

Development of a surgical decision aid for patients with nephrolithiasis: Shockwave lithotripsy versus ureteroscopy

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Running Title: Surgical decision aid: SWL vs URS

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Abstract: Introduction and Objective: Shared decision-making is recommended to guide medical/surgical treatment strategies. We aimed to develop a surgical decision aid (SDA) facilitating decision-making between ureteroscopy (URS) or shockwave lithotripsy (SWL) in patients with symptomatic nephrolithiasis.

Methods: The SDA scope was identified through discussions with patients and urologists in the Michigan Urological Surgery Improvement Collaborative (MUSIC). Steering committee of patient advocates, MUSIC coordinating center, content experts, biostatisticians and urologists was formed. Content domains were assessed through best available evidence and content experts. For content validation we anonymously surveyed 35 MUSIC urologists. Content Validity Ratios (CVR), numeric value indicating degree of expert validity, were calculated. Face validation interviews were conducted with patient advocates.

Results: SDA prototype using descriptive plain language and pictorial information was designed for nephrolithiasis patients, candidates for SWL or URS. It first provides patients procedural education while the second section informs urologists of patient goals. Six content domains were chosen: anesthesia type, effectiveness, number of procedures, risk, pain and recovery. 91.4% and 85.7% of MUSIC urologists indicated that each section accomplished their goals, respectively. Anesthesia received an unacceptable CVR. High levels of face validation overall were reported with unacceptable scoring for anesthesia and recovery.

Conclusions: We developed a SDA facilitating treatment choice between SWL and URS with promising content and face validity. Agreement and contradiction between anesthesia type and recovery validation results indicate the importance of shared decision-making and the need for a validated SDA. Future work should focus on the SDAs value and opportunities for refinement in practice.

Introduction

Shared decision-making is the process of balancing the best available evidence with patients' preferences and values to reach a medical decision.¹ This process is most relevant in decisional scenarios where the risk/benefit ratio is uncertain, equivalent or preference sensitive.² Shared decision-making is recommended by the National Academy of Medicine, Affordable Care Act, and several American Urological Association (AUA) guideline statements.² Specifically, the AUA recommends shared decision-making to help deciding between ureteroscopy (URS) or shockwave lithotripsy (SWL) in patients with non-lower pole nephrolithiasis ≤ 2 cm.³ Yet, in the state of Michigan, wide variation in treatment modality exists for these patients with many urologists exclusively utilizing only one procedure for these patients,⁴ sometimes contrary to guideline recommendations.⁵ URS and SWL are both minimally invasive treatment options that are the most common surgical intervention for patients with nephrolithiasis, a condition that is estimated to affect 11% of the population.^{6,7} AUA guidelines recommend offering both URS or SWL to patients with symptomatic renal stones ≤ 2 cm and lower pole renal stone ≤ 1 cm.³ Given the relatively high incidence of nephrolithiasis, the subsequent commonality of its surgical treatment, and the seemingly inequitable variability of treatment choice, it is important to improve the quality of the decision-making process for patients.

Shared decision-making is underutilized in practice.² Clinicians report that the process is too time consuming⁸ and data suggests that less than 10% of providers utilize shared decision-making correctly.⁹ Moreover, defining and measuring outcomes of this process is inexact, making study of quality metrics difficult.¹⁰ Decision aids are tools that facilitate shared decision-making and evidence suggests that decision aid use leads to increased patient knowledge, more accurate risk perceptions, and alignment between care options and patient values.¹¹ Prior work in endourology has demonstrated that decision aid use is well accepted by patients, has a positive impact on patients' level of stone disease and treatment options knowledge.^{12,13} A Cochrane review on the use of decision aids for patients facing treatment decisions found evidence of improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation.¹⁴ An increased level of disease and treatment specific knowledge has the

potential to improve the patients' contribution to the shared decision-making process, however, there remains a paucity of widely utilized, validated decision aids for all eligible patients deciding between URS and SWL.¹⁵

