in stone surgery.

Our study is not without potential limitations. Because of the observational, prospectively collected nature of the data, we could not extrapolate causality to changes in treatment modality with time. There are numerous theories of why we see these patterns but those conclusions cannot be made from the data used in our study. Additional studies are needed to better test these hypotheses. Furthermore, because the case logs are limited to urologists who completed initial ABU certification after 1985, there is selection bias toward a younger overall population of urologists. It would be interesting to explore how the practice patterns of this older cohort differ from those of its younger counterparts. Furthermore, the ABU data set does not contain specific patient or stone data that could help elucidate possible referral biases or explain these practice patterns. Subspecialty designations are self-reported and do not reflect specific fellowship training.

As health care spending increases, it is imperative that we identify ways to improve the value of the care that we provide as urologists and understand the factors influencing treatment modality choices. We used case logs as a representation of the average work load of urologists and the ABU independently reviewed and approved the submitted logs. Although individual audits of the practice of each candidate are not feasible, the overall accuracy of the described data is strong. To date these data provide one of the most reliable representations of the work loads and practice patterns of urologists in the United States. Surgical practice patterns can be powerful data when accurately captured, and they have the potential to guide health care spending, work force estimations and clinical decision making.

CONCLUSIONS

Treatment of upper tract calculi remains an evolving field and provider specific attributes continue to affect stone treatment decisions. Our study of ABU surgical case log data provides strong evidence that URS has surpassed SWL as the primary treatment modality for upper tract stones for newly trained as well as senior urologists. PCNL continues to be performed in disproportionate numbers by those who specialize in endourology. The findings from this prospectively collected data cohort are observational in nature but provide the necessary tools to generate hypotheses. Given the current health care climate, there no doubt exists a pressing need for further illumination of the driving forces behind these trends.

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Extracorporeal Shockwave Lithotripsy Falling Out of Favor

Alicia Ault June 04, 2015

NEW ORLEANS — Extracorporeal shockwave lithotripsy, once the gold standard for removing smaller kidney stones, has fallen out of favor, in part because it might be less effective than ureteroscopy, but does that mean it should be taken out of commission altogether?

That question was debated by four experts — two pro and two con — during a special session here at the American Urological Association 2015 Annual Meeting.

Moderator Ralph Clayman, MD, from the University of California, Irvine, opened the debate by reporting that fewer graduating urologists are doing lithotripsy, and that more urologists recertifying for the first time than for the second time are choosing the procedure for stones (29% vs 50%).

Arguing for the retention of extracorporeal shockwave lithotripsy as an option was John Denstedt, MD, from the University of Western Ontario in London, Ontario, Canada.

It has been increasingly argued that lithotripsy does not break up stones reliably, retreatment rates are higher with lithotripsy than with endoscopic procedures, and lithotripsy costs too much.

"My argument is that patient selection is the key," Dr Denstedt explained. There are strategies to enhance the efficacy of lithotripsy and it is still the least invasive therapy. "If you look closely at the literature, patient preference, cost, and morbidity all favor extracorporeal shockwave lithotripsy," he pointed out.

Patients who are obese or who have large stones are better treated with ureteroscopy, he said. In fact, with ureteroscopy, stone-free rates in the distal ureter are greater. However, with lithotripsy, stone-free rates in the proximal ureter are 80%, which is as good as or better than with ureteroscopy, he argued.

Patient selection is the key.

A Cochrane review revealed higher complication rates for ureteroscopy, even though it produced higher stone-free rates (*Cochrane Database Syst Rev.* 2012;5:CD006029). Dr Denstedt said that 2% to 6% of patients will experience perforation, evulsion, or mucosal entry, and that other studies have pointed to problems with the introduction of the urethral access sheath and the placing of stents. "We all know this is a huge problem for the patients," he said.

Low Complication Rate

The lower complication rate makes lithotripsy the preferred choice of many patients. Adding to this is the fact that clinicians skilled in ureteroscopy might be harder to find, Dr Denstedt explained.

Lithotripsy still has a place, said founding director of the International Kidney Stone Institute, James Lingeman, MD, from Indiana University in Indianapolis, who joined Dr Denstedt on the pro side of the debate.

"We don't break up stones with shockwave as we did 25 years ago," he said. "But we can maximize the effectiveness of extracorporeal shockwave lithotripsy by focusing on proper patient selection and the technique of shockwave."

To ensure effectiveness, Dr Lingeman uses what he calls a "triple D score," which takes into consideration skin-to-stone distance, stone density, and stone volume and size. "By choosing wisely, you can get very good stone clearance with shockwave lithotripsy," he explained.

Clinicians should take their time with the procedure, he said, noting that with the dry lithotripters, breaking a stone causes a cloud. If you don't wait for that cloud to dissipate, it can block the succeeding wave, he added.

New types of lithotripters — like the burst wave machine — might improve results, but in the meantime, although lithotripters are less efficient, they still work for the majority of stones, he said. "The type of lithotripter might not be as important as the shockwave technique you use," he added.

Arguing against the retention of extracorporeal shockwave lithotripsy was Olivier Traxer, MD, from University Pierre et Marie Curie in Paris.

Time to Move On

Even though lithotripters have been evolving since they were introduced in the early 1980s, "the stone-free rate in 2015 is the same" as it was 30 years ago, he said.

Over the same period of time, there have been dramatic advances in endourology, including in visualization, laser technology, and miniaturization. As a result, "in many, many centers all around the world, endourology is slowly replacing shockwave lithotripsy," Dr Traxer reported.

The European Urology Association issued new guidelines this year that recommend ureteroscopy for most stones, although lithotripsy is considered the first choice for small stones in the proximal ureter, he said.

"Shockwave lithotripsy is slowly dying," Dr Traxer said. "If shockwave lithotripsy technology doesn't improve in terms of stone treatment," he noted, "it will be completely retired very soon and replaced with endourology."

The technologic advances in endoscopic equipment have made lithotripsy practically obsolete, said Glenn Preminger, MD, from Duke University in Durham, North Carolina, adding his voice to the con side of the debate.

He cited the reasons he thinks lithotripsy should be retired. With lithotripsy, the stone-free rate depends on stone size and the procedure is reliant on renal anatomy for effective stone elimination. In contrast, endoscopy has a lower retreatment rate and is more cost-effective, and ureteroscopy no longer requires a stent for placement.

"Shockwave lithotripsy is a lot like sex; it might feel good and it might be a lot of fun, but is it right?" said Dr Preminger, who was quoting another clinician.

Dr Clayman explained that he does not view lithotripsy as an either/or proposition.

Currently, about 30% of procedures involve extracorporeal shockwave lithotripsy, down from 70%. That could decline further, he said, although that might not be the right thing.

"The future is going to be very much dependent upon the reinvention of shockwave lithotripsy and the training of our future urologists," Dr Clayman said.

Dr Clayman reports that he has an investment interest in Applied Urology, and financial relationships with Boston Scientific, Cook Urological, Greenwald Inc., and Complete Orthopedic Services. Dr Denstedt reports that he is an owner of Cook Urology and is involved in product development, and that he has a leadership and publishing position with the Endourological Society. Dr Lingeman reports that he is an owner of Beck Analytical Laboratories and is involved in product development; is a consultant or advisor to Boston Scientific Corporation and Lumenis; has an investment interest in Midstate Mobile Lithotripsy and is involved in product development; and is involved in a trial with Richard Wolf Instruments. Dr Traxer has disclosed no relevant financial relationships. Dr Preminger reports that he is a consultant or advisor to Boston Scientific and Retrophin; a meeting participant for Olympus; a leader of the Endourological Society; and is involved in health publishing with UpToDate.

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Ureteroscopy now used more than shock wave lithotripsy for treating kidney stones

Increase in hospital re-admissions, ER visits observed over 20-year period

June 01, 2012
By Wayne Kuznar

Atlanta—Ureteroscopy has overtaken extracorporeal shock wave lithotripsy (ESWL) as the treatment of choice for kidney stones, Canadian researchers recently reported.

At the same time, the need for ancillary treatments has declined but morbidity associated with kidney stone treatment has increased, said first author Michael Ordon, MD, who presented his findings at the 2012 AUA annual meeting in Atlanta.

Population-based evaluations to accurately assess trends over time in the use of different treatment modalities in the management of kidney stones have not been previously conducted. Instead, physician surveys or series from single centers have been the predominant methods used to document an increase in the use of ureteroscopy.

Studies showing high success rates, low rates of retreatment, and low rates of complications with modern ureteroscopy have largely been completed at high-volume centers with vast technical expertise.

"Accordingly, guidelines have changed to recognize ureteroscopy as a first-line treatment option along with ESWL for ureteral stones at all levels," said Dr. Ordon, fellow in endourology and minimally invasive surgery at St. Michael's Hospital, University of Toronto.

Many centers, however, may lack the up-to-date equipment and technical expertise necessary to achieve these same excellent results, said Dr. Ordon, who worked on the study with Kenneth T. Pace, MD, and colleagues.

His group sought to evaluate population-based trends in kidney stone management as well as the effects of treatment trends and technologic advances on patient morbidity in the "real world," including the need for ancillary treatment. Through the use of administrative databases, the authors designed a population-based cross-sectional time series to measure the utilization of ESWL, ureteroscopy, and percutaneous nephrolithotomy (PCNL) over the past 20 years on patients in Ontario.

All patients who underwent treatment for a kidney stone in Ontario between July 1, 1991 and Dec. 31, 2010 formed the study population. Three main data sources were used: the Ontario Health Insurance Plan's physician claims database, the Canadian Institute for Health Information-Discharge Abstract Database, and the National Ambulatory Care Reporting System.

The three principal outcomes were treatment utilization, the need for ancillary treatment (defined as a repeat or ancillary stone procedure within 90 days of the index treatment), and the proportion of treatments that required hospital readmission or emergency room (ER) visit within 7 days of hospital discharge.

The study sample included 116,115 patients who underwent 194,781 kidney stone treatments (ESWL: 96,807 treatments; ureteroscopy: 83,923 treatments; PCNL: 14,051 treatments).

The use of ESWL decreased significantly over the study period, from 68.5% of all stone procedures in 1991 to 33.7% by the end of the period ($p<.0001$). During the same time, the proportion of stones treated with ureteroscopy increased significantly, from 24.6% to 59.5% of procedures ($p=.0002$). There was no significant change over time in the proportion of kidney stones treated with PCNL (6.88% in 1991 vs. 6.85% in 2010).

The proportion of procedures that required ancillary treatments declined significantly, from 23.1% to 15.3% ($p<.0001$).

"Most of this decrease occurred after 2004," said Dr. Ordon, when ureteroscopy became the most widely used procedure for the treatment of kidney stones in Ontario.

Of the three treatment modalities, the need for ancillary treatment was lowest with ureteroscopy.

Sharp increase in hospital readmissions

Overall, the rate of hospital readmission increased significantly over the study period, from 7.27% to 10.8% ($p<.0001$), with this increase occurring mainly after 2004. Similarly, the percentage of ER visits increased significantly, from 7.11% to 10.5% ($p=.0024$). Further analysis is planned to better evaluate the increase in hospital admissions and ER visits over time. Specifically, Dr. Ordon said, "We plan to separate ER visits for non-urologic versus urologic causes to see if it changes the findings."

"Part of the influence over time [in Ontario] is that ureteroscopy became much more accessible, and so now a lot of the physicians in the community may not be offering [referral for] shock wave lithotripsy but rather offering ureteroscopy because that is something that they can provide and be reimbursed for," he said.

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Ureteroscopy and stones: Current status and future expectations

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Abstract

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Urolithaisis is becoming an ever increasing urological, nephrological and primary care problem. With a lifetime prevalence approaching 10% and increasing morbidity due to stone disease, the role of ureteroscopy and stone removal is becoming more important. We discuss the current status of stone disease and review the ever increasing role that ureteroscopy has to play in its management. We discuss technological advances that have been made in stone management and give you an overview of when, how and why ureteroscopy is the most common treatment option for stone management. We touch on the role of robotic ureteroscopy and the future of ureteroscopy in the next 10 years.

