# Shared decision-making for the management of small renal masses: Development and acceptability testing of a novel patient decision aid

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# Abstract

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**Introduction:** Shared decision-making incorporates patients' values and preferences to achieve high-quality decisions. The objective of this study was to develop an acceptable patient decision aid to facilitate shared decision-making for the management of small renal masses (SRMs).

**Methods:** The International Patient Decision Aids Standards were used to guide an evidence-based development process. Management options included active surveillance, thermal ablation, partial nephrectomy, and radical nephrectomy. A literature review was performed to provide incidence rates for outcomes of each option. Once a prototype was complete, alpha-testing was performed using a 10-question survey to assess acceptability with patients, patient advocates, urologists, and methodological experts. The primary outcome was acceptability of the decision aid.

**Results:** A novel patient decision aid was created to facilitate shared decision-making for the management of SRMs. Acceptability testing was performed with 20 patients, 10 urologists, two patient advocates, and one methodological expert. Responders indicated the decision aid was appropriate in length (82%, 27/33), well-balanced (82%, 27/33), and had language that was easy to follow (94%, 31/33). All patient responders felt the decision aid would have been helpful during their consultation and would recommend the decision aid for future patients (100%, 20/20). Most urologists reported they intend to use the decision aid (90%, 9/10).

**Conclusions:** A novel patient decision aid was created to facilitate shared decision-making for management of SRMs. This clinical tool was acceptable with patients, patient advocates, and urologists and is freely available at: *https://decisionaid.ohri.ca/decaids.html*.

#### Introduction

Small renal masses (SRMs) are typically defined as solid lesions in the kidney measuring <4 cm. Surgical removal, active surveillance, and thermal ablation each provide excellent short-term cancer-specific survival (all >90% over five years) yet vary significantly in their short-term and long-term risks and benefits.<sup>1-3</sup> The choice for which management option is best for a specific patient depends on patient factors, tumor characteristics, surgeon factors, and the patient's values and preferences.

When several management options are available, patients should be encouraged to weigh the risks and benefits across options and to determine their values when deciding on a treatment option.<sup>2</sup> Studies have shown that high-quality decisions can be achieved when patients are encouraged to clarify and communicate their values, and have the opportunity to determine which management option best matches their individual preferences.<sup>4</sup>

Patient decision aids (PtDAs) are clinical tools that facilitate shared decision-making for a population of patients facing a challenging decision. At a minimum, a PtDA must explain the decision to be made, present the available management options (including risks and benefits), and help patients communicate their values and preferences.<sup>5</sup> A systematic review of over 100 PtDA trials showed improved knowledge, more realistic expectations, lower decisional conflict, and higher participation compared to usual care.<sup>5</sup> The objective of this study was to create a novel, evidencebased PtDA for the management of SRMs and to assess the PtDA for acceptability with patients, patient advocates, urologists, and methodological experts.

# Methods

Institutional ethics board approval was obtained (OHSN-REB 20170729-01H). The International Patient Decision Aids Standards were used to guide the systematic development of the PtDA.<sup>4</sup> The International Patient Decision Aids Standards are a set of criteria that were agreed upon by shared decision-making experts to standardize the development, implementation, and evaluation of high-quality PtDAs.<sup>4</sup> The Ottawa Decision Support Framework was used to guide the evidence-based approach to our PtDA development.<sup>6</sup>

We have previously published the process for developing a high-quality PtDA (Fig. 1).<sup>7,8</sup> The structured process includes: a) needs assessment for decisional support; b) formation of a steering committee; c) literature review; d) determining management options and outcomes to include; e) creation of PtDA prototype; f) acceptability testing (alpha-testing); f) updating PtDA with feedback from alpha-testing to create final product; and g) validation testing.<sup>7-9</sup>