Therefore, we aimed to develop a surgical decision aid (SDA) to facilitate shared treatment decision-making between URS and SWL for the treatment of nephrolithiasis. The Michigan Urological Surgery Improvement Collaborative (MUSIC) has a successful track record of implementing decision aids as demonstrated in prior work for patients diagnosed with prostate cancer.¹⁶ MUSIC is a physician-led consortium of urology practices across the state of Michigan focused on improving the quality and cost efficiency of urological care.^{17, 18} The characteristics of the most widely accepted shared decision-making model include involvement of both the physician and the patient in the process, sharing information with each other, building consensus through the expression of preferences, and mutual agreement on the decision.¹⁹ Using this unique statewide surgical collaborative, we sought to understand the patient and urologist perspective on what aspects of this treatment decision are important and develop a useful SDA in a real-world setting.

Materials and Methods

The International Patient Decision Aids Standards (IPDAS) and the Ottawa Decision Support Framework were used to guide the systematic development of the SDA.²⁰ The scope of the SDA was identified through formal and informal discussions with patients, patient advocates and MUSIC urologists. The Reducing Operative Complications from Kidney Stones (ROCKS) initiative was started in 2016 and currently comprises 38 community and academic urology practices in the state.⁵ ROCKS maintains a clinical registry of URS and SWL procedures performed by these practices and urologists. Each MUSIC practice has obtained an exemption or approval by the local institutional review board for participation in the collaborative. Utilizing this infrastructure, we developed the MUSIC ROCKS SDA.

Steering Committee

A steering committee consisting of three patient advocates who had previously undergone surgery for nephrolithiasis, MUSIC coordinating center personnel, one methodological expert, one biostatistician, and six clinical expert endourologists was established. Using an iterative feedback process, each step in the development of the SDA was planned or reviewed by the steering committee.

Content Domains

Content domains were assessed through best available evidence and content experts. A literature review was performed to identify similar SDAs. Then, the AUA, European Association of Urology (EAU), and Canadian Urological Association (CUA) guidelines were reviewed to identify the accepted differences in the delivery, patient experience and outcomes of SWL versus URS only.

A literature review was performed across areas identified by the steering committee as important to patients and providers when selecting a surgical modality to characterize the outcomes of each treatment. Each treatment option's harms and benefits descriptions were reviewed by the steering committee to ensure the presentation and information is provided in an unbiased manner using evidence-based outcomes from the medical literature.

SDA Development

Literature review was performed by the steering committee to understand how SDA are delivered. The SDA was initially drafted to introduce both the decision being made and the question that the aid is designed to address, clarify the target audience, and describe the medical condition and the treatment options included in simple language. Then, each treatment's indications, harms, benefits, and expectation were described. Once completed, patients would be asked to clarify and communicate their values. The steering committee provided feedback regarding the structure and formatting of the SDA.

Validation

For content validation, we conducted an anonymous survey of MUSIC urologists who perform at least 10 URS or SWL procedures annually. Content Validity Ratios (CVR), a numeric value indicating degree of expert validity, were calculated as described by Yusoff.²¹ The value should be >0.78 for a domain to be considered valid. Face validation interviews were conducted with patient advocates. The results of the content and face validation processes were then reviewed and analyzed by the steering committee. These data were utilized to develop the final version of the SDA (Supplement A).

Results

Content Domains

The SDA was divided according to treatment modality (URS versus SWL). The literature review identified patient and clinical factors to help differentiate between treatment modality and associated outcomes. The steering committee selected the following domains as important areas of differences in the delivery and outcomes of URS vs SWL, where a SDA would be applicable: anesthesia type, treatment effectiveness, number of procedures required, risk of complications, pain and recovery time associated with the treatment.

SDA Development

A two-page SDA prototype using descriptive plain language and pictorial information was designed. Page 1 addressed patient facing educational information and page 2 informed urologists of patient treatment goals. Educational information was oriented around the six content domains.