Keywords: Ureteroscopy, Techniques, Ureteral stones, Calculi, Treatment, Advances

Core tip: This manuscript demonstrates the advent, technical progression and modern use of ureteroscopy for stone disease. It begins with a brief epidemiology of renal stone disease, technological advances in flexible ureteroscope, use of laser for stone disease and the different types of surgical options available. We also share the current evidence of ureteroscopy for stone treatment in obesity, pregnancy, pediatrics and patients with bleeding diathesis and large renal stones. In the end we discuss what the future holds for ureteroscopy including an insight into robotic ureteroscopy.

INTRODUCTION

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With an increasingly ageing population, rising obesity, poor dietary habits and lack of adequate fluid intake we are seeing a rise in the incidence of renal and ureteric calculi[1-9]. This directly effects patient morbidity and places an ever increasing demand on healthcare resources. The concept of urinary stones is not new, indeed "cutting for the stone" was one of the classic three operations described more than 2000 years ago. It is somewhat ironic now, that endourological surgeons rarely "cut for the stone", but more "fish out" the stone with ureteroscopy (URS). Without doubt, the technological advances over the last 30 years has revolutionised our current management of urinary tract stone disease. We aim to highlight the importance of stone disease and take you through the important technological changes, discuss current concepts in stone management, explain what is new in ureteroscopy and touch on the future of ureteroscopy in the management of stone disease.

EPIDEMIOLOGY OF STONE DISEASE

Urolithiasis is a major clinical and economic burden for modern healthcare systems[10]. International epidemiological data suggest that the prevalence of stone disease is increasing[11]; with a rise in lifetime prevalence between 7%-12%. The mean age of patients with upper tract stones has remained constant at 49 years, although there has been an alarming increase of 19% in the number of children diagnosed[11]. The ever increasing prevalence of stone disease has a direct effect on healthcare resources, with the number of URS performed for stone disease increasing by 127% over the last 10 year period 2000-2010[11].

The rising prevalence of stone disease is multifactorial, but poor dietary habits and fluid intake, increasing levels of obesity and "metabolic syndrome" may further increase stone-related clinical episodes[12,13]. This emphasises the importance of education and lifestyle adaptations in attempting to prevent stone formation for at risk groups and the critical role of secondary prevention for those who have already suffered with stones.

TECHNOLOGICAL ADVANCES IN URETEROSCOPY

Go to:

The use of URS has dramatically increased over the last 30 years mainly due to the rapid speed of technological advances. Since the advent of the first recorded URS in 1912[14]; the past century has seen a continued development of the ureteroscope alongside diversification of its use. Evaluation of the urinary tract was initially explored with specula, next came urethroscopy with dilatations of the urethra using knives and wax instruments [15]. The prototype endoscope, the "Lichtleiter", was introduced back in 1806 by Phillip Bozzini, and consisted of a hollow tube transmitting candlelight *via* a mirror[15]. This enabled the first true endoscopic operation in 1853 when Desormeaux extracted a urethral papilloma through the endoscope[15]. Further modifications to the endoscope were introduced by the dermatologist Grunfield of Vienna, who developed an endoscopic loop threader and scissor forceps allowing the first endoscopic bladder papilloma excision in 1881. The step from idea to realisation of endoscopic surgery was difficult and protracted. Bozzini et al ideas from the early 1800's were well ahead of their time. They were considerably hindered by the technical capabilities of the nineteenth century engineering, which resulted in clumsy and heavy instruments. In parallel with the development of the cystoscope there was continuing advancements in the endoscopic light source. A system of mirrors and lens' were introduced alongside candlelight to transmit light through a hollow tube; this idea was superseded by fibre-optic technology utilising the principle of internal reflection permitting the "bending" of light within flexible glass[16]. These principle and understanding lead onto the development of the first rigid ureteroscope in 1980. This was developed by Perez-Castro in collaboration with Karl Storz, incorporating a separate working and optic channel. These developments allowed the art of ureteroscopy to flourish and develop over the last 35 years[17].

The development of electrohydraulic and ultrasonic lithotripsy soon followed, enabling the fragmentation of ureteric stones[17]. Flexible tip ureteroscopes were introduced in 1983[16], and the modern digital scopes soon followed. Modern digital flexible ureteroscopes consists of a fiberoptic lens, with a single cable electronically transferring the image detected at the tip of a scope to the image display on a monitor ("Chip to tip" technology). Digital and conventional (fibre-optic) flexible ureteroscopes have seen a dramatic improvement in ergonomics, with lighter scopes and improved manoeuvrability[18]. The advent of digital images has resulted in improved resolution and colour discrimination, as well as significantly reduced operative times[16,19-21]. Figure 1 demonstrates the modern flexible ureterorenoscopes that we use in clinical practice today.

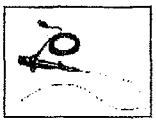

Figure 1
Flexible ureterorenoscope.

Despite improvements in scope technology, one still needs to fragment and/or remove the stone once visualised. Stones are commonly fragmented with a holmium laser (Light Amplification by Stimulated Emission of Radiation). Albert Einstein and Satyendranath Bose proposed the concept of lasers, but lasers were initially seen as a great invention with no obvious use. With time and hard work by laser pioneers, we now cannot imagine a

world in which we don't use lasers. Indeed, the role of the Holmium laser in the management of renal tract stones has resulted in many stones in the urinary tract have been accessible to treatment in a minimally invasive fashion. Laser offers the surgeon a safe, effective method of stone fragmentation. One real benefit is the fact that laser can be manoeuvred around bends, enabling it to be used throughout the kidney. The lithotripter, although a useful adjuvant for ureteroscopy, has its limitations including stone retropulsion back into the kidney. The lithotripter is still commonly used for percutaneous nephrolithotomy surgery (PCNL), where larger stones can be fragmented quickly, without the need to manoeuvre around each calyx.

SURGICAL MANAGEMENT OF STONE DISEASE

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Traditionally ureteric and renal stones were managed by open surgical techniques, and it was not until the 1980s and the advent of the Dormier H3 lithotriptor that shock wave lithotripsy (SWL) became common place[16]. SWL offered a relatively minimally invasive treatment option for patients, with acceptable outcomes in terms of stone free rates (SFR)[22]. With the advent of minimally invasive surgery, particularly URS, SWL treatment numbers are falling. Recent United Kingdom, American and Australian data clearly demonstrate dramatically rising rates of ureteroscopy, which far exceed small rises in the use of SWL[1,11,23].

Current American and European Urology Association Stone guidelines summarise the current evidence based treatment for stone management based on stone size and location[24]. The size and location of the stone are the most important factors in determining which treatment options are most suitable, but individual surgeon's treatment preference is important in making treatment decisions for each treated stone.

The position of the stone in the ureter directly reflects in the success of the procedure. More distal stone have higher success rates when treated with rigid ureteroscopy, compared to the more proximal stones[24]. Indeed proximal stones can fall back into the kidney, therefore they often require a concurrent flexible ureteroscopy to achieve good stone free rates. Current guidelines recommend ureteroscopy, over other treatments including SWL, for the majority of ureteric stones[24].

In terms of stone size conservative management may be appropriate for smaller stones; 95% of stones up to 4 mm pass within 40 d[25]. Current recommendations advise the use of PCNL over URS and laser for larger more complex stones. The recommended size of stone treated by URS is increasing with each new update of stone guidelines, with the current size value of 20 mm and above favouring a percutaneous approach to treatment (PCNL)[24]. Despite this there is very good clinical evidence[26] for using URS for stones greater than 20 mm in size, with 94% deemed stone free after a mean number of 1.6 URS treatments. This data is comparable, and arguably better, than standard PCNL treatment with reduced morbidity and shorter length of hospital stay[27].

Stones greater than 2 cm often require planned two stage URS procedures to achieve complete stone clearance [28]. Although this necessitates staged procedures, it may be a worthwhile sacrifice in view of nephron preservation and the low complication rate[29]. This is not an insignificant consideration when treating an ever-increasing co-morbid patient. A comparison of the available treatment modalities, in terms of advantages, disadvantages and contraindications is summarised in Table 1.

Table 1
Advantages and disadvantages of different techniques[24]

URETEROSCOPY IN THE CURRENT ERA

Go to:

Technological advances in the design and size of the ureteroscopes has enabled easier access to the kidney and ureters *via* the urethra, removing the need for any surgical incision. With rigid and flexible URS nearly all areas in the urinary tract can be readily accessed, with stunning high quality digital optics providing very accurate assessment of stones and mucosal lesions. One of the main benefits of URS is that there are minimal contra-

indications for the procedure. A general anaesthetic is often required, but upper tract access with spinal or local anaesthetic can be achieved[30]. The only real contraindication would be a ureteric stricture preventing successful ureteric access and scope passage[24]. Fluoroscopy is required during URS, but radiation exposure can be reduced with careful consideration of when and how much fluoroscopy is needed. The benefits of URS are clearly evident in the literature, with low complication rates, high SFR, and short length of stay[26,28].

As with any procedure complications can happen, but the reported complication rates are relatively low[29,31]. The overall complication rate for URS is approximately 3.5%; which are mostly minor. Probably the most feared complication of ureteroscopy is ureteral avulsion, however it is rare (< 1%). Common complication include mucosal or ureteric injury (1.5%-1.7%), post-operative fever (1.8%), urosepsis, haematuria, ureteral stricture (0.1%) and persistent vesicoureteric reflux (0.1%)[29,32]. Due to its minimally invasive nature, URS can be performed as a day case procedure. This has obvious benefits for hospital finances, as well as patient satisfaction levels[11].

In recent years the role of URS has expanded, particularly with reference to an increasingly obese population, during pregnancy, bleeding diathesis and paediatric stone disease. With obesity rates at an all-time high[12,13] and the association of kidney stones in such patients, these groups can often be difficult to manage. The anaesthetic risk can be significantly increased and other treatment such as SWL or PCNL are often less successful [33]. Ureteroscopy is often ideal for such patients, as their renal tract can be readily be accessed[34]. Indeed, currently guidelines recommend URS as the most promising therapeutic option in obese patients[24].

Pregnancy offers a unique situation in terms of urinary stones disease. A cascade of metabolic changes occurs during pregnancy that may be associated with an increased likelihood of stone formation, particularly in the second and third trimester[35,36]. Whenever possible, conservative treatment of stones are encouraged. If complications do develop, URS can offer a minimally invasive treatment option for patients and hopefully avoid the need for long term urinary diversion with either a stent or nephrostomy tube[37,38]. A recent systematic review suggests that URS is a safe and effective procedure that can be used as the first line surgical management of symptomatic stones during pregnancy[36].

Patient with bleeding diathesis are at significantly increased risk of complications with treatments including SWL, PCNL, laparoscopic or open surgery[39-42]. For such patients, URS offers a safe and effective treatment modality. With ever increasing use of anticoagulation, based on risk assessment, these patients are an at-risk group and can be very difficult to manage surgically[24,43]. In term of URS and anticoagulation the literature is limited. A critical analysis of the published literature has shown good SFR with minimal complications when performing URS whilst the patient remains on anticoagulation. One worries about the rate of bleeding, but the combined data on URS reports a relatively low figure of 4% minor bleeding whilst on anticoagulation[44].

Childhood urolithiasis is becoming more prevalent, with a significant number of patients experiencing their first stone episode in childhood[24]. Such patients present diagnostic and treatment dilemmas, particularly their suitability for treatment due to their organ size. Traditionally the majority of these patients were treated with SWL, with reported SFR of approximately 80%[45]. With smaller calibre scopes and improved scope instrumentation such as smaller baskets and laser fibres, the role for URS has slowly increased. A recent systematic review has demonstrated SFR of up to 93% can be achieved with URS in a paediatric population[45].

