



Application of the decisional regret scale (DRS) in men undergoing anti-incontinence procedures for stress urinary incontinence

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Background: Decisional regret (DR) has previously been applied to other urologic issues (hypospadias, prostate cancer). The present study seeks to evaluate certain patient factors that directly correlate to high DR scores in anti-incontinence procedures.

Methods: Medical records for 119 patients undergoing anti-incontinence procedures between 2009 and 2020 were retrospectively reviewed. Forty-one patients were accessible for telephone follow-up and provided a Decisional Regret Scale (DRS) questionnaire. If patients had both a sling and an artificial urinary sphincter (AUS) placed, questionnaires were administered for each. DRS score was quantified in accordance with prior literature, with scores ranging 0–100. We subdivided patients based on demographics and surgical data, correlating this with DRS score.

Results: In 41 patients, 46 procedures (13 slings, 33 AUS) were performed. Thirty-nine (95.1%) men underwent robotic-assisted laparoscopic prostatectomy, and 11 (26.8%) men reported prior pelvic radiation. Post-procedural continence, irrespective of procedure, yielded an average 2 ± 1.56 pads per day (PPD). Mean DRS score across the cohort was 29.78. DRS score was subdivided into mild, moderate, and severe, with majority noting “none to mild” regret (63%), 15.2% reporting moderate and 21.7% severe. Predictors of higher regret included history of radiation ($P=0.056$), choice of anti-incontinence procedure ($P=0.011$), and need for surgical revision ($P=0.00042$). DR was unrelated to race, complete continence, and time to follow-up.

Conclusions: DRS has recently been applied to anti-incontinence procedures for male stress incontinence; our study highlights novel findings not previously assessed. Majority of men had minimal regret with a subset that had significant regret—history of radiation, multiple revisions/explant, and those who elected for sling upfront. These results highlight the importance of patient selection and pre-operative counselling.

Keywords: Stress urinary incontinence (SUI); anti-incontinence; decisional regret (DR)

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Introduction

Stress urinary incontinence (SUI) most often occurs in men following surgical procedures like radical prostatectomy and transurethral resection of prostate. It can also occur with prostatic radiation therapy, iatrogenic sphincter injury, neurologic conditions, or pelvic floor trauma (1-4).

Despite advances in surgical techniques and application of minimally-invasive robotic procedures, the prevalence of post-prostatectomy SUI ranges from 4–57%. This wide range is largely attributed to advanced age, body mass index (BMI), pre-operative bladder function and urinary continence, prior radiation therapy, pre-operative membranous urethra length, vascular comorbidities, stage

of disease, surgical technique, and varying definitions of incontinence (2,5,6).

Several treatment options have been implemented over the past 45 years, ranging from conservative, less invasive therapy (pelvic floor physical therapy, periurethral bulking agents) to insertion of prosthetic devices (urethral male slings or compressive devices, i.e., artificial urinary sphincters) (5,6). Depending on the severity of the incontinence, shared decision making is utilized to personalize the treatment modality to each particular patient. Per the American Urological Association (AUA) guidelines on incontinence after prostate treatment, both male slings and artificial urinary sphincters can be offered as treatment options for bothersome stress urinary incontinence (7). The appropriate procedure depends on severity of incontinence, degree of bother, and surgeon expertise. Each of the aforementioned options has its shortcomings with regard to overall effectiveness, post-operative complications, and patient decisional regret (DR). The artificial urinary sphincter (AUS) is considered the preferred surgical treatment option for moderate to severe post-prostatectomy incontinence (PPI), as well as in those patients who have received primary, adjuvant or salvage radiotherapy (7,8). Though there have been excellent outcomes concerning pad per day usage and overall patient satisfaction, relatively high revision rates have been reported as the greatest shortcoming (4). Therefore, male slings have been utilized in treating mild to moderate SUI with suitable

results, though they have fallen short in the efficacy of treating severe SUI.

DR, defined as the cognitively based, negative emotion experienced when an individual realizes or imagines that the current situation would have been better had he/she acted differently, has been applied to other urologic issues such as hypospadias, prostate cancer, and pediatric fecal incontinence (9-12). It has only recently been studied in men undergoing treatment options, conservative versus surgical, for SUI (13). The objective of this study was to apply the decisional regret scale (DRS) in men specifically undergoing anti-incontinence procedures for stress urinary incontinence in order to identify factors that may be associated with higher regret. We present this article in accordance with the STROBE reporting checklist (available at <https://tau.amegroups.com/article/view/10.21037/tau-23-105/rc>).

