Delivering patient-centered care through shared decision making in overactive bladder

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Funding information
National Institute of Diabetes and Digestive and Kidney Diseases, Grant/Award Number: UroEPI K12-dk111011-06

Abstract
Introduction: Men and women living with overactive bladder (OAB) face many treatment decisions as they progress through the treatment pathway. Decisions to pursue specific therapies are highly preference sensitive and ideal for shared decision making (SDM). The aim of this narrative review is to provide urologists with a practical summary of methods to elicit preferences and facilitate SDM to promote patient-centered care for OAB.

Methods: We explore OAB as a preference sensitive condition through a review of treatment outcomes and present available data on prediction tools, patient preferences, and decision aids. We propose a paradigm for applying Everyday SDM to OAB care.

Results: Clinical outcome data points to equipoise (balanced outcomes) between options for first-, second-, and third-line OAB therapies, making OAB preference sensitive and appropriate for SDM. Methods to personalize care through individualized outcome prediction calculators and tools to elicit patient preferences are emerging. While patient information about OAB is readily available, we identified few OAB decision aids that facilitate patient preference elicitation and SDM.

Conclusions: OAB is a preference sensitive condition, where treatment is largely based on the patient’s preferences and values. SDM is an ideal approach to supporting patients through these treatment decisions. We propose the application of Everyday SDM, a personalized, clinically efficient methodology as a method to support patient-centered OAB care.

Keywords
discrete choice experiments, overactive bladder care, patient-centered care, patient–provider communication, preference elicitation, preference-sensitive condition, shared decision making

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1 | INTRODUCTION

Overactive bladder (OAB) is a symptom complex consisting of bothersome lower urinary tract symptoms including urinary urgency, frequency, urgency incontinence, and nocturia. OAB is widespread among men and women and is associated with significant interference with daily activity and poor health-related quality of life. People experiencing OAB often have waxing and waning symptoms for years, making the lived experience similar to a chronic condition with many treatment decision points across the lifetime.

Current guidelines advise a stepwise approach through tiers of therapy; these tiers were derived by balancing the potential benefits of treatment with the invasiveness of treatment, duration, severity, and reversibility of adverse events. Providing patients with education and expectation setting are the foundation of OAB care. After establishing this foundation, guidelines outline four tiers of treatments: behavioral therapies (first line), pharmacologic management (second line), chemonervation and neuromodulation (third line), and urinary reconstruction (fourth line). This framework is based on medical evidence and treatment characteristics; however, decision making would be incomplete without incorporation of patient preferences through shared decision making (SDM). One challenge of the tier-based model is the “trial and error” progression through tiers. Use of SDM in OAB may help bridge this gap by expediting treatment choices that align with patient preferences and values.

SDM balances the best available clinical evidence with patient preferences and values to help patients explore options and achieve informed preferences. SDM is most applicable in preference sensitive situations, where multiple, equally efficacious, treatment options exist, and the treatment option is based on patients’ preferences. The term equipoise is used to describe these scenarios, where treatment options are balanced in the desirability of outcomes. One central paradigm of SDM considers self-determination as a desirable goal requiring clinical support whenever possible. In this model, an informed patient makes a treatment decision in partnership with a clinician after a discussion of the patient’s preferences and goals. Despite the benefits, urologists vary in their use of SDM steps, with 87% reporting regularly discussing treatment options for urinary incontinence but only 66% eliciting patient preferences and 54% regularly using decision aids. An alternative and clinically practical approach called Everyday Shared Decision Making has been proposed to personalize care in low-stakes medical decisions. Everyday SDM differs from traditional SDM by providing focused recommendations based on individualized estimates of potential benefit and harm from treatment and then inviting conversation about the recommendation and its alternatives. This paradigm may be well suited for OAB and fits within the context of current clinical guidelines.

The aim of this narrative review is to present OAB care as preference sensitive, discuss patient preferences and values based on literature, and provide urologists with a practical review of methods to facilitate Everyday SDM in OAB care.

2 | OAB CARE AS A PREFERENCE SENSITIVE CONDITION

OAB is a preference-sensitive condition. The best choice for treatment depends on the patients’ preferences and values and how these align with the risks and benefits of individual treatments. The following section reviews clinical efficacy of treatments through the lens of equipoise and SDM.