FUTURE ADVANCES IN URETEROSCOPY

Go to:

The future of URS is one of massive technological advances. With ever decreasing scope size, better optics and new device coming to market no corner of the urinary tract is inaccessible or unsuitable for access with URS. Ever more complex patients, with a plethora of medical problem are now becoming increasingly appropriate for URS.

Robotic surgery has recently entered the field of urology, particularly with reference to prostate, bladder and renal cancer treatment. URS has also had the robotic treatment, with the introduction of robotic flexible ureteroscopy.

This "Robot" offers the surgeon the ability to control their flexible ureteroscope and laser fibre via the comfort of a robotic console. Figure 2 demonstrates this robotic device. The main robotic station holds the flexible ureteroscope whilst the surgeon controls the URS via a console and joystick devices. With only a few prototypes in clinical use and the procedure in its infancy this is a large area for future clinical development. Initial results are interesting; with the biggest benefit seeming to favour surgeon ergonomics rather than SFR[46]. Long term outcome data is awaited with anticipation.

Figure 2
Robotic ureteroscopy.

Another area of future interest is the use of peptide-coated iron oxide-based microparticles[47]. These microparticles selectively adhere to calcium stone fragments enabling quicker retrieval of intraoperative stone fragments with the aid of a magnetic device, when compared to standard stone removal[47]. URS is without doubt an attractive area for technical innovation; where new advances have a huge potential to improve outcome and SFR.

CONCLUSION

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With an ever-increasing prevalence of stone disease careful consideration needs to be given to meet future demand. A large area of attention needs to be placed on primary and secondary stone prevention, with simple but effective patient education and lifestyle interventions.

In terms of URS, the future is one of great excitement. Larger stones, more complex patients, paediatric patients, pregnancy, bleeding diathesis and the obese are becoming more suitable than ever for minimally invasive URS. With the advent of future technological advances, the boundaries of what is achievable will be further expanded. Robotic is entering the playing field and is potentially the next big development in URS. The next 10 years is one of great excitement in URS and is likely to further transform of our current treatment strategies for the management of stone disease.

Footnotes

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Ureteroscopic treatment of renal calculi

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The evolution of renal calculus treatment has developed from the most invasive form of stone removal, including open nephrolithotomy, to those forms that optimize stone removal while minimizing patient morbidity. Extracorporeal shock-wave lithotripsy (ESWL) has revolutionized the treatment of renal calculi, although decreased stone-free rates are tolerated because of its minimal morbidity. ESWL is currently the most common treatment for renal stones, with average stone-free rates for solitary stones of 79.9%, 64.1%, and 53.7% for stones less than 1 cm, 1 to 2 cm, and greater than 2 cm, respectively [1]. Advances in percutaneous nephrostolithotomy (PCNL) have evolved to where stone-free rates of more than 90% can be expected, regardless of stone size or location [2]. Although the risks of PCNL are minimal compared with those in early studies, significant risks are inherent to percutaneous renal access [3]. The role of ureteroscopy (URS) in the management of renal calculi is evolving. This article reviews the indications, technique, results, and complications of using URS to treat renal calculi.

History

The evolution of URS in the treatment of renal calculi parallels advances in flexible endoscope design, development of the holmium laser for intracorporeal lithotripsy, and recognition of limitations of ESWL and PCNL. The production of flexible ureteroscopes with active deflection and small caliber was instrumental in enabling access to the entire collecting system [4–6]. Access to the entire collecting system with modern flexible ureteroscopes and techniques can be expected in up to 94% to 100% of patients [4,7].

Concomitant with the evolution of the ureteroscope, developments in intracorporeal lithotripsy and nitinol instrumentation further facilitated use of URS for renal stones. Small-caliber electrohydraulic lithotripsy (EHL) probes and flexible laser fibers optimized scope deflection, facilitating access to all calyces. The introduction of the holmium laser for intracorporeal lithotripsy was crucial to urologists' ability to ureteroscopically treat renal calculi. Unlike EHL, which destroys stones with a cavitation bubble, the holmium laser works through a photothermal mechanism [8]. Holmium laser energy is rapidly absorbed by water and has minimal tissue effects if activated with the laser fiber tip more than 2 to 3 mm away. These qualities allow extended periods of stone destruction, result in minimal tissue trauma, and maintain optimal endoscopic vision. Furthermore, unlike EHL, difficulties with endoscopic vision typically are not the result of urothelial trauma and bleeding but related to a "snow storm" effect caused by the production of tiny stone fragments.

Ureteroscopic treatment of renal calculi is also gaining popularity because of the recognition of limitations of ESWL and PCNL. Although ESWL is associated with minimal morbidity, its effectiveness is marginal in the treatment of certain stone compositions and stones in locations of the kidney, such as the lower pole. In addition, although more cost-effective than the original Dornier HM3 lithotriptor, modern-day lithotriptors are universally less effective and associated with higher retreatment rates [9]. Although renal stones are efficiently treated with PCNL, percutaneous renal access exposes patients to risks of blood transfusion, partial renal loss, and required inpatient hospital stay. URS avoids the

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risk of transrenal access and can safely be performed on an outpatient basis in more than 95% of patients [7].

Indications for ureteroscopic treatment of renal stones

Several factors influence treatment options for patients with renal stones. These factors include physician preference and experience, patient preference, patient and renal anatomy, stone characteristics, and equipment availability. These factors may preclude the use of PCNL or ESWL. Furthermore, there are specific indications favoring the ureteroscopic approach. Box 1 lists the most common indications to treat patients with renal stones ureteroscopically:

Failed extracorporeal shock-wave lithotripsy

The success of ESWL to treat renal stones ranges from 39% to 92% and varies with stone size, location, composition, and collecting system anatomy. It is now well recognized that treatment of lower pole stones is associated with a higher incidence of retained stone fragments compared to stones treated in other areas of the kidney. Lower calyceal anatomy also influences spontaneous stone passage following ESWL. Elbahnasy et al [10] demonstrated anatomic factors associated with poor stone clearance rates. Stones located in lower pole calyces with an infundibulopelvic angle less than 70°, infundibular length greater than 3 cm, and width less than 5 mm were at greater risk for retained fragments following ESWL. Retained stone fragments were especially common in patients possessing all three poor prognostic variables. Grasso and Ficazzola [11] evaluated the impact of lower calyceal anatomy on their ability to treat lower pole stones ureteroscopically. A long lower pole infundibulum (> 3 cm) and the presence of an infundibular stricture were the only statistically significant anatomic factors affecting success. Patients exhibiting anatomic factors associated with poor ESWL success may be better served with ureteroscopic stone manipulation.

Box 1. Indications for ureteroscopic treatment of renal calculi

ESWL failure
Lower pole stone location
Adverse stone characteristics for ESWL
Morbid obesity
Musculoskeletal deformities
Bleeding diathesis
Calyceal diverticular stone
Infundibular stenosis
Horseshoe/ectopic kidney
Ureteroscopy in conjunction with PCNL
Patient preference

Stone characteristics

Stone fragility and radiographic visibility are also factors influencing ESWL efficacy. Cystine and calcium oxalate monohydrate stones, which are refractory to ESWL, might preferentially be treated ureteroscopically. The holmium laser is universally effective in fragmenting all stone types. In addition, radiolucent stones that may be difficult to localize for ESWL may be more definitively treated with URS.

Patient obesity

The treatment of obese patients who have an upper urinary tract stone is challenging, even in the best of circumstances. Ureteroscopic laser lithotripsy provides the best combination of an effective yet minimally procedure to treat renal stones in obese patients. Obese patients with a body mass index greater than 28 have been shown to have inferior success rates with ESWL [12]. Factors making ESWL difficult in obese patients include the following: patient weight exceeding lithotriptor table limits, the treatment distances exceeding focal lengths of lithotriptors, and difficulty imaging stones because of body habitus thickness. PCNL to remove renal calculi in obese patients is feasible but should be reserved for centers with experienced personnel who have access to specialized equipment. Pearle et al [13] showed that, with modifications in PCNL technique and by using longer nephroscopes and working sheaths, success rates and morbidity were comparable to an unselected patient population. There are few special requirements necessary to perform URS on an obese patient (Fig. 1). The limiting factors include having an anesthesiologist capable of providing anesthesia and an operating table able to sustain the weight of the patient. URS is performed with standard equipment. The size of the patient and lack of an optimal operating table often preclude use of fluoroscopy. Dash et al [14] reported an 83% success rate using URS to treat 16 morbidly obese patients who had renal stones.

Fig. 1. A 450-lb patient positioned for ureteroscopic lithotripsy of renal stone.

Scoliosis/body deformities

Patients who have physical deformities other than obesity also may favor the ureteroscopic approach to remove kidney stones. This situation applies most commonly to patients with severe spinal deformities from spina bifida or limb contractures from spinal cord injury. Positioning difficulties caused by these abnormalities may preclude either PCNL or ESWL, making a ureteroscopic approach preferable. Fig. 2 shows an example of a patient with a body deformity that prevents stone localization by ESWL or percutaneous renal access for PCNL. She was successfully treated with ureteroscopic laser lithotripsy.

Bleeding diatheses

Ureteroscopic lithotripsy has been found to be safe in patients with uncorrected bleeding diatheses and patients who are anticoagulated [15]. Watterson et al [15] performed ureteroscopic lithotripsy in 25 patients who had bleeding diatheses or were on coumadin with a mean international normalized ratio of 2.3. Their stone-free rate was 96%, with a single complication. One patient treated with ureteroscopic EHL developed a significant retroperitoneal hemorrhage requiring transfusion. ESWL and PCNL require complete reversal of anticoagulation, which may carry a significant risk.

Associated collecting system obstruction

Patients who have renal stones associated with collecting system obstruction are also candidates for ureteroscopic treatment. This situation applies to those patients with stones contained within calyceal diverticula and calyces with stenotic infundibulae. ESWL of calyceal diverticular stones is associated with relatively poor long-term symptom-free and stone-free rates. Although percutaneous endoscopic removal of diverticular stones provides success rates greater than 80%, accessing small diverticulae in the upper pole or anterior calyces is challenging and carries significant risks [16,17]. The use of the flexible ureteroscope and holmium laser allows endoscopic incision of the obstruction followed by laser lithotripsy of the contained stone. Unlike ESWL, ureteroscopic incision offers correction of the underlying obstruction and permits ablation of the diverticulum. URS is best reserved for small stones contained in diverticula with short necks located in the upper or middle calyces (Fig. 3). Renal calculi associated with ureteropelvic junction obstruction may also be treated with URS, although alternative minimally invasive approaches are preferable.

Renal abnormalities

Stones associated with abnormally positioned renal units may represent an indication for the

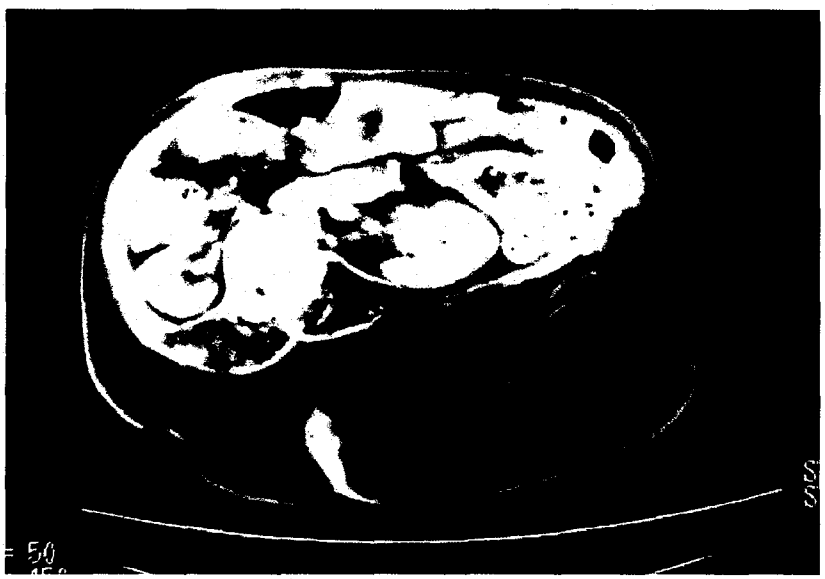

Fig. 2. CT image of patient with back abnormality precluding treatment of her renal stone with either ESWL or PCNL.

ureteroscopic approach. Horseshoe and ectopic kidneys are prone to urinary stasis and calculi formation. ESWL success rates of stones located in horseshoe and ectopic kidneys are consistently lower and retreatment rates higher than for normal kidneys [18]. Studies show only a 54% stone-free rate in patients undergoing ESWL for stones located in pelvic kidneys [19]. The poor success rate of ESWL in such situations relates to difficulties with shock-wave transmission to sites of ectopic kidneys and drainage abnormalities affecting spontaneous stone passage. Although PCNL is possible in ectopic kidneys, percutaneous renal access can be challenging because of their unpredictable vascular supply and frequently close proximity to surrounding bowel [20,21]. Although it is more invasive, good results have been demonstrated using laparoscopic-assisted percutaneous removal [22,23]. URS offers a minimally invasive treatment option for patients with small (< 2 cm) accessible stones within horseshoe or ectopic kidneys.