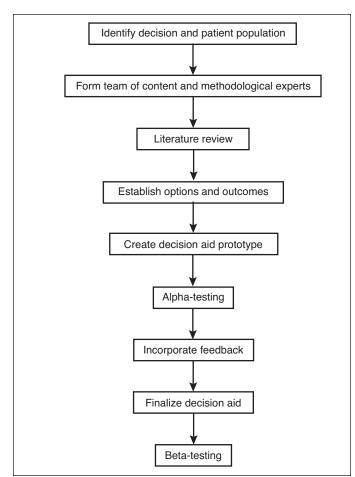


Fig. 1. Development process of patient decision aid. Recreated from Coulter et al (2013).  $^{7:9}$ 

# Needs assessment

A previous survey of kidney cancer experts highlighted the development of decisional tools for kidney cancer patients as one of the top 10 priorities for kidney cancer research.<sup>10</sup> Surveys of patients who have previously been treated for kidney tumors show most patients and caregivers report inadequate resources for patients.<sup>11</sup> These studies confirmed the need for a PtDA to support the decision for management of SRMs.

### Creation of steering committee

A steering committee was assembled that included content and process experts. Content experts included five academic urologic oncologists. Process experts included an international leader in the development and evaluation of PtDAs, a urology resident, and a research assistant. In addition, feedback was solicited from kidney cancer patients and patient advocacy groups to inform the committee of perceived resource gaps and topics of interest for inclusion.

### Literature review for management options and outcomes

A thorough literature review was performed to determine the best available evidence for management of SRMs. Medline, EMBASE, and Ovid databases were searched. Current practice guidelines from urological associations were referenced and sources cited were reviewed.<sup>12-14</sup> The literature was searched for the highest quality of evidence on outcomes for each management option. Once the literature review was completed, the management options and outcomes were discussed by the steering committee until consensus was reached.

# Alpha-testing

A prototype of the PtDA was created and alpha-testing was performed to assess the acceptability. Stakeholders, including patients, urologists, patient advocates, and methodological experts, were invited to review the PtDA prototype and complete the alpha-testing. Patient responders were individuals who had previously faced the decision regarding management of a SRM. Urologists were individuals who routinely see patients with SRMs in consultation, provide counselling and perform/order all the proposed management options. Patient advocates were representatives from kidney cancer organizations who are highly involved in patient advocacy. Finally, methodological experts were individuals with an advanced degree in the study of shared decision-making.

Alpha testing was performed by inviting individuals to review the PtDA and answer a 10-question survey that was based on a validated acceptability scoring system (Appendix 1; available at *cuaj.ca*).<sup>15</sup> Patients completed the

Risk – Post-treatment bleeding	MIS radical (total) nephrectomy	MIS partial (sub-total) nephrectomy	Open partial (sub-total) nephrectomy	Tissue ablation	Active surveillance (No surgical treatment)
After treatment, the chance of having bleeding requiring a blood transfustion is: <sup>1,8-10</sup>					
	<ul> <li>a post-operative bleed</li> </ul>	©©©©©©©©©©© ©©©©©©©©©©©©©©©©©©©©©©©©©©	©©©©©©©©©©©©©©©©©©©©©©©©©©©©©©©©©©©©©©	<ul> <li>after treatment</li> </ul>	©0000000000 ©0000000000 © have bleeding

Fig. 2. Pictorial representation of outcomes. This diagram presents the rates of post-treatment bleeding for each treatment option.

survey at the end of their routine urology followup clinic appointment. Urologists, patient advocates, and methodological experts completed an online survey after reviewing the PtDA prototype.

Survey results were analyzed with descriptive analyses. All feedback provided was reviewed by the steering committee and used to update the PtDA prototype to create a final product. We intended for the PtDA to be used as a handout after or in conjunction with a patient's initial consultation with their urologist. This would allow patients to understand the context of the decision and would provide time to allow clarification of their personal preferences and values before a decision was made.

#### Results

Following the International Patient Decision Aids Standards, an evidence-based PtDA was created.