2.1 | Equipoise in first-line therapy

Pelvic floor physical therapy, bladder training, urge suppression, biofeedback, and fluid management comprise some of the available first-line therapies for OAB. These therapies have low medical risk profiles but require patient engagement and commitment. Outcome evidence is mixed, without clear support of one first-line modality over another, in decreasing OAB symptoms; recent systematic review data finds that data regarding pelvic floor muscle therapy to be heterogenous and inconclusive. This supports the notion that the choice between first-line therapy for OAB is a low-stakes, preference sensitive decision, and ideal for a treatment discussion guided by SDM principles.

2.2 | Equipoise in second-line therapy

Pharmacotherapy with either anticholinergics or beta-3 adrenergic receptor-agonists (beta-3 agonists) is second-line therapy for OAB. Several meta-analyses have shown decreased frequency of micturition and urgency incontinence episodes with either class of medication. Anticholinergics have been found to significantly decrease symptoms of OAB compared to placebo; however, all medications within this class are associated with side effects such as dry eyes, dry mouth, and constipation. A meta-analysis reported that, compared to placebo, anticholinergics results in increased patient
perception of cure though modest overall decrease in number of incontinence episodes. A 2012 Cochrane review compared the effects of differing anticholinergics for OAB and found similar efficacy, but distinct adverse effect profiles, between various anticholinergics. Data regarding the beta-3 agonists are mixed. A systematic review found that overall, the efficacy of mirabegron and vibegron on micturition frequency and on urgency urinary incontinence episodes and continence was superior to placebo and comparable to anticholinergics. Again the main distinction between mirabegron and anticholinergics was tolerability. A network meta-analysis of 54 studies looking at 25 different drug formulations and doses, also found no significant differences in medical efficacy. Recently concerns of cognitive impacts of anticholinergics have also distinguished beta-3 agonists from anticholinergics. As evidence to elucidate the cognitive impact of bladder anticholinergic develops, the balance of equipoise in second-line therapy may shift to favor beta-3 adrenergic agonists, which have not been associated with this adverse effect. Though, as the authors of the network meta-analysis on pharmacotherapy noted, “finding the best treatment for every patient can be done by considering [the patient’s] most bothersome symptoms/signs, their general health and predisposition to specific adverse events, and their values and preferences.” These findings reinforce that there is clinical equipoise between second-line therapies and decisions between specific agents are largely based on patient’s preferences and values regarding adverse effects.

2.3 | Equipoise in third-line therapies

Neuromodulation and chemodenervation represent the currently available third-line therapies for OAB. Neuromodulation can be performed via posterior tibial nerve stimulation (PTNS) or sacral neuromodulation (SNM) while chemodenervation is achieved through cystoscopic injection of type A botulinum toxin (BTX). The 2014 randomized, open label, ROSETTA trial compared SNM to 200 units BTX and found that at 6 months posttreatment, BTX had a statistically, but not clinically significant improvement in the number of urgency incontinence episodes per day. However, the two treatments had distinct adverse effect profiles, with more urinary tract infections (UTIs; 35%) and need for self-catheterization (8%) with BTX and device removal or revision (3%) for SNM. There is limited literature directly comparing BTX or SNM with PTNS and the findings are mixed. A randomized study comparing 100 units of BTX to PTNS found higher efficacy among those who underwent BTX but more adverse effects with BTX. Indirect evidence available in a 2020 network meta-analysis found that at 3 months all three modalities (PTNS, BTX, and SNM) had improved efficacy compared to placebo, but that SNM was associated with greater reduction in total incontinence episodes compared to PTNS. Together, these data suggest that SNM and BTX have similar clinical efficacy for OAB and that PTNS may be less clinically effective but carries a lower risk of adverse events. Distinction in delivery and risk profiles, rather than clinical efficacy, distinguish third-line therapies from each other, making this an ideal context to employ SDM.