Conjunction with percutaneous nephrostolithotomy

The ureteroscopic manipulation of renal calculi also can serve as an adjunct to PCNL. Upper and middle calyces occasionally may be more accessible to retrograde URS than existing percutaneous nephrostomy tracts. The use of URS in combination with PCNL may obviate patients from having either ESWL or the creation of additional percutaneous tracts to remove stones inaccessible through an existing access site.

Patient preference

It is the treating physician's responsibility to outline all available options with a balanced discussion of risks, benefits, and success rates. Some patients may prefer a retrograde endoscopic approach for cosmetic reasons, to avoid the inherent risks of PCNL, or to have a more immediately definitive treatment than ESWL. Patients must understand that ureteroscopic management, although safer, is relatively inefficient compared with PCNL for fragmentation and removal of large renal stones.

Fig. 3. Retrograde pyelogram demonstrating stone contained within calyceal diverticulum.

Technique

The ureteroscopic treatment of renal calculi is best performed under general anesthesia and endotracheal intubation. Movement of the kidney caused by respiratory motion complicates intracorporeal lithotripsy in the kidney. Endotracheal intubation is preferable over a laryngeal mask because it allows the possibility for anesthesiologists to suspend respiration for short periods of time if needed.

Retrograde ureteroscopic stone manipulation is best performed with a flexible ureteroscope. The small-caliber, fully deflectable, flexible ureteroscopes allow access to stones in the entire collecting system. Ureteroscope diameters ranging from 7 to 10 F minimize ureteral trauma and decrease the need for intramural ureter dilation [24,25]. The miniaturization of ureteroscopes, however, came at a cost of endoscope durability. Afane et al [26] evaluated scope durability in the first generation of small-caliber (≤9 F) ureteroscopes. They found scopes required repair after an average of 6 to 15 uses. The loss of tip deflection was the most common problem, occurring most frequently after procedures requiring access into the lower pole. Manufacturers of endoscopes aim to develop ureteroscopes with improved durability and deflection capabilities. The DUR-8 ureteroscope offered by ACMI (Southborough, Massachusetts) has a 6.75-F tip, gradually expanding to a 10-F base. In the authors' experience, this scope exhibits improved durability compared with other flexible ureteroscopes with tip diameters less than 9 F. More recently, ACMI developed the DUR-8 Elite ureteroscope (Fig. 4). This ureteroscope incorporates active secondary deflection in addition to primary tip deflection, purportedly improving access to lower pole calyces.

Small-caliber flexible ureteroscopes minimize the need for dilation of the intramural ureter before scope introduction. In a study of 155 patients undergoing URS, only 8% of patients required ureteral orifice dilation [7]. Bagley [27] evaluated dilation requirements associated with different-caliber ureteroscopes. He found that the use of a 9-F ureteroscope required dilation 33% of the time, whereas ureteroscopes with a diameter less than 8.4 F required dilation less than 5% of the time.

The use of a ureteral access sheath may further facilitate flexible URS (Fig. 5). These hydrophilic sheaths have outer diameters ranging from 12 to 14 F and are fluoroscopically positioned. The use

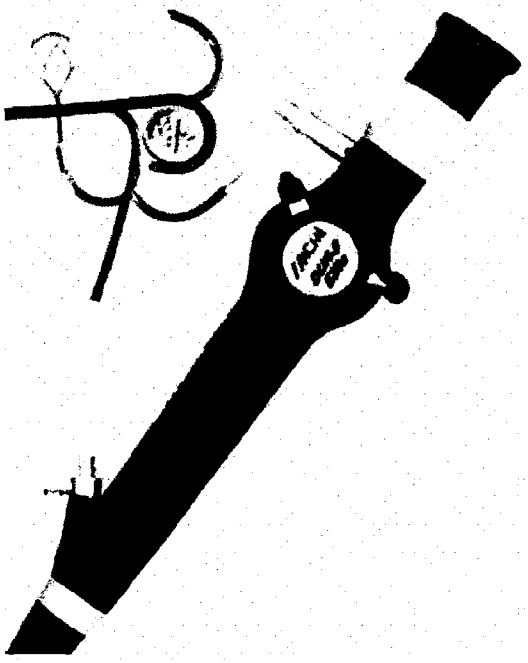

Fig. 4. The DUR-8 Elite ureteroscope incorporates active deflection of ureteroscope tip and secondary deflection mechanisms. (Courtesy of ACMI Corporation, Southborough, MA; with permission.)

of an access sheath reportedly reduces operative time and cost [28]. These sheaths facilitate egress of irrigant and small stone fragments through their lumens during flexible URS. The efflux of irrigation maintains endoscopic vision, especially during treatment of large renal calculi. Furthermore, this drainage decreases intrarenal pressures, thereby reducing the risk of bacteremia [29]. If an access sheath is not used, the placement of a small-caliber Foley catheter into the bladder facilitates bladder and upper tract drainage.

Modern flexible ureteroscopes typically possess a 3.6-F working channel. Many innovative ureteroscopic instruments have been designed for intrarenal stone manipulation. The development of small-caliber intracorporeal lithotrite probes and laser fibers minimizes loss of scope deflection while maximizing irrigation capabilities. EHL probes are available in sizes as small as 1.9 F and laser fibers as small as 200 μm. The holmium laser has revolutionized endoscopic lithotripsy for renal calculi. Its ability to fragment stones of all compositions while causing minimal urothelial trauma enables urologists to treat stones of any size while maintaining optimal endoscopic vision.

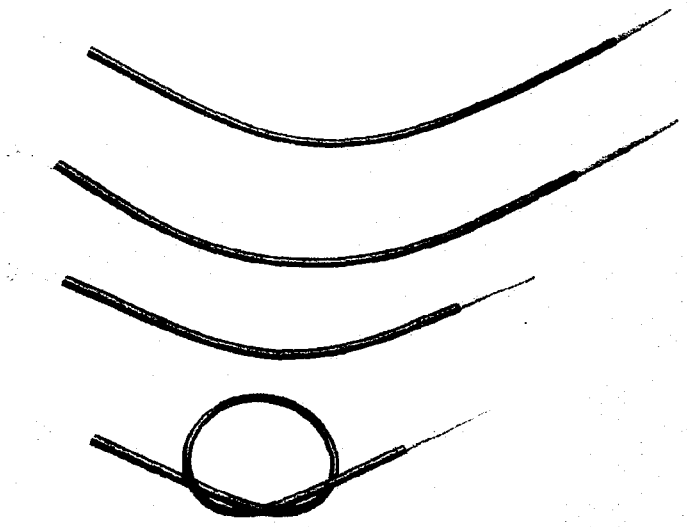

Fig. 5. The ureteral access sheath can be used to facilitate URS. (Courtesy of Applied Medical, Rancho Santa Margarita, CA; with permission.)

The development of nitinol instrument devices also has facilitated the advances of ureteroscopic stone treatment. Nitinol baskets are less traumatic and more durable than standard steel wire instruments. Nitinol's flexibility profile also minimizes loss of scope tip deflection, which is most important during treatment of lower pole stones.

The ureteroscopic treatment of lower pole stones requires knowledge of technical nuances and the availability of crucial equipment. Having access to a small-caliber flexible ureteroscope with 180° tip deflection is required. With use, all scopes progressively lose tip deflection capabilities. If endoscopic access to the desired lower calyx is not possible on full deflection of the ureteroscope tip, the scope should be advanced to make use of its passive secondary deflection mechanism (Fig. 6). As previously mentioned, ACMI recently released the Elite ureteroscope, which has both active primary and secondary deflection. Repositioning of the patient may also be useful. Patients who have stones in the lower calyx should be positioned in Trendelenberg, and manual syringe irrigation should be used to flush stone fragments to a more cephalad position. Herrell and Buchanan [30] described positioning patients in the flank position to facilitate calyceal stones falling into the renal pelvis.

If patient repositioning and irrigation are unsuccessful, lower calyceal stones can be grasped and repositioned to a more accessible cephalad calyx. Repositioning of lower pole stones enhances the ability to perform intracorporeal lithotripsy and reduces strain on endoscopes. Auge et al [31] found that use of a 2.6-F nitinol grasping device (Graspit, Boston Scientific, Natick, Massachusetts) or a 2.4-F nitinol basket resulted in less deflection loss than a 200-μm laser fiber (Fig. 7). The Dimension basket (Bard Urological, Covington, Georgia) is a nitinol basket with articulating wires to facilitate stone capture and release (Fig. 8). Landman and Clayman [32] described use of a "bare-naked" basket. Removal of the outer sleeve of a nitinol basket increases scope deflection and maximizes irrigation capabilities. Stones contained within a bare-naked basket are entrapped by pulling the

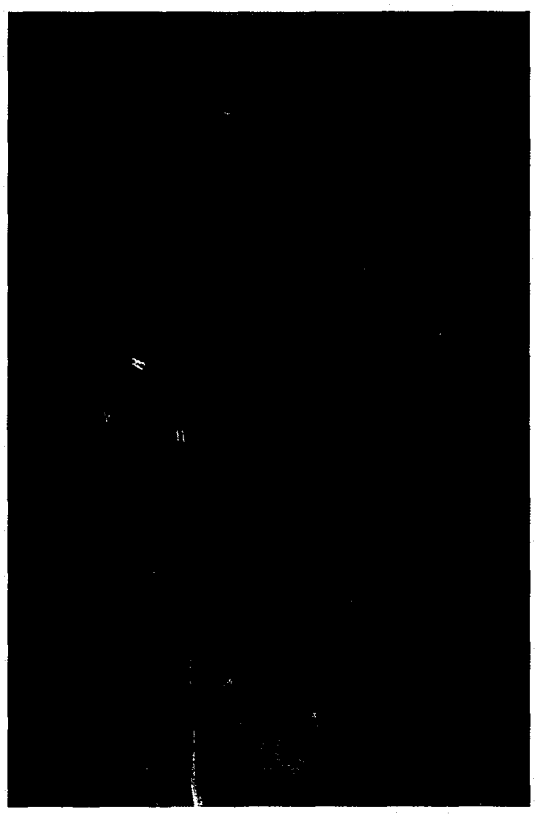

Fig. 6. Radiograph depicting use of secondary deflection to access the lower pole.

basket back against the tip of the ureteroscope. Repositioning of stones to a more cephalad calyx also allows use of larger-diameter, more-efficient laser fibers. Vassar et al [33] showed that the 365-μm holmium laser fiber was more efficient and less prone to fiber degradation than smaller fibers that are often required to treat lower pole calculi in situ. Studies on stone repositioning also demonstrated improved success rates compared with treating stones in situ [31,34]. Auge et al [31] found the 3-month stone-free rate for 36 patients treated ureteroscopically for renal stones favored stone repositioning versus in situ lithotripsy (90% versus 83% success rates, respectively).