#### Literature review

The literature review revealed three current practice guidelines on the management of localized renal masses.<sup>12-14</sup> There were five systematic reviews and meta-analyses, one randomized controlled trial, two prospective cohorts, and several retrospective studies that reported data relevant to the PtDA.<sup>1,3,16-26</sup> Summary of evidence tables were created to synthesize the data (Supplementary Table 1; available in Appendix 2 at *cuaj.ca*).

#### Patient decision aid prototype

Following the literature review, a prototype of the PtDA was created. The PtDA specifically indicated that a decision needs to be made. The management options included were active surveillance, thermal ablation, minimally invasive (laparoscopic, robotic) partial nephrectomy, open partial nephrectomy, and minimally invasive radical nephrectomy. Open radical nephrectomy was not included as an option, as it is invasive and is not standard of care for the management of SRMs.<sup>12</sup> Information regarding the role of renal mass biopsy was included to provide patient education on this component of SRM management. While the results of a renal mass biopsy may be important and influence management decisions for SRMs, this PtDA does not explicitly address whether or not to have a renal mass biopsy because decision aids are designed to address one decision. The steering committee viewed the decision to perform a biopsy as separate from management of the SRM because many patients may be managed without having a biopsy. For example, some patients may select surveillance without a biopsy if the mass is small or they have competing risks. The PtDA does educate patients about renal mass biopsy and encourages them to discuss this topic with their urologist.

The benefits included on the PtDA were cancer-specific survival at five years, disease-free survival at five years, and length of hospital stay. Harms included were probability of metastases at five years, major complications from treatment (Clavien-Dindo grades III–IV), post-treatment urine leak, post-treatment bleeding, rates of renal replacement therapy at five years, expected incisions, and probability of flank bulge. Outcomes were presented using pictorial diagrams (Fig. 2). For clarification of values, patients were instructed to rate the importance of each outcome on a scale from 0–5. The use of diagrams, consistent figures, and simple language were used to facilitate understanding by patients of various levels of health literacy. Language was targeted at an eighth-grade reading level (SMOG readability level 8.1, grade 8).

The final PtDA prototype was 23 pages (Appendix 3; available at *cuaj.ca*). All six International Patient Decision Aid Standards qualifying criteria were met, as were all six certification criteria.<sup>27</sup> The PtDA met 21 of 23 quality criteria, with the two missing criteria pertaining to validation testing (Table 1). This PtDA was based on the Ottawa Decision Support Framework approach that has been tested in over 20 randomized controlled trials.<sup>28</sup>

#### Alpha-testing

Alpha-testing was completed by 20 patients, 10 urologists, two kidney cancer patient advocates, and one methodo-

Table 1. International Patient Decision Aid Standards criteria met by patient decision aid <sup>4,7,8</sup>						
ltem dimension	Qualifying criteria	Certification criteria	Quality criteria			
Information	Describes the health condition or problem for which decision is required	Shows the negative and positive features of options with equal detail	Describes the natural course of the health condition or problem if no action is taken			
	Explicitly states decision that needs to be considered		Makes it possible to compare the positive and negative features of available options			
	Describes the options available for the index decision					
	Describes positive features of each option					
	Describes negative features of each option					
Probabilities			Provides information about outcome probabilities associated with the options			
			Specifies the defined group of patients for whom the outcome probabilities apply			
			Specifies the event rates for outcome probabilities			
			Allows the user to compare outcome probabilities across options using the same time period			
			Allows the user to compare outcome probabilities across the same denominator			
			Provides more than 1 way of viewing the probabilities (e.g., words, numbers, diagrams)			
Values	Describes what it is like to experience consequence of the options		Asks patients to think about which positive and negative features of options matter most to them			
Guidance			Provides a step-by-step way to make a decision			
			Includes tools like worksheets or lists of questions to use when discussing options with a practitioner			
Development			Development process included a needs assessment with clients or patients			
			Development process included a needs assessment with health professionals			
			Development process included review by clients/ patients not involved in producing the decision support intervention			
			Development process included review by professionals not involved in producing the decision support intervention			
			Field tested with patients who were facing the decision			
			Field tested with practitioners who counsel patients who face the decision			
Evidence		Provides citations to the evidence selected	Describes how research evidence was selected or synthesized			
		Provides a production or publication date	Describes the quality of the research evidence used			
		Provides information about the update policy				
		Provides information about the levels				
		of uncertainty around the event or outcome probabilities				