Validation

Content validation: 35 MUSIC urologists were surveyed anonymously. 91.4% of urologists reported that Page 1 accomplished the goal of educating patients and 85.7% reported that Page 2 accomplished the goal of presenting patients treatment goals (Table 1). The content validity index was calculated for each domain. Anesthesia type was the only domain to receive a lower than acceptable with a CVR of 0.43.

Face validation: Patient advocates' demographics and procedure history were obtained and are reported in table 2. Patient advocates reported high levels of face validation (Table 2). Anesthesia type and recovery time were the only domains to receive lower than 100% relevance agreement. The results of the content and face validation processes were then reviewed and analyzed by the steering committee.

SDA Refinement

Results of the content and face validations were reviewed. Due to the low content and face validation scores of anesthesia type domain, the two-page SDA prototype was refined by removing this domain from the tool. (Supplement A)

Discussion

We developed and validated a novel SDA for patients with nephrolithiasis deciding between SWL and URS treatment. In doing so, we evaluated the best available evidence and the prevailing opinions as to what aspects of the decision-making process are important to patients and urologists in the state of Michigan. Our work has multiple key findings. First, our steering committee found that anesthesia type, effectiveness, number of procedures, risk, pain and recovery were the most important areas where URS and SWL differ. Second, the SDA received acceptably high overall content and face validity from practicing urologists and patient advocates. Third, while the steering committee identified anesthesia type as an important area where URS and SWL differ, both patients and practicing urologists do not find anesthesia type relevant to the decision-making process. Lastly, patients did not feel that recovery time was relevant to their decision-making process. Collectively, these findings of overlap and divergence between content experts, practicing urologists and patients regarding the relevance of differing aspect of URS and SWL, indicates the importance of improving the shared decision-making process for patients considering these treatments.

AUA guidelines recommend offering both URS or SWL to patients with symptomatic renal stones ≤ 2 cm and lower pole renal stone ≤ 1 cm.³ The reported treatment differences in the delivery, outcomes, and patient experience between URS and SWL include anesthesia type required for the procedure, effectiveness of the intervention,

number of procedures typically required for treatment, risks of the procedure, postoperative pain, and recovery.^{3,22} Despite this, patients with nephrolithiasis usually have more than one acceptable treatment option,¹² and the choice is often not straight forward. Gokce et al. reported the development and validation of a SDA for patients symptomatic non-lower pole renal stones <2 cm.¹³ This SDA was developed in a booklet format which provided written information for patients describing general information of stone disease, SWL and URS procedures along with their respective success and complication rates. After receiving acceptable validation results, this SDA was later tested in a randomized trial of 113 patients, finding that patients who utilized the SDA had higher levels of knowledge and lower levels of decisional conflict.¹³ These results are encouraging as we developed a SDA for all patients eligible for URS or SWL that not only is designed to inform patients but also to inform urologists of the patient goals of care. We believe that with the addition of pictorial information, identifiable validated decisional domains that facilitates shared decision-making during the urologist evaluation, the MUSIC ROCKS SDA will provide higher value for patients and urologists.

Prior work surveying 100 patients with nephrolithiasis by Omar and colleagues reported that the most important variables impacting treatment choice were success rate and risks of the surgery.²³ Their study also identified that avoiding general anesthesia was an important factor in the decision-making process.²³ We found that both patients and urologists did not find anesthesia type relevant to the decision-making process. In general, it is understood that SWL can be performed without general anesthesia whereas URS typically requires it. We identified this distinction as an appropriate domain for the SDA due to steering committee expert panel. Interestingly, both the content and face validation of our SDA resulted in low levels of importance, informing us to remove it from the tool. The rationale behind why this domain is deemed not important to the treatment decision is an area of future study, but in contradiction to prior work and available patient information, patient choice between URS and SWL appears unaffected by consideration of general anesthesia.