In 1994, the American Urological Association's Nephrolithiasis Guidelines Panel provided recommendations for treatment of staghorn calculi [35]. They concluded that, under most circumstances, patients with staghorn calculi are best served by initial PCNL followed by adjunctive ESWL or PCNL as needed. Several centers have reported using ureteroscopic lithotripsy to treat patients with large renal calculi (including staghorns). The most common indications to treat these patients ureteroscopically were comorbidities that precluded PCNL. The treatment of large calculi commonly requires more than one staged procedure. The placement of ureteral catheters to irrigate stone fragments following intrarenal lithotripsy has been described. Grasso and Ficazzola [11] described a technique of positioning a 5-F Cobra catheter with its tip in the lower pole adjacent to a second 6-F ureteral catheter used for outflow. A dilute antibiotic solution was used to irrigate through the Cobra catheter at a rate of 100 cc per hour. The authors further described irrigation with alkalizing agents or tromethamine for uric acid or cystine stones, respectively. Irrigation for 36 to 48 hours is performed before a second-look procedure.

Knowledge of the previously described technical maneuvers and availability of the described equipment should facilitate ureteroscopic treatment of stones in any location of the kidney. Increasing surgeon experience along with continued improvements in endoscopic instrumentation will allow urologists to successfully treat more patients ureteroscopically who are currently being treated percutaneously.

Results

Multiple studies have evaluated the efficacy of treating renal stones ureteroscopically [11,34,36–42]. Although few differences in technique are described, studies vary significantly in definition and time interval to determination of treatment success. In general, continuing intracorporeal lithotripsy until residual stone fragments are no greater than 2 mm is the preferred method. Overall, reported treatment success rates for ureteroscopic treatment of renal stones varies from 50% to 92% (Table 1).

Three studies evaluated ureteroscopic treatment of lower pole calculi and the benefit of stone repositioning [11,34,36]. Overall stone-free rates varied from 65% to 85%. Kourambas et al [34] repositioned only stones that could not be effectively treated in situ. Stone repositioning was required in 10 of 36 patients who had lower pole stones. Stone-free rates seemed to be improved in lower pole stones that were repositioned compared with those treated in situ. Stone repositioning improved stone-free rates from 61% to 79% in the Schuster et al [36] study and from 83% to 90% in the Kourambas et al [34] study.

Fig. 7. The nitinol "Graspit" device used to reposition lower pole stones. (Courtesy of Microvasive, Boston Scientific Corporation, Natick, MA; with permission.)

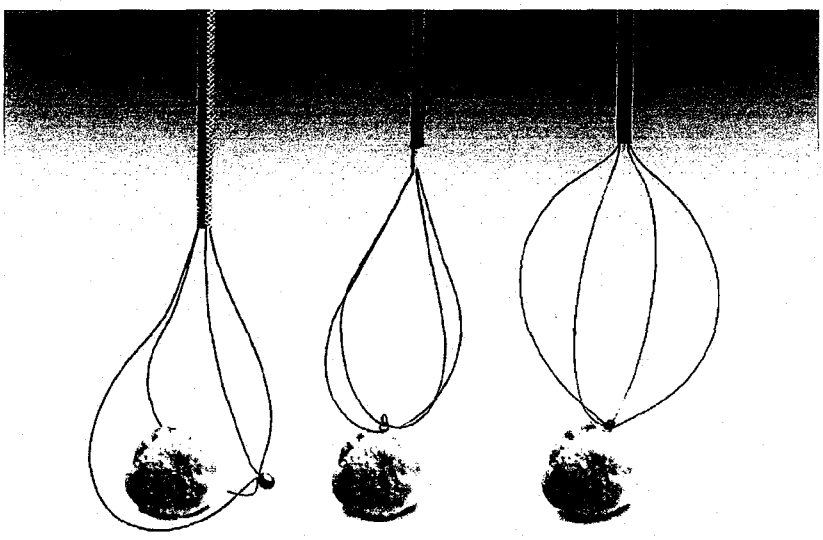

Fig. 8. The nitinol "Dimension" stone basket provides articulating basket wires to facilitate stone entrapment and release. (Courtesy of Bard Urological, Covington, GA; with permission.)

Table 1
Results from studies evaluating URS for renal stones

First author	No. patients	Success (%)	Comment
Schuster [36]	78	79[a]	LPS
Kourambas [34]	36	85[b]	LPS
Grasso [11]	90	76[b]	LPS
Sofer [38]	54	84[b]	—
Elashry [37]	45	92[b]	Ureteral/renal
Fabrizio [39]	100	77[b]	—
El-Anany [40]	35	77[b]	Stones >2 cm
Grasso [41]	45	84[a]	Stones >2 cm
Aso [42]	34	50[b]	Staghorn calcull

[a] Fragments < 2 mm.
[b] Stone-free.
Abbreviation: LPS, lower pole stones.

Treatment success also highly depends on the size of treated stones. Grasso et al's [11] study of 90 patients reported the following treatment success rates: 82% for stones that were 10 mm or smaller, 72% for stones 10 to 20 mm, and 65% for stones that were larger than 20 mm. Three studies examined the utility of using URS to treat large renal stones (>2 cm) [40–42]. Overall success rates defined as either stone-free or stones smaller than 2 mm varied from 50% to 84%. Multiple procedures were often required. Sixteen of 45 patients in Grasso et al's [41] study required more than one procedure, whereas 34 patients in Aso et al's [42] study required an average of 1.6 procedures. As previously mentioned, adjunctive upper tract irrigation was performed in some patients in the study reported by Grasso et al [41].

Reported complication rates are few and typically minor. Minor complication rates range from 0% to 13% and consist primarily of pain or urinary tract infection. No major complications other than the retroperitoneal hemorrhage occurring in a patient with the uncorrected bleeding diathesis have been reported [15]. Significant complications, including ureteral stricture, have been reported to occur in 1.5% of nonspecific patients undergoing URS [43]. Longer-term follow-up periods may be required to determine the true stricture risk associated with ureteroscopic treatment of renal calculi.

Summary

Although ureteroscopic treatment of renal calculi is safe and effective, it is relatively inefficient compared with ESWL and PCNL. It should be considered primary therapy for patients with lower pole stones who have adverse ESWL characteristics and patients who are not suitable candidates for PCNL. There are also numerous clinical situations, as outlined previously, where the ureteroscopic approach is favored over other treatment modalities.

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EXHIBIT C

Comments on Petition to the State Health Coordinating Council Regarding New Technology and Equipment Policy TE-3
2017 State Medical Facilities Plan

March 18, 2016

Commenter:		*Contact:*	
Name:	Triangle Lithotripsy Corporation	**Name:**	David B. Driggs; William Pinna; Nancy Lane
Address:	2601 Oberlin Road, #100 Raleigh, NC 27608	**E-mail:**	D5205@aol.com; bpinna@pjb-law.com; nlane@pda-inc.net
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SUMMARY OF REQUESTED ADJUSTMENT

Hampton Roads Lithotripsy, LLC, a Virginia company based in Norfolk, filed a petition requesting a new Policy TE-3 for the 2017 State Medical Facilities Plan.

The petition's stated intent is to permit applicants who own mobile lithotripsy equipment to increase access to rural areas in North Carolina. The proposed policy would:

- Benefit only companies that operate outside the state of North Carolina, in contiguous states including states as far away as Georgia;
- By-pass the Need Methodology for Lithotripsy in Chapter 9 of the *State Medical Facilities Plan*;
- Not require the applicant to be serving North Carolina at the time it applies for a Certificate of Need under the proposed policy; and
- Permit operation only at hospital sites.

We appreciate the state's consideration of our comments on the petition and welcome any questions.

COMMENTS

UNFRIENDLY TO NORTH CAROLINA

Petition Policy Elements 1 and 2 would prohibit a mobile lithotripsy company that serves only North Carolina from applying. Specifically the petition requires the following:

> *... has regulatory approval if needed, to operate in a state contiguous to North Carolina*
>
> *..currently provides services to at least one host site in one of the states that is contiguous to North Carolina*

The petition had no letters of support from North Carolina and the petitioner chose not to exercise the opportunity to make a case in person before the State Health Coordinating Council at its meeting in March 2016.

UNFRIENDLY TO RURAL NORTH CAROLINA

The petition's third Policy Element requires that a Certificate of Need application filed under the proposed new policy TE-3 to serve only rural hospital sites.

> *Will serve only hospital sites in areas defined as rural...*

Several North Carolina counties do not have a hospital; Alexander, Graham, and Warren are a few examples. The petition actually notes that these counties would not be appropriate for mobile lithotripsy (page 9 of 12).

INSIGHTFUL CONSIDERATIONS

The petition raises good questions about access to lithotripsy in rural North Carolina. However, the petition favors only the solution that benefits this one out-of-state company. The petition would give Hampton Roads Lithotripsy, and other out-of-state companies, unrestricted access to grow business in North Carolina at the expense of companies that are in North Carolina and serve North Carolina. A North Carolina company that operates at full capacity could not apply for a CON under the policy as written, but an out of state company with no track record, would have permission to create a case and that applicant would not be subject to the standard performance requirement. It would only need to serve an area defined as rural. It could compete where others could not. The proposed policy would create two classes of lithotripsy providers.

The petition's arguments that the 1994 use rates merit re-examination are valid, but the petition falls short of resolution on alternatives. However, it appropriately opens the door for additional discussion. The petition makes an excellent case that service to out of state locations should be discounted in the state methodology, even noting without so saying that the out-of-state cases exceed the state threshold for an additional lithotripter. However, the petition makes a blanket assumption that no provider could serve rural areas, instead proposes a solution that serves the petitioner's interest in Northeastern North Carolina. It appropriately notes the planning obstacles associated with the state's missing patient origin data, but only generally references its own data on service to North Carolina residents. It notes that patients of urologists in the Hampton Roads area could be served by lithotripters in rural North Carolina, but fails to discuss whether those urologists would go to the rural North Carolina lithotripter.

The proposed policy is incomplete with regard to the narrative. The narrative suggests using a placeholder to count service to counties the out of state unit would serve, but does not apply the same to North Carolina units that go out of state. Over time, this will create an imbalance that favors the out of state unit.

INAPPROPRIATE TIMING

As the petitioner notes, the *2016 SMFP* shows a statewide need for one additional lithotripter. Applications are due mid-year and the review may not finish before the end of the year. Consideration of the policy now, before filing the batch applications, would put the state in an untenable position. Certificate of Need staff would be constrained in their comments because of a review in progress.

STATEMENT OF ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS IF THE ADJUSTMENT IS MADE

The petition would permit duplication of resources. For example, it could permit location in a county, at the border of very urban county Thoughtful review and consideration could eliminate such unintended consequences.

REMEDY

The petitioner clearly raises issues that merit consideration.by a group that understands the full spectrum of lithotripsy treatment, disease indicators, cost of operations and quality program requirements. A work group could be appointed and could convene in late fall, to provide recommendations to the Technology Committee in spring 2017.

The petition correctly notes that the development of the current methodology occurred in 2001. Now, fifteen years later, it is appropriate to revisit the methodology and its research foundations.

A new methodology could include more current nephrolithiasis disease incidence and kidney stone prevalence information, as well as utilization patterns and underserved areas. It could make adjustments for fixed and mobile unit status, as is the case with MRI. The methodology could exclude counts of procedures provided outside the state by adding one extra step to the current methodology.

As a first step, in 2016, the SHCC could remedy the problem of missing patient origin data, by asking DHSR Planning to add one table to the required Registration and Inventory of Equipment forms. When the SHCC expanded the MRI methodology, a similar panel looked at underserved areas and adjusted thresholds to favor redistribution of resources. A study group could look at that.

CONCLUSION

The petition raises important questions about the methodology for calculating need for lithotripter capacity and the best ways to serve rural communities in North Carolina. The Hampton Roads Lithotripsy petition should be tabled until the conclusion of the 2016 Lithotripsy CON review cycle. A work group should then be created to review the petition and make recommendations to the SHCC. This allows the work group to account for the 2016 application decision and yield the best recommendations.

