

Predictors of Regret among Older Men after Stress Urinary Incontinence Treatment Decisions

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Study Need and Importance: Men with stress urinary incontinence face complex risks and benefits when making treatment decisions for management of their incontinence within the context of their own goals, values and health. We set out to understand how often patients have regret related to their treatment choices, and to identify factors associated with this regret.

What We Found: Through evaluating 130 men with stress urinary incontinence, we found that 1 in 5 men reported moderate to severe decisional regret. Regret was highest among those electing not to have surgery; 35% of men who did not have surgery reported moderate to severe regret, compared to 8% of men undergoing slings or sphincters. We found that depression, lack of shared decision making and worse incontinence were independently associated with regret.

Limitations: Our study population was relatively homogeneous, given that it was mostly White and college educated and had high health literacy. In addition, some of the data were collected through a telephone survey, which is subject to recall bias. Despite these limitations, this is the first study to evaluate regret among men with stress urinary incontinence, and it in particular allows evaluation of those electing nonsurgical management.

Interpretation for Patient Care: Decisional regret is seen among men making treatment choices for stress incontinence management, particularly those who elect conservative management. Given the disproportionately high levels of regret among these men, we may be underutilizing surgery among this population, not incorporating necessary information in treatment counseling and/or do not have a good understanding of what is important to patients in making these treatment

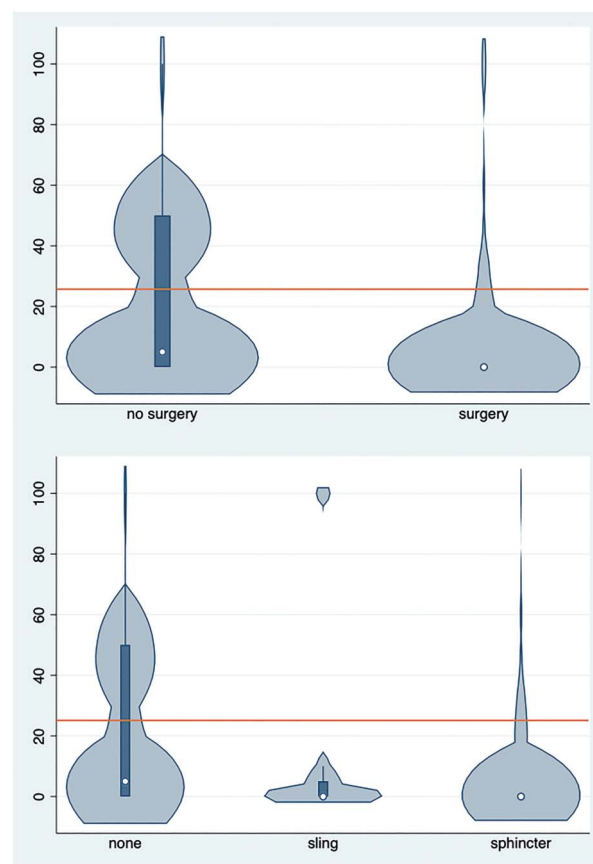


Figure. Distribution of decisional regret score (0–100) by treatment choice. Orange line indicates a cut point of 25. Score ≤ 25 = no to minimal regret, >25 = moderate to severe regret.

decisions. Our findings suggest that improving shared decision making may be one tool to improve satisfaction with treatment decisions, and that recognizing and addressing depression may also be important in this vulnerable patient population.

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Abbreviations and Acronyms

DRS = decisional regret score

ICIQ-UI-SF = International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form

mSUI = male stress urinary incontinence

QOL = quality of life

SDM = shared decision making

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Purpose: When seeking treatment for male stress urinary incontinence (mSUI), patients are faced with weighing complex risks and benefits in making treatment decisions within their individual context. We sought to quantify the frequency of decisional regret among this population and to determine factors associated with regret.

Materials and Methods: A cohort of 130 males aged ≥ 65 years seen for initial mSUI consultation at the University of California, San Francisco Medical Center and the San Francisco Veterans Affairs Medical Center between June 2015 and March 2020 was developed. Using retrospective chart review and telephone interviews, we ascertained decisional regret as well as other patient-, disease- and treatment-related characteristics. Decisional regret was analyzed by treatment type and patient-, disease- and treatment-related factors. Multivariable logistic regression models were built to examine the factors most associated with decisional regret.