Postoperative pain and morbidity after treatment for nephrolithiasis can result in significant lost economic revenue due to work incapacity.²⁴ However, we identified

discordance in face and content validation with regard to procedure recovery time. While urologists deemed it important to the decision-making process, our patients did not feel that recovery time was relevant to their treatment choice. This domain was kept in the final version of SDA due to its acceptable content validity results. A prior survey study of urologists identified the most important surgeon factors influencing treatment choice were: practice location (community versus academic), time since training, lithotripter ownership, concern for stent pain, and surgeon stated modality preference.²⁵ The contradictory results regarding recovery time in our study and discrepancies between what influences urologist treatment recommendation and patient decision illustrates the need for shared decision-making assisted by a SDA to inform patients about realistic expectations of their options and to inform urologists about their patients' goals and preferences. Shared decision-making ideally works to bridge the gap between the urologist expertise and patient goals of treatment. The utilization of a validated SDA in practice may help to ensure and provide a framework for a shared decision-making process.

While the MUSIC ROCKS infrastructure includes a variety of patients and urologists across the state of Michigan which enables representation of real-world practice, limitations are noted. Face validation was conducted via videoconference survey with three MUSIC ROCKS patient advocates. Additionally, all patient advocates identified as white and had high levels of education. All the advocates had previously undergone URS procedures only. While validation can be completed with limited sample sizes, the results would be more generalizable with a larger and more diverse population. However, MUSIC ROCKS patient advocates volunteer and are selected due to their knowledge and passion for the disease process and the patients they represent. Their answers reflect their own personally experiences in the context of how most patients would likely respond. As a next step in implementation, we will be soliciting feedback from patients who utilize the SDA.

Limitations notwithstanding, our work has several implications. We identified important and validated domains for both patients and urologists in the decision-making process. We also identified areas of where patient and urologist results disagree. Future work will focus on evaluating the outcomes of SDA utilization in practice for both the patients and the urologists. ROCKS Patient Reported Outcomes (PRO) is an automated

system that collects patient reported outcomes data, including treatment satisfaction, after URS and SWL procedures through email surveys and text messages in MUSIC ROCKS. We plan to utilize this to understand the differences in patients who do and do not utilize the SDA in their preoperative decision-making process after either URS or SWL. We will also seek broader feedback from patients who utilized the SDA to understand if further refinement is required. Additionally, because MUSIC ROCKS tracks case selection and volume by both urologists and practices, it is uniquely positioned to study how the implementation of this SDA changes practice in the collaborative.

Conclusion

We developed a SDA to facilitate shared decision-making in the treatment choice between SWL and URS with promising content and face validity. Agreement and contradiction between content and face validation regarding the relevance of anesthesia type and recovery time indicate the importance of shared decision-making and the need for a validated SDA in practice to help provide a framework for a shared decision-making process. Future work is required to determine the SDAs clinical utility and to understand its potential ability to improve patient knowledge, values concordant treatment choices and treatment satisfaction.

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Authorship confirmation/contribution statement

All authors have made a substantial contribution to the concept or design of the article; or the acquisition, analysis, or interpretation of data for the article; AND drafted the article or revised it critically for important intellectual content; AND approved the version to be published; AND agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Author(s') disclosure (Conflict of Interest) statement(s)

None of the authors any relevant conflicts of interest to disclose.

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Tables**Table 1:** Expert panel surgical decision aid content validity survey results

	Yes (n)	I-CVI	CVR
Page 1 accomplishes stated goal	32	.914	-
Page 2 accomplishes stated goal	30	.857	-
Domain relevance			
- Anesthesia	25	.714	0.429
- Effectiveness	32	.914	0.829
- Number	32	.914	0.829
- Risk	33	.943	0.886
- Pain	34	.971	0.943
- Recovery	32	.914	0.829
Scale CVI		.893	

I-CVI – Item Content Validity Index; CVR – Content Validity Ratio

Table 2: Patient advocate surgical decision aid face validity interview responses

	PA 1	PA 2	PA 3
Age	71	69	50
Primary language	English	English	English
Gender	Female	Male	Male
Race	White	White	White
Education level	Doctorate	Bachelor	PhD
Urologic history			
- Number of procedures	2	1	1
- Stone location	Ureter	Kidney	Ureter
- Procedure	URS x 2	URS x 1	URS x 1
- Stent history	Yes	No	Yes