2.4 | Equipoise between tiers of OAB therapies

There is evidence suggesting similar clinical efficacy between treatment tiers for OAB. For example, randomized data comparing first- and second-line therapy found no significant outcome differences between the four comparator groups, though there was a higher dropout rate with anticholinergics. In contrast, a 2014 systematic review found no difference in urinary frequency but better subjective outcomes with anticholinergics compared to bladder training. There is also data to suggest that clinical efficacy may be similar between second- and third-line therapy. The 2012 randomized, placebo, and sham controlled comparison of anticholinergics versus 100 units of BTX (ABC trial) found similar reduction in mean daily episodes of urge incontinence per day. However, women who were randomized to BTX were more likely to report complete resolution of symptoms and were less likely to report dry mouth but also had higher risk of UTI and intermittent catheterization. This evidence suggests that between tiers of treatment for OAB, a driving factor in decision making is patient preferences and values regarding adverse effects.

3 | SHARED DECISION MAKING IN OAB

With similar clinical efficacy between treatment modalities within tiers, and perhaps between tiers, we propose a framework for SDM in OAB to educate patients and elicit preferences early and often in the treatment process (Figure 1). Patient education and engagement is central to SDM and is a guiding principle in OAB care. However, studies have documented the difficulties in implementing SDM in urologic care.
where competing priorities, limited appointment time, clinician preferences, and other barriers deter its routine use.4,24

Recent developments in SDM allow for flexible and practical approaches that fit well within the clinical constraints of primary and subspecialty practice. Everyday SDM, a focused method of SDM, is rooted in the use of individualized estimates to make personalized treatment recommendation and support discussion of tradeoffs (Data SI).5 Everyday SDM has three main steps: (1) develop individualized estimates of net potential benefit and harm of treatments based on patient characteristics, (2) identify which decisions are preference sensitive, for OAB care many decisions fall into this category, and (3) lead SDM conversations with an initial recommendation and review of tradeoffs based on individual patient characteristics and their preferences and follow the recommendation with a conversation that supports patient autonomy and is tailored to patient concerns.

4 PERSONALIZED OAB CARE

How can clinicians make personalized recommendations to guide Everyday SDM? Several innovative paradigms and analytic methods have been applied to this problem; some improve on the current tier-based approach while others argue for a shift towards individualized care.25,26

There is emerging data to predict response to pharmacotherapy and evaluating best options for patients based on various criteria.27-29 A model to predict the individual treatment response of fesoterodine was created in 2016.27 A machine learning model to predict the likelihood of anticholinergic treatment failure based on patient age and number of previously failed medications is also available.28 Multicriteria decision analysis, an analytical method performed by content experts, has also been applied to evaluate the benefit-safety balance of pharmacotherapy for OAB.29 The authors ranked medications based on their benefits and side effects to emerge with recommendation that fesoterodine had the best benefit-safety balance as judged by the content experts.29 They noted the involvement of patients in the assessment and analysis as an important future step.29

There has been less conclusive research available to predict outcomes for advanced therapies for OAB. While patients’ clinical characteristics and their preferences for the potential adverse effects or additional benefits may help guide advanced therapy, predicting individual outcomes can be challenging. Studies evaluating predictors of treatment success for SNM have not found any consistent predictive factors.30,31 At least five studies have analyzed whether demographic or urodynamic factors can predict success or complications from BTX injection.32-36 In studies including men and women, women are more likely to have successful outcomes.33-35 No urodynamic variables have been consistently linked
to successful outcomes for BTX. However decreased voiding efficiency, lower minimum urinary flow rates, male gender, and prior hysterectomy have been associated with urinary retention requiring catheterization. The next step in this research has focused on use of machine learning algorithms. Data from the ABC and ROSETTA trials have been used to develop prediction models for time to OAB symptom recurrence over 12 months, change from baseline urgency incontinence episodes at 6 months, and need for catheterization for 6 months. The research found that more baseline urinary urgency incontinence episodes, older age, higher body mass index, and 200-unit injections had decreased time to recurrence. The c-index was 0.63 (95% confidence interval: 0.59–0.67), corresponding to a modest to good fit. The authors also created a model to predict the median change in daily urge incontinence episodes as well as the risk of catheterization. A machine learning algorithm based on the ROSETTA trial was recently found to be superior to expert urologists at predicting BTX outcomes and noninferior to expert urologists at predicting SNM outcomes. Together, this shows that researchers are moving towards clinically accessible data to guide personalized discussions for OAB care, though more research in this space is needed.