Results: Among the entire cohort, 22% reported moderate to severe decisional regret. Regret was highest among those electing conservative management, with 34.7% having decisional regret (vs with surgery: 8.3% sling, 8.2% sphincter; $p < 0.001$). In multivariable analysis, depression, lower rating of shared decision making and higher current incontinence scores were significantly associated with decisional regret.

Conclusions: Recognition of depression, improved efforts at shared decision making and more individualized treatment counseling have the potential to improve patient satisfaction with treatment choice. In addition, given high levels of regret among those electing conservative treatment, we may be underutilizing mSUI surgery in this population.

Key Words: urinary incontinence, stress; decision making; decision making, shared; geriatrics

RATES of male stress urinary incontinence (mSUI) after prostatectomy vary, with studies showing that anywhere from 8% to 29% of men will have moderate to severe distress or leakage at 18 to 24 months, depending on how incontinence is defined

and assessed, though even single pad leakage can cause significant decrements in quality of life (QOL).^{1–3} Fortunately, treatment options do exist, including conservative measures and surgical treatment. Given that there is no imperative for treatment of

mSUI other than improvement of QOL, it is especially important that patients understand the risk-benefit tradeoffs of various treatment options and how treatment fits into their goals and values.

Treatment options for mSUI vary significantly in terms of risks, benefits and leakage-related outcomes.⁴ Though it is suggested as first-line therapy and has virtually no risks, pelvic floor muscle training has not shown good success in improving long-term continence rates.⁵ Surgery has been shown to result in near-term QOL improvements, with 85%–95% satisfaction after undergoing artificial urinary sphincter or sling surgery.^{6–8} Sphincters are considered the gold standard for mSUI given the high success rates for even severe leakage, but do require manual dexterity and have higher rates of short- and long-term complications compared to slings.⁵ Slings allow for physiological voiding, but have lower success rates in men with higher grade incontinence and/or prior radiation.⁵ Adding to the complexity of treatment decisions, data show that patients and their providers are faced with weighing these risks and benefits within the context of existing multimorbidity, frailty and functional limitations, and limited life expectancy.⁹

Guidelines and studies tend to focus primarily on incontinence outcomes after treatment and less on eliciting the patient's individual goals and values around treatment. One study that evaluated patient choice found that 25% of patients who were counseled by their urologist to choose an artificial urinary sphincter would still choose a sling, even though this was not what was recommended or what is considered “gold standard” in their situation, with the most common rationale being the desire to avoid a mechanical device.⁶ Given that most patients adhere to treatment recommendations made by the urologist, it becomes essential that urologists are making tailored, individualized recommendations that take into account patient context and values.⁶ To move toward improved decision making for mSUI treatment, we aimed to quantify the frequency of decisional regret among this patient population and to determine factors associated with regret.

MATERIALS AND METHODS

Participants and Data Collection

Methods have been described in detail previously and are summarized here.⁹ A total of 186 men age ≥ 65 years at the University of California, San Francisco and the San Francisco Veterans Affairs Healthcare System underwent consultation for mSUI between June 2015 and March 2020 and were recruited to participate in the study. We recruited participants by phone, using electronic medical record review and a telephone survey to assess various characteristics among those who consented. Participants were provided a \$20 Amazon gift certificate after

completion of the interview. Institutional review board approval for the study was obtained at the University of California, San Francisco (IRB No. 19-28455).

Measures

Our primary outcome of interest was decisional regret, as measured by the validated Decisional Regret Scale (DRS), which results in a score between 0 (no regret) and 100 (high regret) and has been previously used in elderly patient populations.^{10–12} An established cut point >25 was selected *a priori* and used to indicate “moderate to severe regret,” while a score ≤ 25 was used to indicate “no to minimal regret.”^{13,14} The DRS user manual provides details about the questions and scoring (https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Regret_Scale.pdf).