PA – Patient advocate; PHD – Doctor of Philosophy; URS – Ureteroscopy

Table 3: Patient advocate surgical decision aid face validity interview responses

Evaluation Questions	P A 1	P A 2	PA 3	Yes
I understand the advantages of the options given	Ye s	Ye s	Yes	100 %
I understand the disadvantages of the options given	N o	Ye s	Yes	67 %
I feel like the aid would help make a more informed decision	Ye s	Ye s	Yes	100 %
I feel like the aid would help me feel more involved in the decision-making process	Ye s	Ye s	Yes	100 %
I feel like the aid is presented in a balanced manner	Ye s	Ye s	Yes	100 %
Domain Relevance				
- Anesthesia	Ye s	N o	No	33 %
- Effectiveness	Ye s	Ye s	Yes	100 %
- Number of procedures	Ye s	Ye s	Yes	100 %
- Risk of complications	Ye s	Ye s	Yes	100 %
- Pain	Ye	Ye	Yes	100

				18
	s	s		%
	Ye	N		33 %
- Recovery time	s	o	No	

	P A 1	P A 2	PA 3	Mea n
- The information is sufficient for the goals of the Decision Aid	4	4	5	4.3
- The information is clearly provided	5	5	5	5
- The decision aid is useful	5	5	5	5
- The decision aid helped improve my knowledge	5	5	5	5
- I would recommend this aid to others	5	5	5	5
- Overall, can you score the decision aid?	4	5	5	4.7

PA – Patient Advocate

Figures



Figure 1. Summary of the MUSIC ROCKS SDA study stages

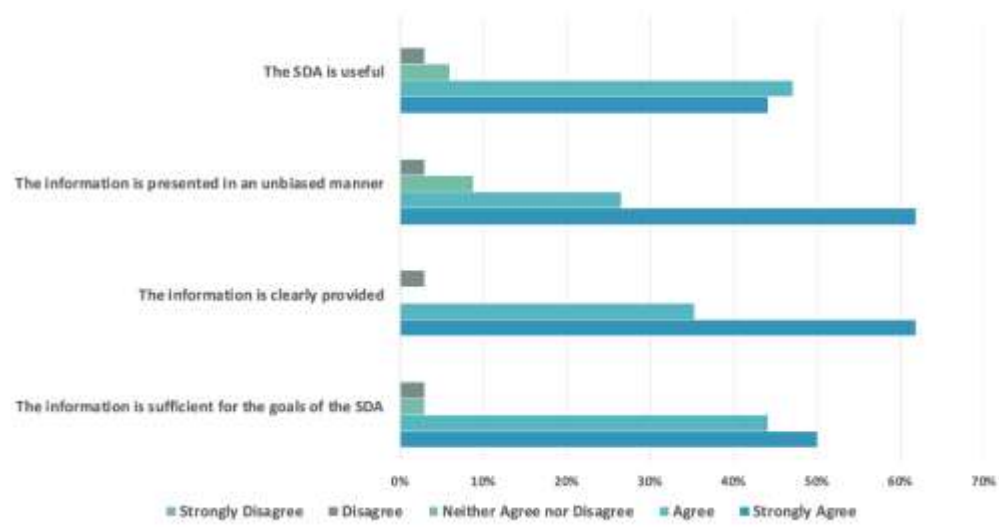


Figure 2. Expert panel surgical decision aid content LikertScale Evaluation survey results

ABBREVIATIONS:

AUA	-	American Urological Association
URS	-	Ureteroscopy
SWL	-	Shockwave Lithotripsy
SDA	-	Surgical Decision Aid
MUSIC	-	Michigan Urological Surgery Improvement Collaborative
IPDAS	-	International Patient Decision Aids Standards
ROCKS	-	Reducing Operative Complications from Kidney Stones
EAU	-	European Association of Urology
CUA	-	Canadian Urological Association
CVR	-	Content Validity Ratio