5 | PATIENT PREFERENCES IN OAB TREATMENT DECISIONS

Identifying preference sensitive areas and preference elicitation are the next aspects of Everyday SDM. As outlined above, most treatment decisions in OAB are preference sensitive. Researchers have used qualitative studies and discrete choice experiments (DCE) to assess which attributes of treatments are most important to patients. In DCE choices are analyzed to assess the attributes that drive patients’ treatment choices. Use of DCE for OAB is a relatively new phenomenon, with only a few studies exploring patient preferences through DCEs. A review of the key themes from DCE in OAB are summarized in Table 1.

On the basis of DCE, patients put strong emphasis on assured benefits while limiting risks associated with treatments for OAB. The potential for cognitive decline was ranked as the most unwanted side effects of pharmacotherapy followed by severe constipation, blurred vision, and dry mouth. When comparing third-line therapies, assurance of treatment efficacy (testing phase) and convenience (lack of repeated visits) are valued alongside clinical efficacy. Whereas concerns about self-catheterization and repeated office visits associated with third-line therapies were barriers to advanced therapy. Patients’ desire for assured benefit of therapy may be at odds with the stepwise treatment approach for OAB, this disconnect can lead to frustration and lack of clinical effectiveness. SDM is one method to provide education and facilitate expectation setting to arrive at treatment plans that align within patients’ informed preferences. In addition to patients’ desire to reduce OAB symptoms and avoid adverse effects, caregiver burden concerns, social interaction constraints, and psychological distress have all been found to be important attributes to patient decision making. Qualitative studies have reinforced this finding, showing that the impact of OAB on social interaction and daily life were also central reasons to pursue third-line therapy for OAB.

Patient preferences may also help explain low rates of third-line therapy. The decision to progress to advanced therapy has been linked to patients’ desire to avoid invasive treatments and out-of-pocket cost. For example, one study found that while patients rank clinical efficacy of treatment highly, treatment delivery method was the most important attribute to patients with oral and transdermal treatments being favored. Patients in another considered third-line therapy to be an extreme leap rather than a natural progression to more advanced care. Lastly, three studies have shown patients are sensitive to costs associated with third-line therapy indicating out-of-pocket cost to be an important barrier to treatment.

These attributes help inform SDM for OAB by bringing patient-centered concerns to the forefront of treatment decisions. It is intuitive that patients value clinical efficacy and reduction of adverse effects. DCE and qualitative studies provide nuance to less obvious patient preferences, such as the importance patients place on social and psychosocial benefits. Everyday SDM is a method to further personalize decision making by inviting patients to explore which potential benefits and harms of treatment are most important to their decision and allowing clinicians to give tailored recommendations.