EXHIBIT D

Carolina Lithotripsy, LTD
January - July 2016

FacilityState	FacilityName	FacilityCity	Machine ID 8121
NC	Beaufort Vidant Hospital	Washington	15
NC	Carolina East Medical Center	New Bern	39
NC	Carteret General Hospital	Morehead City	15
NC	Columbus Regional Healthcare	Whiteville	5
NC	Lenoir Memorial Hospital	Kinston	20
NC	New Hanover Regional Med Ctr	Wilmington	74
NC	Novant Brunswick Medical Ctr	Bolivia	19
NC	Pitt Vidant Medical Center	Greenville	87
NC	Wayne Memorial Hospital	Goldsboro	8
NC	Wilson Medical Center	Wilson	16
			298

			Machine ID 8122
NC	Duke Raleigh Hospital	Raleigh	3
NC	Firsthealth Moore Regional Hsp	Pinehurst	93
NC	Firsthealth Richmond Memorial	Rockingham	5
NC	Halifax Regional Medical	Roanoake Rapids	19
NC	Highsmith Rainey Spec Hosp	Fayetteville	67
NC	Johnston Med Ctr Smithfield	Smithfield	45
NC	Rex Hospital	Raleigh	9
NC	Rex Surgery Center Of Cary	Cary	30
NC	Southeastern Regional Med Ctr	Lumberton	22
NC	Wakemed Raleigh Campus	Raleigh	39
			332

Grand Total **630**

Fayetteville Lithotripter Limited Partnership - SC II
January - July 2016

FacilityState	FacilityName	FacilityCity	Machine ID OR197
NC	Harris Regional Hospital	Sylva	64
NC	Haywood Regional Medical Ctr	Clyde	63
NC	Margaret Pardee Hospital	Hendersonville	46
NC	Mcdowell Hospital	Marion	15
NC	Park Ridge Hospital	Hendersonville	39
NC	St Lukes Hosp Columbus	Columbus	9
NC	Transylvania Community Hosp	Brevard	16
NC	V A Asheville Medical Center	Asheville	16
			268
SC	Oconee Medical Center	Seneca	17
	Grand Total		**285**

Fayetteville Lithotripter Limited Partnership - SC II
January - July 2016

FacilityState	FacilityName	FacilityCity	Machine ID OR159
NC	Albemarle Hospital	Elizabeth City	18
NC	Vidant Chowan Hospital	Edenton	14
			32
VA	Mary Immaculate Hospital	Newport News	41
VA	Mary Washington Hospital	Fredericksburg	8
VA	Riverside Doctors Surgery Ctr	Williamsburg	10
VA	Riverside Tappahannock	Tappahannock	1
VA	Southside Regional Med Center	Petersburg	54
			114
	Grand Total		**146**

EXHIBIT E

Technology and Equipment Committee
Agency Report
Lithotripsy Technology and Equipment Policy
Proposed 2017 State Medical Facilities Plan

Petitioner:
Hampton Roads Lithotripsy, LLC
225 Clearfield Avenue
Virginia Beach, VA 23462

Contact:
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Request:
Hampton Roads Lithotripsy, LLC requests that the *North Carolina 2017 State Medical Facilities Plan (SMFP)* include a new policy regarding lithotripsy.

Background Information:
Chapter 2 of the State Medical Facilities Plan (SMFP) describes the purpose and process for submitting petitions to amend the SMFP during its development. Early in the planning year petitions related to basic SMFP policies and methodologies that have a statewide impact may be submitted. The SMFP defines changes with the potential for a statewide impact as *"the addition, deletion, and revision of policies and revision of the projection methodologies."* The review requested by this petitioner could affect a methodology or policies in the SMFP and should be considered before publication of the Proposed 2017 SMFP.

The policy proposed by Hampton Roads Lithotripsy is as follows:

> *Policy TE-3: Use of Existing Mobile Lithotripsy Units to Increase Access in Rural Areas of the State*
>
> *Applicants that own existing mobile lithotripsy units that are approved to operate in states contiguous to North Carolina may apply for a Certificate of Need (CON) to serve host sites in North Carolina if the applicant(s) demonstrates in the CON application that the mobile lithotripsy unit:*
>
> 1. *Has regulatory approval, if needed, to operate in a state contiguous to North Carolina, including Georgia, South Carolina, Tennessee or Virginia;*
> 2. *Currently provides services to at least one host site in one of the states that is contiguous to North Carolina and commits to continue doing so following completion of the project;*
> 3. *Will serve only hospital sites in areas defined as rural by the United States Department of Agriculture, which includes areas other than:*

a. A city or town that has a population greater than 50,000 inhabitants; and,
b. The urbanized area contiguous and adjacent to such a city or town.

4. *It is reasonably expected to improve the quality of, access to, or value of lithotripsy services in the area served by the host site.*

The performance standards in 10A NCAC 14C .3202 would not be applicable.

Lithotripsy has been governed by the Certificate of Need (CON) law since 1993. The 1997 SMFP began to include inventories of lithotripsy equipment and the number of procedures performed. During this time, the State Health Coordinating Council (SHCC) sought comments on the need for lithotripters. As a result, beginning with the 1998 SMFP, the SHCC first articulated a need determination methodology for lithotripsy.

The methodology assumed an annual incidence of 16 cases of urinary stone disease per 10,000 population, with 85-90 percent of cases appropriate for lithotripsy. In addition, given that mobile units provide most lithotripsy procedures, the SHCC defined the service area to be the entire state. To gauge the sufficiency of the current inventory of equipment, the SMFP compared North Carolina's inventory to two nearby states that governed lithotripters under their CON law. Specifically, the Kentucky State Health Plan's methodology did not identify a need unless all units performed "at least 1,000 procedures in the previous year. One thousand procedures represents 50 percent utilization of 50 weeks of operation at 40 hours per week allowing an average of one hour per procedure" (1998 SMFP. p. 76). Based on this information, North Carolina determined the treatment capacity of a lithotripter to be between 1,000 and 1,500 procedures per year. The methodology has not changed since that time.

In 1998, North Carolina had 14 lithotripsy units, 11 of which were mobile. The remainder were fixed units based at hospitals. Given the methodology and the 1998 population, the state needed a maximum of 11 lithotripters at that time – 3 fewer than the inventory. Thus the SHCC concluded that North Carolina had sufficient units to serve the population, and that there was no need for additional lithotripters in 1998.

One unit was sold in 2003, leaving the state with 13 lithotripters. In 2006, Stone Institute of the Carolinas filed a petition for an adjusted need determination for Mecklenburg County. The petitioner argued that the one unit available in Mecklenburg County could not support the area's continued population growth. As a result, the 2007 SMFP contained a need determination for one lithotripter in Mecklenburg County, returning the inventory to the original 14 units.

The total inventory of lithotripters remains unchanged, but 13 are now mobile and 1 is fixed. Although the state population has increased substantially since 1998, the 2016 SMFP represents the first time that the methodology has triggered a need for a lithotripter.

Analysis/Implications:
A primary rationale for the proposed policy expresses the concern that the current complement of lithotripsy equipment in North Carolina may not meet the needs of patients in rural areas. To solve this problem, the petitioner recommends a new policy that limits a mobile lithotripsy unit to rural areas. Because these mobile units would serve patients in sparsely populated areas, the petitioner

proposed that they should be exempt from the standards in 10A NCAC 14C .3203. This rule requires a CON applicant to show that in the third year of operation the unit is projected to perform 1,000 procedures per year and that it will perform an average of 4.0 procedures per day per site.

An analysis of lithotripsy procedures in the 2016 SMFP shows that of the 10,164 procedures performed on mobile equipment 8,833 were performed in North Carolina. The remaining 1,331 were performed out of state. The petitioner correctly observes that the residence location of lithotripsy patients is not available on the Registration and Inventory forms. As a proxy for patient residence, the agency's analysis of access to lithotripsy services used the location where the procedures were performed.

To determine whether the procedures were performed in a rural area, the agency's analysis used the definition proposed by the petitioner – the U.S. Department of Agriculture's (USDA) Business and Industry Guaranteed Loan program. "Rural areas are any areas other than:

(1) A city or town that has a population of greater than 50,000 inhabitants; and
(2) The urbanized area contiguous and adjacent to such a city or town, as defined by the U.S. Bureau of the Census using the latest decennial census of the United States." http://eligibility.sc.egov.usda.gov/eligibility/welcomeAction.do?pageAction=rbs

The designation of a place as rural or urban was based on the street address of the hospital where the mobile lithotripsy unit operated during 2013-2014. Lithotripsy equipment that operates in North Carolina may also operate in adjacent states. These proportions include only the procedures performed in North Carolina. Table 1 summarizes the number of procedures performed at each location and identifies the areas as either rural or urban (as of the 2010 Census). It shows that 39.4% of the procedures were performed in rural areas and 60.6% were performed in urban areas. Attachment A shows the number of procedures for each facility, by provider.

Table 1. Mobile Lithotripsy Procedures Performed in North Carolina

	Number of Procedures				
	North Carolina				
Provider (number of machines)	**Rural**	**Urban**	**Total North Carolina**	**Out of State**	**Total Procedures**
Carolina Lithotripsy (2)	655	705	1,360	0	1,360
Catawba Valley Medical Center (2)	563	0	563	0	563
Fayetteville Lithotripters (1)	315	178	493	100	593
Fayetteville Lithotripters (1)	92	0	92	220	312
Piedmont Stone Center (4)	1,290	2,160	3,450	816	4,266
Stone Institute of the Carolinas (2)	352	1,398	1,750	195	1,945
Triangle Lithotripsy Corp. (1)	215	910	1,125	0	1,125
Total	3,482	5,351	**8,833**	**1,331**	**10,164**
% of Procedures by Type of NC Area	39.4%	60.6%	**100.0%**		

Source: Table 9A, 2016 North Carolina State Medical Facilities Plan

The petitioner claims that rural areas are not well served by lithotripters. Since the lithotripter service area is the entire state, procedures performed in rural versus urban areas should be proportional to the population in rural and urban areas of the state.

Based on the 2010 census (see Table 3), 66 percent of North Carolina's population is urban, using the Census Bureau's standard definition of "urbanized Areas of 50,000 or more people and urban clusters of at least 2,500 and less than 50,000 people" (https://www.census.gov/geo/reference/ua/urban-rural-2010.html). This definition differs slightly from that used by the USDA.

Table 2. North Carolina Urban and Rural Population, 2010

	N	Percent
Urban	6,301,756	66.1%
Rural	3,233,727	33.9%
Total Population	**9,535,483**	**100.0%**

Source: U.S. Census Bureau. (http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=DEC_10_SF1_P2&prodType=table)

Table 1 shows that 60.6 percent of procedures were conducted in urban areas and 39.4 percent were conducted in rural areas of North Carolina during 2013-2014. Table 2 shows that 66.1 percent of North Carolina's population resides in urban areas and 33.9 percent resides in rural areas. The slight variation in the definition of rural and urban between the 2010 Census and that used by the USDA may yield slight variation in results. In addition, the lithotripsy procedure data does not identify the residence of the patients, but rather identifies the location of the service.

On a statewide basis, there does not appear to be a substantial disproportion in procedures performed in rural versus urban areas. The small imbalance indicates that more procedures are performed in rural areas than suggested by their proportion of the state population. Therefore, an access issue suggested by the petitioner does not appear to exist. Moreover, the 2016 SMFP reports a statewide need determination for one lithotripter, bringing the projected inventory to 15 machines. With the addition of the new machine, and given that the service area for lithotripters is statewide, the proposed policy may lead to duplication of resources. Finally, the petitioner may apply for the 2016 statewide need determination.

Agency Recommendation:

Given available information and comments submitted by the March 18, 2016 deadline for comments on petitions and comments, and in consideration of factors discussed above, the Agency recommends denial of the petition. The Agency supports the standard methodology for lithotripsy services.