Covariates included demographics as well as measures of comorbidities and functional status, mental health and cognition, incontinence and treatment data. Demographics collected included age, race, education, marital status and health literacy; details on the collection of patient data have been previously reported in detail.⁹ To assess baseline and followup incontinence details, participants were provided with the International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form (ICIQ-UI-SF), which collects patient-reported incontinence data on frequency of leakage, amount of leakage and leakage bother.¹⁵ An overall score is calculated from these responses, which ranges from 0 (no incontinence) to 21 (significant, bothersome incontinence). Shared decision making (SDM) was assessed during the telephone interview using the validated 9-item Shared Decision Making Questionnaire, which rates SDM on a scale from 0 to 100, where 0 indicates lowest possible extent of SDM and 100 indicates highest extent of SDM.¹⁶

Statistical Analysis

Descriptive summary statistics are reported using mean \pm standard deviation for continuous variables, and count and percentages for categorical variables. Decisional regret was analyzed by treatment type using one-way analysis of variance. Patient-, disease- and treatment-related factors were then analyzed by presence or absence of decisional regret using chi-square or Fisher's exact test and independent group Student *t*-tests where appropriate. As per our *a priori* analytical plan, multivariable regression models were created to evaluate decisional regret as both a continuous and binary outcome to examine the combination of factors that are most important in identifying decisional regret, incorporating variables with a *p* value <0.1 on univariate analysis and adjusting for pre-decision ICIQ-UI-SF leakage score. Additional multivariable linear regression models were constructed to evaluate factors associated with DRS score by treatment choice in subgroup analysis. Stata® 16.1 was used for analysis, with *p* <0.05 considered significant.

RESULTS

Of 186 eligible participants 130 (70%) completed the interview and were included for analysis (mean \pm SD time since initial consultation 31.6 \pm 15.8 months; table 1). Participants were on average 75 years of

Table 1. Characteristics of older men presenting for stress urinary incontinence consultation by decisional regret

	All	None to Minimal Decisional Regret (DRS score ≤ 25)	Moderate to Severe Decisional Regret (DRS score >25)	p Value
No. pts	130	101	29	
Demographics:				
Mean \pm SD age (yrs)	74.9 \pm 4.6	75.0 \pm 4.4	74.4 \pm 5.0	0.509
No. White vs nonWhite race (%)	113 (86.9)	87 (86)	26 (89)	0.245
No. college graduate (%)	99 (76.2)	23 (23)	8 (28)	0.592
No. married/partnered (%)	102 (78.5)	82 (81)	20 (69)	0.158
No. low health literacy (%)	5 (3.9)	3 (3)	2 (6)	0.332
Comorbidities and functional status:				
Mean \pm SD Charlson Comorbidity Index	5.2 \pm 2.0	5.2 \pm 2.0	5.1 \pm 2.2	0.676
No. 10-yr mortality risk $>50\%$ (%) [*]	93 (71.5)	74 (73)	19 (65)	0.415
No. help with 1+ activities of daily living (%)	13 (10.0)	9 (9)	4 (14)	0.440
Mean \pm SD TUG score in seconds [†]	9.6 \pm 2.4	9.1 (2.3)	10.0 (2.9)	0.274
No. prefrail/frail: TUG >10 seconds (%) [†]	29 (22.3)	20 (26)	9 (36)	0.316
Mean \pm SD upper extremity function score [‡]	52.9 \pm 3.6	52.8 \pm 3.8	53.3 \pm 2.7	0.519
Mean \pm SD physical QOL [§]	51.3 \pm 9.1	52.0 \pm 8.8	48.9 \pm 9.8	0.099
Mental health and cognition:				
No. anxiety (%)	5 (3.9)	3 (3)	2 (7)	0.332
No. depression (%) [¶]	13 (10.0)	6 (6)	7 (24)	0.004
No. cognitive impairment (%) [#]	0	0 (0)	0 (0)	1.000
Mean \pm SD mental QOL [§]	55.6 \pm 8.4	56.8 (8.1)	52.3 (8.7)	0.015
Incontinence characteristics:				
No. etiology (%):				
History of surgery only	58 (44.6)	83 (82)	26 (90)	0.335
History of surgery+radiation therapy	69 (53.1)	57 (56)	14 (48)	0.437
Other etiology	3 (2.3)	1 (1)	0 (0)	0.591
No. prior radiation (%)	71 (54.6)	57 (56)	14 (48)	0.437
No. prior hormone therapy (%)	30 (23.1)	25 (25)	5 (17)	0.397
No. amount of leakage (%):				0.527
Small amount	25 (19.2)	18 (18.0)	7 (24.1)	
Moderate amount	72 (55.4)	55 (55.0)	17 (58.6)	
Large amount	32 (24.6)	27 (27.0)	5 (17.1)	
No. frequency of leakage (%)				0.621
2–3 times per wk	3 (2.3)	3 (3.0)	0 (0.0)	
Daily	15 (11.5)	10 (10.0)	5 (17.2)	
Several times a day	42 (32.3)	31 (31.0)	11 (37.9)	
All the time	69 (53.1)	56 (56.0)	13 (44.8)	
Mean \pm SD leakage interference, 0–10	5.7 \pm 3.2	5.8 \pm 3.2	5.3 \pm 3.2	0.117
Mean \pm SD pre-decision leakage ICIQ-UI-SF score ^{**}	14.2 \pm 4.4	14.4 (4.5)	13.4 (4.3)	0.324
No. urgency symptoms at presentation (%)	29 (22.3)	23 (25)	6 (21)	0.720
Treatment characteristics:				
No. treatment type (%):				0.001
Conservative (no surgery)	69 (53)	45 (44)	24 (83)	
Sling	12 (9)	11 (11)	1 (3)	
Sphincter	49 (38)	45 (45)	4 (14)	
Mean \pm SD shared decision-making score	72.9 \pm 26.1	77.4 \pm 4.7	56.9 \pm 4.5	0.002
No. any complication (%)	17 (28)	15 (27)	2 (40)	0.528
Mean \pm SD post-decision leakage ICIQ-UI-SF score ^{**}	8.90 (5.1)	7.80 (4.7)	13.10 (4.5)	< 0.001
Mean \pm SD time since consultation (mos)	31.6 (1.4)	31.8 (1.5)	30.6 (3.3)	0.710
Mean \pm SD time since surgery (mos), where relevant	28.6 (2.0)	28.8 (2.1)	26.3 (6.8)	0.740