ltem dimension	Qualifying criteria	Certification criteria	Quality criteria
Disclosure		Provides information about the funding source used for development	Includes authors'/developers' credentials or qualifications
Plain language			Reports readability levels
Evaluation		Describes what the test is designed to measure*	Evidence improved match between preferences of the informed patient and the option chosen
			Evidence patient decision aid helps patients improve their knowledge about options' features

logical expert. All responders completed the entire 10-question survey and had an opportunity to provide additional narrative feedback.

The length of the decision aid was felt to be appropriate by 82% of responders (27/33). Most responders reported that the language was easy to follow (94%, 31/33) and most felt the presentation of management options was well-balanced (82%, 27/33). All responding patients felt the PtDA would have been a valuable tool during their decision-making process (100%, 20/20) and would recommend this PtDA for future patients referred with a SRM (100%, 20/20). Most responding urologists intend to use this PtDA in their practice (90%, 9/10).

Narrative feedback from responders highlighted several important strengths of the PtDA. Consistently, responders commented on the PtDA filling an unmet gap in the resources for patients with a SRM. Other strengths included the diagrams, thoroughness, and clarity. Patient advocates had suggestions with regards to sequencing of the information to ensure the PtDA was patient-centered. For example, the explanation of a biopsy was suggested to precede the presentation of management options.

#### Creation of final patient decision aid and dissemination

The results of the alpha-testing were reviewed by the steering committee and used to update the PtDA prototype. Once the PtDA was revised and agreed upon by the steering committee, the final version was made freely available on our institutions' research website and included in the international A to Z inventory of PtDAs: *https://decisionaid. ohri.ca/decaids.html*.

# Discussion

In this study, we developed a PtDA to facilitate shared decision-making for the management of SRMs following the International Patient Decision Aid Standards. Alpha-testing confirmed high acceptability of the PtDA among patients and urologists. In fact, 100% of patients and urologists found the PtDA to be valuable for guiding the decision-making

process, with 90% of urologists reporting they would use the tool in their clinic. It is anticipated that use of this PtDA would improve patient satisfaction with care.

This study describes the evidence-based development process and acceptability testing of a novel PtDA for the management of SRMs. PtDA use improves patients' knowledge of their health condition and satisfaction in the decisionmaking process.<sup>5</sup> PtDAs also decrease patients' decisional conflict and indecisiveness.<sup>5</sup> In 2015, a panel of kidney cancer experts and patient-partner advocates highlighted the lack of decisional supports for patients with kidney cancer, and appealed for the development of these tools as one of the top 10 priorities in kidney cancer research.<sup>10,29</sup> To directly address this call for action, we followed an evidencebased process to develop a PtDA for the management of SRMs. This tool was found to be acceptable and valued by key stakeholders, including patients, urologists, patient advocates, and methodological experts. Importantly, several international kidney cancer patient-centered organizations, including Kidney Cancer Canada, have reviewed this PtDA and have begun distributing it to patients and caregivers online. While these groups provided feedback, the PtDA was created free of commercial bias following a rigorous and standardized process.

Patients with a SRM are optimally positioned to benefit from a PtDA. The management options provide comparable short-term cancer control yet vary significantly in their risks and benefits. Where active surveillance avoids surgery and its associated risks, patients may find this approach anxietyprovoking, as the renal mass remains in situ. Furthermore, long periods of followup may impose a burden on patients who place more value on definitive care. Surgical removal, on the other hand, usually results in cure, yet patients are exposed to the risks associated with surgery and anesthesia, as well as long-term risk of decreased renal function. Thermal ablation may provide definitive treatment with less risk of complications but is supported by less evidence for long-term cancer control.