Attachment A: Mobile Lithotripsy Providers and Locations Served in North Carolina

Machines 2; Areas Generally Served: Eastern North Carolina

Facility and Location	*Procedures*	*Rural*	*Urban*
CarolinaEast Medical Center, New Bern, NC	103	103	
Carteret General Hospital, Morehead City, NC	53	53	
Columbus Regional Healthcare System, Whiteville, NC	12	12	
Duke Raleigh Hospital, Raleigh, NC	10		10
FirstHealth Moore Regional Hospital, Pinehurst, NC	162	162	
FirstHealth Richmond Memorial Hospital, Rockingham, NC	25	25	
Halifax Regional Medical Center, Roanoke Rapids, NC	30	30	
Highsmith-Rainey Specialty Hospital, Fayetteville, NC	177		177
Johnston Health, Smithfield, NC	81	81	
Lenoir Memorial Hospital, Kinston, NC	21	21	
New Hanover Regional Medical Center, Wilmington, NC	201		201
Novant Health Brunswick Medical Center, Supply, NC	12	12	
Onslow Memorial Hospital, Jacksonville, NC	4		4
Rex Hospital, Raleigh, NC	125		125
Southeastern Regional Medical Center, Lumberton, NC	73	73	
Vidant Beaufort Hospital, Washington, NC	28	28	
Vidant Medical Center, Greenville, NC	138		138
WakeMed, Raleigh, NC	50		50
Wayne Memorial Hospital, Goldsboro, NC	17	17	
Wilson Medical Center, Wilson, NC	38	38	
Total Procedures:	**1,360**	**655**	**705**

Machines 2; Areas Generally Served: Western and Central North Carolina

Facility and Location	*Procedures*	*Rural*	*Urban*
Carolinas HealthCare System- Blue Ridge, Morganton, NC	39	39	
Catawba Valley Medical Center, Hickory, NC	321	321	
Rutherford Regional Medical Center, Rutherfordton, NC	68	68	
Scotland Memorial Hospital, Laurinburg, NC	135	135	
Total Procedures:	**563**	**563**	

Machines 1; Areas Generally Served: Western North Carolina and South Carolina

Facility and Location	*Procedures*	*Rural*	*Urban*
Charles George VA Medical Ctr, Asheville, NC	25		25
Harris Regional Hospital, Sylva, NC	118	118	
Haywood Regional Medical Center, Clyde, NC	112	112	
Margaret R Pardee Memorial Hospital, Hendersonville, NC	93		93
Park Ridge Health, Hendersonville, NC	60		60
St. Luke's Hospital, Columbus, NC	7	7	
The McDowell Hospital, Marion, NC	32	32	
Transylvania Regional Hospital, Brevard, NC	46	46	
Total Procedures:	**493**	**315**	**178**

Machines 1; Areas Generally Served: Eastern North Carolina and Virginia

Facility and Location	*Procedures*	*Rural*	*Urban*
Sentara Albemarle Medical Center, Elizabeth City, NC	24	24	
The Outer Banks Hospital, Nags Head, NC	17	17	
Vidant Chowan Hospital, Edenton, NC	51	51	
Total Procedures:	**92**	**92**	

Machines 4; Areas Generally Served: Western and Central North Carolina and Virginia

Facility and Location	*Procedures*	*Rural*	*Urban*
Alamance Regional Medical Center, Burlington, NC	186	186	
Annie Penn Hospital, Reidsville, NC	14	14	
Carolinas HealthCare System-Blue Ridge, Valdese, NC	94	94	
Davis Regional Medical Center, Statesville, NC	45	45	
High Point Regional Health System, High Point, NC	498		498
Hugh Chatham Memorial Hospital, Elkin, NC	182	182	
Iredell Memorial Hospital, Statesville, NC	144	144	
Lexington Medical Center, Lexington, NC	64		64
Maria Parham Medical Center, Henderson, NC	60	60	
Morehead Memorial Hospital, Eden, NC	172	172	
Northern Hospital of Surry County, Mount Airy, NC	50	50	
Novant Health Forsyth Medical Center, Winston-Salem, NC	116		116
Novant Health Rowan Medical Center, Salisbury, NC	213		213
Novant Health Thomasville Medical Center, Thomasville, NC	41		41
Piedmont Stone Center, Winston-Salem, NC	799		799
Randolph Hospital, Asheboro, NC	115	115	
Wake Forest Baptist Medical Center, Winston-Salem, NC	103		103
Watauga Medical Center, Boone, NC	144	144	
Wesley Long Hospital, Greensboro, NC	326		326
Wilkes Regional Medical Center, North Wilkesboro, NC	75	75	
Yadkin Valley Community Hospital, Yadkinville, NC	9	9	
Total Procedures:	**3,450**	**1,290**	**2,160**

Machines 2; Areas Generally Served: Western and Central North Carolina

Facility and Location	*Procedures*	*Rural*	*Urban*
Carolinas HealthCare System-Lincoln, Lincolnton, NC	60	60	
Carolinas Medical Center, Charlotte, NC	153		153
Carolinas Medical Center-Huntersville, Charlotte, NC	72		72
Carolinas Medical Center-Northeast, Concord, NC	220		220
Carolinas Medical Center-Pineville, Charlotte, NC	217		217
Carolinas Medical Center-Union, Monroe, NC	115		115
Carolinas Medical Center-University, Charlotte, NC	211		211
Caromont Regional Medical Center, Gastonia, NC	126		126
Cleveland Regional Medical Center, Shelby, NC	108	108	
Lake Norman Regional Medical Center, Mooresville, NC	184	184	
Novant Health Matthews Medical Center, Matthews, NC	197		197
Novant Health Presbyterian Medical Center, Charlotte, NC	87		87
Total Procedures:	**1,750**	**352**	**1,398**

Machines 1; Areas Generally Served: East Central North Carolina

Facility and Location	*Procedures*	*Rural*	*Urban*
Central Carolina Hospital, Sanford, NC	126	126	
Duke Regional Hospital, Durham, NC	28		28
Durham Ambulatory Surgical Center, Durham, NC	104		104
Nash General Hospital, Rocky Mount, NC	127		127
North Carolina Speciality, Durham, NC	13		13
Rex Hospital, Raleigh, NC	217		217
Rex Surgery Center, Cary, NC	168		168
Sampson Regional Medical Center, Clinton, NC	15	15	
WakeMed, Raleigh, NC	253		253
Wayne Memorial Hospital, Goldsboro, NC	74	74	
Total Procedures:	**1,125**	**215**	**910**

Total Mobile Procedures Performed in North Carolina: ***8,833***

From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment"
Source: Table 9A, 2016 North Carolina State Medical Facilities Plan

EXHIBIT F

Gregory F. Murphy, MD, FACS*
H. Mallory Reeves, MD, FACS*
Jonathan H. Taylor, MD, FACS*
Caroline D. Ryan. MD, FACS*
J. Nathaniel Hamilton, MD, FACS*
Matthew A. Collins, MD*
Steve Benson, PA-C
Wanda Hancock, PA-C
* Diplomate of the American Board of Urology

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July.29, 2016

To whom it may concern,

I was very recently made aware of a CON application for an additional lithotripter in eastern North Carolina. As the regional representative for Carolina lithotripsy I am sending you this letter to express several concerns regarding the application and/or the claims made in this application.

First and foremost I would plainly state that the overall volume of lithotripsy in eastern North Carolina has been declining especially for the past several years. This has little to do with utilization but more to do with increased use of alternative modalities for treatment. A decision made by the attending surgeon and patient together in concert but very rarely made due to the equipment being unavailable for the procedure.

During this time of change Carolina lithotripsy has done their part to try to maximize utilization of their lithotripsy equipment. Continuous evaluation of how to make the process more efficient is undertaken to allow maximal patient access.

Furthermore neither my group nor I as an individual were contacted in anyway by the applicant regarding access to and/or availability of the equipment. There are claims that we have felt underserved and I can wholeheartedly tell you this is inaccurate.

I feel certain that you will hear echoing comments from both my partners in practice and multiple other providers in the community at large. Simply stated I feel that additional lithotripter services in eastern North Carolina are unlikely to provide any greater access and/or utilization of lithotripsy as a modality for treatment. Nor do I think the application which was submitted was fully accurate in its description of the overall situation.

In summary, I feel certain that upon your own review of the application for this CON you will come to the same conclusions as I.

J. Nathaniel Hamilton, MD, FACS

Eastern Urological Associates

Affiliate professor of surgery East Carolina University

Regional representative for Carolina Lithotripsy with Healthtronics

J. Richard Gavigan, MD, FACS*
Edward O. Janosko, MD, FACS*
Benjamin G. Hines, Jr., MD, FACS*
Gregory F. Murphy, MD, FACS*
Dieter Bruno, MD
*Diplomate of the American Board of Urology

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Greenville, NC 27834
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Toll Free: 1-888-752-5077
Fax: 252-752-9544

RE: Eastern Carolina Lithotripsy CON Application

July 28, 2016

To Whom it may concern:

As Chief of Urology at Vidant Medical Center as well as President of Eastern Urological Associates, I write you to adamantly opposed the requested CON application made by Eastern Carolina Lithotripsy. As leader of the busiest urology practice in eastern NC, I was taken by great surprise to hear that a group 90 miles to our west made an application for services we provide without even the slightest consultation.

There are several blatant inaccuracies in their application not the least of which is the claim that the Urologists in Pitt County, which are comprised of my group, have expressed frustration with the present situation of Lithotripsy in eastern NC. This is an outright misrepresentation of the facts. We have NEVER stated such a claim. In reality we have seen a marked decrease in the demand for lithotripsy services over the last few years. Simply put there is NO 'unmet need' in eastern NC as is erroneously contended in the application. We have created a 'spoke and wheel' concept for health care in our 29 county catch basin and provide the full range of appropriate services for kidney stones for our patients.

Pointing out there is no lithotripsy service in 28 eastern NC counties merely states a fact that those of us in the east, who actually treat patients here, already know. The population density does not warrant a urologist to be in those counties, much less a specific service such as lithotripsy. Putting lithotripsy service in a county where there is no urologist defies logic much less common sense.

In summary this application is filled with clinical falsehoods and inaccurate suppositions. There is simply no need for an additional lithotripsy service in eastern NC. The lithotripsy company that has provided excellent quality service for over 30 years is totally fulfilling the present need as I see from someone who has lived and practiced in eastern NC for over 20 years. There is no need whatsoever for another lithotripsy company when the data would show the demand for lithotripsy has actually been decreasing rather than ~~decreasing~~ increasing.

I ask that you review the application with a negative judgment.

Sincerely,

Gregory F. Murphy, MD, FACS
Chief Division of Urology, Vidant Medical Center
President, Eastern Urological Associates, PA

July 28, 2016

Hugh M. Reeves, Jr., MD, FACS

Eastern Urological Associates

Greenville, NC 27834

To Whom It May Concern,

I became aware of the certificate of need application this week by Eastern Carolina Lithotripsy (ECL). I am writing to discourage awarding this certificate as it would duplicate services in our surrounding communities and unnecessarily waste healthcare resources. I feel that this application by ECL is motivated by monetary gain as the justifications for awarding the CON are exaggerated. The basis of the ECL application is that the stone disease population needs in eastern North Carolina from a lithotripsy standpoint are not met with the current provider and that many Urologists in the region are asking for additional provider services. Well, this is simply not true.

Lithotripsy utilization nationally and statewide has declined over the last 5-10 years. This is not a function of our current provider, Carolina Lithotripsy, not being able to keep pace with demand but rather a sign of a change in practice patterns by a younger generation of Urologists. Patient slots at each facility are dictated by demand and the demand for additional services has just not been there. There are instances when a patient may have to wait an additional week for treatment because a particular day may be full but that is exceedingly rare. At any rate, shockwave lithotripsy (SWL) is not the treatment of choice for the patient with the acute stone episode. SWL patients are typically minimally to moderately symptomatic and are stable. If these standard of care guideline are followed and our current utilization patterns persist then there is no need for additional lithotripsy services in eastern North Carolina. Thank you for your consideration.