Bold text signifies statistical significance ($p < 0.05$).

^{*} Ten-year mortality determined by the Lee index.

[†] TUG, Timed Up and Go Test. TUG score >10 seconds indicates prefrail or frail.

[‡] Upper extremity function determined by Neurological Quality of Life Short Form v1.0—Upper Extremity Function: Fine Motor Activities of Daily Living. Raw scores are transformed into a standardized T-score, where 50 represents the mean of the reference population with a standard deviation of 10.

[§] Physical and mental QOL determined by PROMIS (Patient-Reported Outcomes Measurement Information System) Scale v1.2—Global Health. Raw scores are transformed into a standardized T-score, where 50 represents the mean of the reference population with a standard deviation of 10.

^{||} Anxiety determined by Generalized Anxiety Disorder 2-item scale.

[¶] Depression determined by PHQ-2 (Patient Health Questionnaire 2-item scale).

[#] Cognitive impairment determined by Short Portable Mental Status Questionnaire.

^{**} Incontinence score determined by ICIQ-UI-SF. Score ranges from 0 (no incontinence) to 21 (significant, bothersome incontinence).

age; the majority were White (87%), college educated (76%) and married (79%); and 4% had low health literacy. Incontinence was due to surgery alone in 45% of cases and surgery in addition to radiation therapy in 53% of cases, with the vast majority related to an underlying prostate cancer

diagnosis. At the time of consultation, the majority of men reported leaking a moderate (55%) or large (25%) amount of urine, with leakage occurring daily (12%), several times per day (32%) or all the time (53%). Leakage was noted to have moderate interference with daily activities, with a mean \pm SD