6 | OAB DECISION AIDS

Decision aids are tools that can support SDM by clarifying the decision that needs to be made, providing information about options and outcomes and helping patients understand and express their preferences and values. While there are many educational resources available for patients with OAB, there is a paucity of decision aids that help patients clarify their values. In 2021, two decision aids have emerged for OAB: OABcare uses DCE to guide preference elicitation for individual patients while a Streamlined is a mobile patient decision aid.
| Authors                                      | Purpose                                                                 | Study type                  | Major themes                                                                 | Attributes most important to patients                                                                 |
|----------------------------------------------|-------------------------------------------------------------------------|----------------------------|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Swinburn et al.41 (funder: Pfizer UK)        | Examine patient preferences in the use of antimuscarinics               | Discrete choice experiment | People with OAB placed major emphasis on reduction in symptoms and experiencing an adverse event could easily motivate change in treatment preference | Incontinence, urgency, micturition, constipation, and dry mouth (in the order of importance)          |
| Hashim et al.42 (funder: Medtronic)          | Evaluate patient preferences in the use of third-line therapy           | Best–worst scenario        | Perception of treatment effectiveness associated with choice of most preferred treatment | Lasting symptom improvement, test phase to determine treat effectiveness, needles, repeated visits not preferred |
| Heisen et al.43 (funder: Astellas Pharma Europe BV; Astellas Global Development) | Examine patient and physician preferences for antimuscarinics and beta-3 adrenoceptor agonists | Discrete choice experiment among patients and surveys with physicians | Patients put emphasis on limiting risks while physicians put emphasis on increasing benefits | Avoidance of incontinence, nocturia, risk of increased myocardial infarction and hypertension, avoidance of currency, and reduction in frequency and constipation |
| Decalf et al.44 (funder: Eurocept)            | Assess older people’s preferences for side effects associated with antimuscarinics | Discrete choice experiment | Older people with OAB more concerned about the loss of cognitive functions over other possible side effects of antimuscarinics | Avoidance of severe cognitive effects, constipation, blurred vision, and dry mouth                  |
| Athavale et al.45 (funder: Astellas Pharma; Astellas Pharma Global Development Inc.) | Assess pharmacotherapy treatment preferences for people with OAB symptoms | Discrete choice experiment | Preferences varied by demographics and disease comorbidities                  | Drug delivery method identified as the most important attribute. Preferences for oral and patches over injectable therapies. Preferred treatment with reduced daytime micturition and nocturia |
| Davenport et al.46                          | Explore treatment decision making among women who do not pursue third-line therapy | Qualitative, semistructured phone interviews | Lack of patient counseling by clinicians is a major barrier to third-line therapy. Pursuit of third-line therapy perceived by patients as an extreme leap | Belief that OAB is a natural part of the aging process, aversion to procedures involving surgery, needles, or implantable devices |
Streamlined, was created based on qualitative interviews showing that women with OAB expressed need for personalization of treatment options and desire to participate in decisions. The study found that patients spent less than 8 min with the application, resulting in decreased decisional conflict. Our prototype for a third-line therapy decision aid can be found in the supplemental information (Data SII). The lack of readily available patient decision aids for a largely preference sensitive condition such as OAB highlights an opportunity for further research.

7 | LIMITATIONS

Our proposed paradigm of patient-centered care in OAB using Everyday SDM is not without limitations. Challenges to implementation and use of SDM have been well documented within urology. Recent data point to urologists as key facilitators of SDM and decision aid use and clinician engagement may be a way to overcome this barrier. We present SDM for OAB within the context of the tier-based treatment framework recommended by the American Urological Association guidelines and focus our review on therapies included in the guidelines. Prior researchers have noted that a sequential treatment approach may not foster a patient-centered approach. However, by presenting SDM within the context of the current treatment pathways, we develop a practical framework as an initial step towards a tailored treatment approach. Research is needed to evaluate outcomes for SDM in OAB that may guide policy change to promote flexibility in the treatment pathway. Specifically, whether this paradigm improves attrition, efficiency, access to advanced therapy, or cost of OAB care for patients and stakeholders.

8 | CONCLUSION

OAB is a preference sensitive condition, where treatment is largely based on the patient’s preferences and values. SDM is an ideal approach to supporting patients through these treatment decisions. As the need to tailor treatments to fit patients’ preferences grows, it is necessary to find patient-centered approaches that are clinically efficient. Everyday SDM is a parsimonious and flexible approach that lends itself to OAB care. Tools to predict OAB treatment outcomes and preference elicitation are growing, and ongoing improvement in these tools will facilitate Everyday SDM.

AUTHOR CONTRIBUTIONS

Roshan Paudel and Giulia I. Lane have made substantial contributions to the conception of this manuscript. Roshan
Paudel and Giulia I. Lane have substantially contributed to drafting and revising the manuscript. Roshan Paudel and Giulia I. Lane have given final approval of the version to be published. Finally, Roshan Paudel and Giulia I. Lane agree to be accountable for all aspects of the work.

ACKNOWLEDGMENT
Giulia I. Lane receives research support from UroEPI K12-DK111011-06 UroEPI Career Development Program at the Department of Urology, University of Michigan.

CONFLICTS OF INTEREST
The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT
Data sharing are not applicable to this article as no datasets were generated or analyzed during the current study.

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SUPPORTING INFORMATION
Additional supporting information can be found online in the Supporting Information section at the end of this article.