Sincerely,

Hugh Mallory Reeves, Jr., MD, FACS

Vice President, Eastern Urological Associates, PA

Affiliate Clinical Professor of Surgery

East Carolina University, Brody School of Medicine

Eastern UROLOGICAL Associates, P.A.

RE: Eastern Carolina Lithotripsy CON Application

July 28, 2016

To Whom It May Concern:

I have been practicing Urology in Eastern North Carolina since 2007 and am appalled at the misrepresentations made in the CON application referenced above. As a native of this area growing up in a small farming community in Craven County, I am proud of the Lithotripsy services that are currently in place and servicing this area of the state. I hope that those with a vote in this issue do not vote in favor of granting this CON as it would actually be detrimental to our area.

There are more issues than can be completely covered in this letter but I would like to highlight a few items. First, quality has been of utmost importance to us and I believe our group monitors and provides follow up on quality measures far beyond most groups in this state let alone the country. Secondly, access to care in our area is always an issue but Lithotripsy services are one of the few areas where there are very little in the way of wait times and it is quite convenient for the public. Contrary to the what the application implies, patients often choose Lithotripsy instead of surgery because Lithotripsy is more readily available than surgical options. Volumes for Lithotripsy across the country are down significantly over the past decade so making the argument that we need more companies providing that service is quite ridiculous. Furthermore, we have made efforts to provide this service to those who lack insurance which shows the commitment to our patients in this area of the state.

Without laboring through a host of other details that I believe are either false or misleading in the application, I again encourage those with a vote to deny the CON as I believe the citizens of Eastern North Carolina have been well served by this group for over 30 years and hopefully for a long tern to come. If there are any questions or concerns please feel free to call or contact me.

Sincerely,

Jonathan H. Taylor, MD FACS
Associate Clinical Instructor
East Carolina School of Medicine
Department of Surgery
Eastern Urological Associates

July 27, 2016

To whom it may concern:

It has come to my attention that a business known as Eastern Carolina Lithotripsy (ECL) has submitted an application to the state alleging that the urologists of Craven County are frustrated by the services of the existing lithotripsy provider, Carolina Lithotripsy. As one of only seven urologists operating in Craven County, I was surprised to hear about this. To my knowledge, the owners of ECL did not solicit the opinions of any Craven County urologists aside from their colleague, Dr. Robert Whitmore. I can speak only for myself, but since I began working at CarolinaEast two years ago, I have not had a single patient who has been turned away from lithotripsy, or had their lithotripsy procedure delayed because of a lack of access. Actually, I have had many days that I was scheduled to perform lithotripsy but had no patients who needed the service.

It has been suggested that with increased access to extracorporeal shock wave lithotripsy (ESWL), CarolinaEast will be performing 30 procedures per month by 2020, up from a supposed 10 per month at the current time. Reasonable people may disagree about the utility of increasing lithotripsy availability, but to suggest that the number of ESWL procedures could reach that level over the next 4 years betrays a basic lack of understanding of current surgical stone management.

Ureteroscopy is the principal procedure that competes with ESWL for management of renal and ureteral stones. Over the last 10-15 years, the performance of the technology used for ureteroscopy has undergone revolutionary improvement. Put simply, ureteroscopy is safer and more effective than ESWL for a greater number of kidney stones every year. This is reflected in recent guidelines by the American Urological Association. Note that it is not the *availability* of ureteroscopy that makes it superior for many kidney stones, but rather improved efficacy for stones at many locations within the urinary tract. For this reason referrals to lithotripsy have been in decline nationally over the last few years. They have been in decline at CarolinaEast for the same reason. In the last 6 months we have performed only 33 lithotripsies in Craven County, despite having 93 slots available. Note also that this is just over 5 procedures/month, rather than the 10 reported in support of the ECL Certificate of Need. Tripling the populations of Craven, Pamlico, and Jones Counties could probably produce a demand for 15 ESWLs per month, but opening up another half day on the schedule for ESWL most certainly will not.

Most major medical centers in this country share their lithotripters with other hospitals, and offer ESWL one day per week. I would consider this a national standard of care. ESWL is not an emergency procedure, and patients usually need to wait 5-7 days after discontinuing their NSAIDs and anti-platelet medications before having the procedure. For this reason, I would not expect to refer any more patients to ESWL even if it became available two days per week or five days per week. ESWL is an excellent treatment for a small and select group of patients, and I believe that our current lithotripsy capacity is more than adequate to cover CarolinaEast's current and future patients, Center of Excellence or not.

I applaud any investment in the medical infrastructure of eastern North Carolina. I can only wish ECL the best with what appears to be an audacious investment decision. Please take note, however, that the demand for ESWL in Craven County is not accurately represented by their Certificate of Need application.

If you have any additional questions on this matter, please feel free to contact me.

Sincerely,

Hoyt B Doak IV MD

Hoyt B. Doak, MD
CarolinaEast Urology Center
705 Newman Rd.
New Bern, NC 28562
252-633-2712

July 27, 2016

George Mark Doyle, MD
Carolina East Urology
705 Newman Rd
New Bern, NC 28562

To Whom It May Concern:

I was recently informed that a Certificate of Need application was submitted for another lithotripter in Eastern North Carolina. At no point was the application discussed with the majority of physicians who actually take care of these patients and perform lithotripsy. The physician who helped initiate this process has cut back significantly on his surgical care of stone patients over the past 6 months.

My patients have only experienced a delay of service on rare occasions due to the breakdown of equipment. Our current utilization is less than 50% of the designated ESWL slots at Carolina East Health Care Systems. Current treatment recommendations for stones are moving towards ureteroscopy and away from ESWL. Our hospital is currently developing a "Center of Excellence" for stone management. One of the primary goals of this effort is to reduce stone formation by non-surgical alternatives. Given these facts, I do not anticipate a significant increase in need for ESWL availability.

In addition, I am concerned that the LithoGold lithotripter does not provide a registered nurse during treatments. I believe this has the potential to increase patient risk if there is an unanticipated event.

I hope this helps in your decision process.

Sincerely,

George Mark Doyle, MD

Debbie Scott

From: Ryan Holland <ryan.holland@gmail.com>
Sent: Friday, July 29, 2016 6:46 AM
To: Debbie Scott
Subject: Re: Carolina Lithotripsy

Debbie,

It has been a crazy week. Please see my letter below.

To whom it may concern,

This remark is written to underscore the lack of need for another lithotripter to treat kidney stones at CarolinaEast Medical center.

As a urologic surgeon working at that particular hospital, I can say without any doubt that our current lithotripter service (Carolina Lithotripsy) is not running at full capacity. Said another way, if there were more patients with kidney stones that needed lithotripsy, they would get excellent and timely treatment at our medical center.

It is well known that the incidence of kidney stones is rising nationally. The number of lithotripsies being performed nationally, however, has been shown to be decreasing. This is due to advances in minimally invasive surgical techniques for kidney stone removal. I see a trend locally and nationally for the use of lithotripsy to remain stable or even continue to decrease.

The access to kidney stone care at CarolinaEast medical center is outstanding and will remain so without the addition of a CON for another lithotripter unit. Regardless, we will continue to provide the highest level of kidney stone care to to Craven county and its surrounding region including all of Eastern North Carolina.

Ryan Holland

On Thursday, July 28, 2016, Debbie Scott <debbie.scott@healthtronics.com> wrote:

> Dr. Holland,
>
> Will you able to respond to my email below so that I can include it in our comment response regarding Eastern Carolina Lithotripsy's CON application? I need the responses by tonight if possible.
>
> Thanks,
>
> Debbie

Debbie Scott

Vice President – Customer Relations

HealthTronics, Inc | 9825 Spectrum Dr, Bldg 3 | Austin, TX 78717

July 26, 2016

Thomas S. Stewart, MD, MBA, FACS
CarolinaEast Urology
705 Newman Rd.
New Bern, NC 28562

To Whom it may Concern:

I recently learned that a Certificate of Need application was submitted for additional lithotripsy services in eastern North Carolina, and Carolina East was one of the hospitals listed in the application. This application was submitted without the support or even the knowledge of the majority of urologists at this hospital. In fact, to my understanding only one of seven urologists was even aware of the application. Dr. Robert Whitmore, the lone urologist to send a letter of support from our group, is actually scaling back his practice such that he no longer takes call, no longer performs lithotripsy, and has curtailed most of his operative practice including a majority of his operative stone cases.

Currently Carolina East has 3 lithotripsy slots per week, on Friday morning. The day of the week and number of slots was dictated by the hospital. The urologists and Carolina Lithotripsy, the current supplier of lithotripsy services, have requested additional slots and options for different days of the week, and these have been refused by the hospital.

Currently the availability of lithotripsy services with our current provider exceed the our current need. If you look at the numbers from the beginning of the year, we have used 8 out of 15 slots in January, 5/12 in February, 2/12 in March, 8/15 in April, 1/12 in May, 6/12 in June, and although we filled 7/12 slots in July, we had 0/3 last week. If you total them up this is 37 out of 90 slots, or a utilization of 41%.

We have had times when patients had to wait additional time for lithotripsy services. This is rare, but when this has happened it occurred because of the hospital's unwillingness to allow us additional time, not lack of lithotripsy services. We have asked multiple times for more availability and have been refused. Addition of a fourth slot would likely have alleviated these delays, and the physicians and lithotripsy provider would have accommodated (and both strongly requested) if the hospital would have been willing to provide support for it. The hospital administration is well aware of this fact as we have discussed this in multiple meetings with the urologists and members of the administration.

I hope these facts will help you understand why a Certificate of Need is clearly not appropriate for this application, and should not be granted.

Respectfully yours,

Thomas S. Stewart, MD, MBA, FACS

Debbie Scott

From: reed underhill <reed_underhill@yahoo.com>
Sent: Wednesday, July 27, 2016 7:40 AM
To: Debbie Scott
Subject: Re: Carolina East Medical Center

I would like to say it false that Litho services are so busy that we in Eastern NC need another machine. The number of procedures has actually gone down significantly over the last number of years so there is no need for another machine. Also when we have tried to add on extra our pre and post op areas have said they cannot handle extra cases. I also noticed the cost of the extra machine is significantly higher for commercial payers. $2,900 verse $[redacted] do not see any need for another machine. We are not under served in Eastern N. C.-- Reed Underhill MD
Sent from Yahoo Mail on Android

On Tue, Jul 26, 2016 at 5:53 PM, Debbie Scott
<debbie.scott@healthtronics.com> wrote:

Dr. Underhill,

I wanted to bring a matter to your attention regarding our service at Carolina East Medical Center. Triangle Lithotripsy (under the name of Eastern Carolina Lithotripsy) has filed an application with the State Planning Board to be granted a new CON for lithotripsy that is going to be awarded this year. In their application, they have targeted 4 host sites for their new lithotripter; one of those sites is Carolina East Medical Center in New Bern. In exhibits to their applications, they have provided support letters from Mr. Raymond Leggett and Dr. Robert Whitmore.

Among their reasons for requesting the new CON are:

1) The lack of available ESWL services in eastern North Carolina;

2) The need for developing a Kidney Stone Center of Excellence for all residents of eastern North Carolina;

3) Patients who are candidates for ESWL treatment often wait one to two weeks for services with some sites getting as little as one day per month.

4) They state that urologists in Pitt and Craven counties reflect frustration with Carolina Lithotripsy's responsiveness to their accessibility concerns.

Their application proposes:

1) They will provide service 1 day per week at Carolina East Medical Center with a LithoGold lithotripter.

2) They do not provide the use of a registered nurse.

3) Their proposed pricing would be $2900 for commercial patients and $1900 for government patients. (Carolina Lithotripsy's pricing at Carolina East is $[redacted] for all patients regardless of insurance type.)