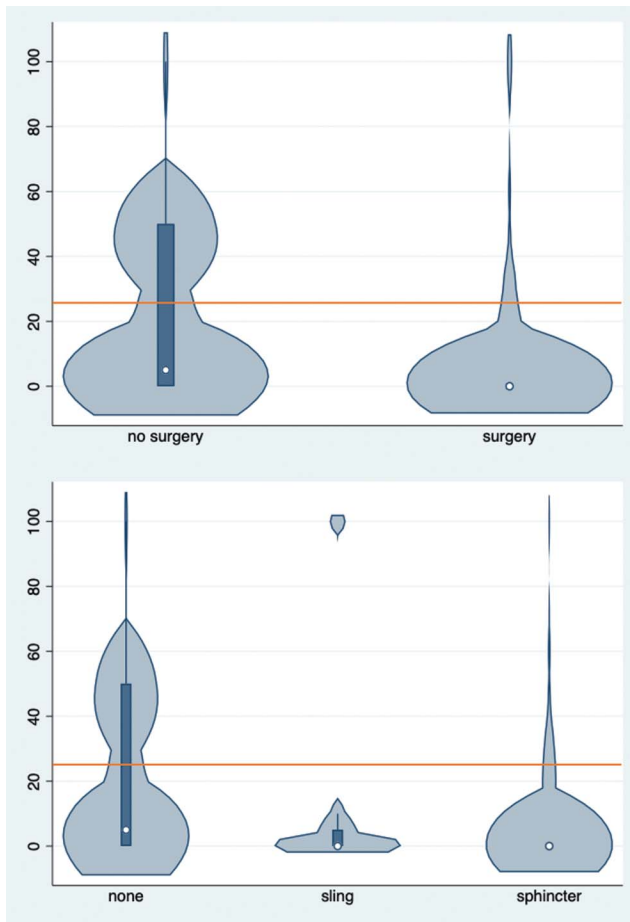


Figure. Distribution of DRS score (0–100) by treatment choice. Orange line indicates a cut point of 25. Score ≤ 25 = no to minimal regret, >25 = moderate to severe regret.

interference score of 5.7 ± 3.2 on a scale of 0 (not at all) to 10 (a great deal). The mean \pm SD pre-consultation ICIQ-UI-SF score of the cohort was 14.2 ± 4.4 , representing moderate leakage and interference. In terms of treatment, 53% of patients elected conservative management, 9% underwent sling placement and 38% underwent sphincter placement. Mean \pm SD SDM score was 72.9 ± 26.1 .

Among the entire cohort, the mean \pm SD DRS score was 14.0 ± 23.1 , with 22% having moderate or high regret. (table 1). Regret scores were highest among those who elected conservative management (19.5 ± 23.4) compared to those who underwent sling (10.0 ± 28.5) and sphincter (7.3 ± 19.4) surgery, with 34.7% of those conservatively managed having moderate to severe decisional regret (vs 8.3% with sling and 8.2% with sphincter, $p < 0.001$; see figure). Those with decisional regret were significantly more likely to report depression (24% vs 6%, $p < 0.004$) and have lower mental QOL scores (mean 52.3 vs 56.8, $p = 0.015$) compared to those with no to minimal regret. Decisional regret strongly correlated with SDM scores, as those with decisional regret had a mean

SDM score of 56.9, compared to 77.4 in those without regret ($p = 0.002$). Finally, current leakage scores were also significantly associated with decisional regret, with a mean score of 13.1 in those with regret vs 7.8 in those with no to minimal regret ($p < 0.001$).

In multivariable analyses of decisional regret both as a binary and a continuous outcome, depression ($p = 0.026$ and $p = 0.004$, respectively), SDM ($p = 0.017$ and $p = 0.002$) and current leakage score ($p = 0.001$ and $p < 0.001$) were noted to be significant drivers of regret in both analyses (table 2). Additional covariates that were not significantly associated with decisional regret on univariate analysis were added to the models sequentially and were not significant predictors and did not change the significance of depression, SDM or current leakage score.