Importantly, most patients with a SRM have time to consider their management options, review the risks and benefits, and clarify their values and preferences. Thus, the use of a PtDA for the management of SRMs allows for highquality decisions for these individuals facing a preferencesensitive decision.<sup>30</sup> Additionally, this clinical tool provides information for all patients with a SRM regarding the range of management options in a patient-centered format regardless of what options are recommended/available for them. Improving patients' knowledge of their health condition provides patient education and may empower patients to seek clarification and/or a second opinion to ensure the treatment they receive meets the standard of care and aligns with their values. There are few patient decision aids available that address urological decisions and most that are available are for prostate cancer screening or treatment of localized prostate cancer.<sup>5</sup> This paper provides the framework necessary for researchers to create similar tools to expand the availability of PtDAs in urological practice.

The management of SRMs is a common and challenging decision faced by patients and urologists around the world. This PtDA was designed to apply to a broad audience, therefore, the management options included on the PtDA are based on the best available evidence from the international literature. For example, the inclusion of a minimally invasive radical nephrectomy was included as a management option because in many parts of the world, this would be an option offered and many patients searching for information online may read about this option. We included a page on the PtDA for urologists to indicate to their patients what options are available and recommended for them to ensure patients are not misled about the management options they must choose between. Additionally, the outcomes that were included on the PtDA were chosen because they were felt to be patient-important outcomes and were reviewed and updated by the kidney cancer patient advocates. Finally, information was included on the role of renal mass biopsy, however, biopsy was not included as a management option because it is a diagnostic test used to inform the decision between management options. Decision aid methodology suggests that a PtDA should focus on one decision. Hence, the choice of whether to pursue a renal mass biopsy or not could be the topic of a separate PtDA.

There are several strengths of this study. First, the development of a PtDA for the management of SRMs fills an unmet resource for patients and urologists that has been highlighted as a top priority in kidney cancer research.<sup>10</sup> Second, the inclusion of several groups of stakeholders provided input and feedback from individuals with various expertise and vantage points. Finally, the PtDA directly responds to a call for decisional supports for patients with kidney cancer and their caregivers.

There are some limitations to the study. We did not include community-based urologists in the steering committee or alpha-testing. It is possible their practice varies from an academic setting and is not represented by this tool. Second, the outcomes included on the PtDA represent the best available evidence at this time. As further evidence becomes available, the PtDA will need to be updated. This is a known component of maintaining high-quality PtDAs. Finally, patients and kidney cancer patient advocates provided feedback regarding the format and content during the PtDA development. However, the lack of patient involvement at the initial step of PtDA design is a limitation.

# Conclusions

We have developed a novel PtDA to facilitate shared decision-making for the management of SRMs. This PtDA was acceptable and valued by patients and urologists and meets a significant gap in the resources available for patients. The PtDA is freely available at: *https://decisionaid.ohri.ca/decaids.html*.

**Competing interests:** Dr. Jewett has been an advisory board member for Pfizer and Theralase Tech; has received honoraria from Olympus, Pfizer, and Theralase Tech; and holds investments in Theralase Tech. Dr. Richard has been an advisory board member for BMS and Sanofi; has been a speakers' bureau member for AbbVie, Amgen, Astellas, Ferring, and Janssen; and has participated in clinical trials supported by Calithera and Lidds Pharma. Dr. Morash has attended advisory boards for AbbVie, Astellas, Ferring, Janssen, and Sanofi; and has participated in clinical trials supported by Calithera and Sanofi; and has participated in clinical trials supported by AbbVie (CRONOS II). Dr. Cagiannos has received fees from AbbVie, Ferring, and Janssen. Dr. Lavallée has been an advisory board participant for AbbVie, Bayer, Ferring, Sanofi, and TerSera; and has received an unrestricted research grant from Sanofi. The remaining authors report no competing personal or financial interests related to this work.

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This paper has been peer-reviewed.

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