Additional multivariable linear regression models were constructed to understand factors associated with DRS scores by treatment (see supplementary table, <https://www.jurology.com>). For those electing conservative management, increased leakage scores correlated with higher levels of regret (β 2.35; 95% CI 0.75, 4.0). Leakage scores were also found to be significantly associated with decisional regret for those undergoing surgery, though less impactful in the surgery group than in the conservatively treated group (β 1.58; 95% CI 0.54, 2.62). In addition, within the surgery group higher SDM scores correlated with lower regret scores (β -0.34 , 95% CI -0.57 , 0.10). When analyzing sling and sphincter surgeries, the sling group (12 patients) was too small to create valid models. Within the sphincter group, higher SDM scores (β -0.28 ; 95% CI -0.51 , -0.06) and health literacy (β -24.80 ; 95% CI -46.52 , 3.09) were noted to be independent predictors of lower regret.

DISCUSSION

To our knowledge this is the first study that has evaluated decisional regret among this patient population. Our data show that a fifth of older men who have made mSUI treatment decisions report moderate to high levels of decisional regret. In particular, regret scores are highest among those who elected conservative management, with 35% of men electing conservative management having moderate to severe regret. In addition, incontinence scores, depression and SDM were found to be significant independent predictors of regret. These data suggest that we need to better understand what is important to patients in making these treatment decisions and incorporate these aspects into treatment counseling to make treatment decisions more individualized and values directed.

Our data showed that incontinence score remained an important independent predictor of regret when stratified by treatment type, wherein the coefficient

Table 2. Multivariable DRS score analysis

Covariates	DRS as Binary Outcome		DRS as Continuous Outcome	
	p Value	OR, 95% CI	p Value	β , 95% CI
Physical QOL*	0.152	1.07 (0.97, 1.165)	0.355	0.24 (−0.27, 0.75)
Depression†	0.026	14.82 (1.38, 158.99)	0.004	14.12 (0.77, 27.47)
Mental QOL*	0.213	0.094 (0.86, 1.04)	0.385	−0.25 (−0.82, 0.32)
Pre-decision leakage ICIQ-UI-SF score‡	0.028	0.79 (0.65, 0.98)	0.324	−0.555 (−1.595, 0.486)
Treatment type	0.116		0.351	
Conservative (no surgery)		Referent		Referent
Sling		2.18 (0.14, 3.87)		6.553 (−8.057, 21.162)
Sphincter		0.79 (0.15, 4.27)		0.347 (−9.805, 10.501)
Shared decision-making score	0.017	0.97 (0.96, 0.99)	0.002	−0.183 (−0.327, −0.039)
Post-decision leakage ICIQ-UI-SF score‡	0.001	1.32 (1.13, 1.61)	<0.001	1.806 (0.974, 2.638)

Bold text signifies statistical significance ($p < 0.05$).

* Physical and mental QOL determined by PROMIS (Patient-Reported Outcomes Measurement Information System) Scale v1.2—Global Health. Raw scores are transformed into a standardized T-score, where 50 represents the mean of the reference population with a standard deviation of 10.

† Depression determined by PHQ-2 (Patient Health Questionnaire 2-item scale).

‡ Incontinence score determined by ICIQ-UI-SF. Score ranges from 0 (no incontinence) to 21 (significant, bothersome incontinence).

for incontinence scores was greatest among those who elected conservative management, corresponding to the relatively high level of regret seen among those men. These data suggest that patients who do not elect to have surgery are the most dissatisfied, and this may result from a lack of patients' clarity of their own goals, or providers' lack of understanding of what is important to patients. It was surprising to us to find that among our cohort there were quite a few men who were counseled about mSUI treatment but had deferred surgery. We are undertaking qualitative interviews to ascertain why these individuals elected not to undergo surgery and what drives their treatment decisions, given that these patients seem to have the most regret.

These findings suggest that mSUI surgery may be underutilized in older men, which is echoed by existing data; despite the known QOL improvements that mSUI surgery offers, only 3%–6% of men treated with prostatectomy undergo mSUI surgery.^{17–20} This discrepancy could be due to patients themselves not seeking treatment; in a study of older community-dwelling adults with urinary incontinence, only 38% had told their physician about their incontinence.²¹ Alternatively, one could hypothesize that patients may be reluctant to tell the urologist who performed their prostatectomy about their incontinence or may be concerned about having to undergo another surgery when the last surgery caused their issue to begin with. Thus, we need better ways to encourage patients to share their concerns with urologists and for urologists to better assess mSUI and counsel patients about treatment options.

We also found that higher SDM scores were a significant independent predictor of less decisional regret, in particular among those electing surgery. SDM is at the crux of patient-centered care and requires understanding the best available evidence around risks and benefits across all available treatment options, while ensuring patients' values and preferences are taken

into account. SDM is increasingly advocated, both as an ethical imperative and because there is robust evidence that SDM may actually improve health outcomes.^{22,23} In fact, mSUI treatment guidelines do recognize the complexity of this decision making and advocate using the shared decision-making model to discuss treatment options, yet provide no guidance on how to do this in practice.²⁴ A recent look at SDM in urology practice was carried out using the 2019 American Urological Association Census Shared Decision Making module.²⁵ Of 2,219 respondents, 77% reported regular use of SDM in at least 1 preference-sensitive scenario. SDM can be buoyed by decision support tools, which have been shown in rigorous research to improve patients' knowledge and accuracy of risk perceptions, increase the likelihood of patients making care choices that are congruent with their values, decrease decisional conflict, have a positive effect on patient-clinician communication and improve satisfaction with decisions and the decision-making process.²⁶ While there are many models of decisional support tools, one does not yet exist for mSUI.

Importantly, in our cohort depression was also noted to be strongly independently correlated with decisional regret, and 24% of those with regret screened positive for depression. Depression among older adults is estimated at 3%–15%, and urinary incontinence is also known to be associated with depression.^{27–30} Given the high prevalence of depression among this patient population, as well as its correlation with decisional regret, this is an important factor to take into account. Addressing patients' mental wellness could potentially improve their participation in making a treatment choice that is aligned with their goals and/or improve satisfaction with treatment. However, how and whether to do this in practice is challenging given concerns about how receptive patients will be to such screening and what to do with a positive result.

Our study does have limitations. Overall this represents a cohort that is mostly White and college educated with high health literacy, which means that our results may be less generalizable. In addition, some of the data were collected through a telephone survey after the initial patient consultation, which relies on recollection by the patient and is therefore subject to recall bias (eg reporting the amount and bother of incontinence at the time of consultation). However, we did see significant improvement in pre- to post-incontinence scores among those individuals who received treatment compared to no significant improvement in those who did not undergo surgery, which decreases our concern about recollection bias. Of note, participants were provided a small monetary incentive to participate, though several individuals declined the incentive after completing the study and asked that the funds be used to support more mSUI research instead. Despite these limitations, it is the first study to comprehensively evaluate decisional regret among men making mSUI treatment choices,

and in particular allows comparisons between those pursuing conservative treatment vs surgery and uses a validated metric of decisional regret. We believe these data offer valuable insights into what factors play a role in treatment regret and how we might focus our efforts toward improving treatment counseling in the future.

CONCLUSIONS

A fifth of men with mSUI report decisional regret regarding their initial incontinence management decision. Depression and higher incontinence scores are associated with more regret, while SDM is associated with less. Recognition of depression, improved efforts at SDM and individualized treatment counseling have the potential to improve patient satisfaction with treatment choice. In addition, given the high level of regret among those electing conservative treatment, we may be underutilizing surgery in this population.

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EDITORIAL COMMENT

Most urologists will be familiar with the patient who presents a year or more after radical prostatectomy with ongoing bothersome stress urinary incontinence and who ultimately decides to forgo anti-incontinence surgery in favor of conservative management. Will the patient live to regret this decision? This novel work by Hampson et al suggests that they very well may.

Moderate to severe decisional regret, assessed a mean 2.5 years after initial incontinence evaluation, was identified in over a third of men who elected conservative management and in less than 10% of men who elected surgical treatment. Regret was higher among those reporting depression, more severe incontinence and lower degrees of shared decision making. Individual patient-specific rationale for decision making at the time of incontinence evaluation

was not reported but is actively being assessed by the authors and will be of great interest.

The study population was homogeneous—composed of older, highly educated and health literate men who found their way to an evaluation with an incontinence specialist. How the results of this study apply to the broader population of men living with bothersome post-prostatectomy incontinence is up for debate. Increasing the focus on accurately diagnosing and performing high-quality shared decision making seems prudent for improving quality of life and avoiding decisional regret among these patients.

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