Methods

Study participants and inclusion criteria

Following institutional board review approval, we reviewed the records of 119 patients undergoing anti-incontinence procedures (AUS, male urethral sling) by three surgeons at our institution between 2009 and 2020. Patients were identified through the University of Oklahoma Health Sciences Center database for inclusion. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the University of Oklahoma Health Sciences Center Institutional Review Board (IRB No. 11596) and individual consent for this retrospective analysis was also obtained through telephone consent. To accurately assess outcomes with extended follow-up, the study was limited to patients responsive to telephone follow-up. Patients were excluded from our study if they were under the Department of Corrections (DOC) custody at the time of telephone follow-up, deceased at time of attempted contact, or declined to participate in research consent. Forty-one patients were identified and included in the study, while 9 declined to participate, 57 were unable to be contacted due to non-working telephone numbers, and 12 others were incarcerated/deceased. Demographic data including age at the time of surgery, race, history of pelvic radiation, etiology of SUI, procedure(s) performed, need for repeat procedures/revisions, and overall follow-up time were collected. Additionally, surgical outcomes, continence (less than one pad per day), and complications were noted.

Highlight box

Key findings

- Predictors of higher decisional regret—history of radiation, choice of anti-incontinence procedure, and need for surgical revision.
- Decisional regret was unrelated to race, complete continence, and time to follow up.

What is known and what is new?

- Decisional Regret Scales have been previously applied to other urologic issues (hypospadias, prostate cancer), and most recently conservative versus surgical treatment options for male stress incontinence, in order to guide future treatment options.
- We present novel findings, regarding post-procedural incontinence, that has not previously been assessed.

What is the implication, and what should change now?

- Proper pre-op counselling and patient selection, aided by the use of the validated Decisional Regret Scale, may alter surgical decision-making and ultimately, patient outcomes.

1. I was the right decision.	1 Strongly agree	2 Agree	3 Neither agree nor disagree	4 Disagree	5 Strongly disagree
2. I regret the choice that was made.	1 Strongly agree	2 Agree	3 Neither agree nor disagree	4 Disagree	5 Strongly disagree
3. I would go for the same choice if I had to do it over again.	1 Strongly agree	2 Agree	3 Neither agree nor disagree	4 Disagree	5 Strongly disagree
4. The choice did me a lot of harm.	1 Strongly agree	2 Agree	3 Neither agree nor disagree	4 Disagree	5 Strongly disagree
5. The decision was a wise one.	1 Strongly agree	2 Agree	3 Neither agree nor disagree	4 Disagree	5 Strongly disagree

Figure 1 Decisional regret scale.

Assessment of DR

The primary outcome of our study was DR, based on the initial surgical treatment of choice, as measured by the DRS. The DRS is a validated questionnaire, utilized in healthcare decision making, and can also serve as a quantitative assessment of degree of regret with a healthcare decision. Further details regarding directional use and scoring and interpretation can be found at https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Regret_Scale.pdf (14).

With each of the questionnaires administered to patients via telephone, an introductory statement was first made regarding the research intent of the call. Patients were asked to complete the questionnaire by reflecting on their present opinions regarding the surgical procedure(s) they had undergone. Responses to each of the questions were quantified and converted, in accordance to the validated questionnaire (see *Figure 1*), with scores ranging 0 to 100. DRS score was interpreted as 0 to 25, mild DR, 26 to 65, moderate DR, and 66 to 100, severe DR. The cut-points utilized to designate none to mild, moderate, and severe regret were based upon those previously used in the study involving patient/caregiver regret following surgery for fecal incontinence; the Principal Investigator (PI) of this study also contributed to the aforementioned study. Modifications were made to allow for three set groupings of regret, as opposed to none to mild and moderate to severe regret.

Statistical analysis

Group descriptive statistics were expressed as mean standard deviation (SD) or grouped frequencies. Distribution of the DRS score was significantly positively skewed. Measure of individual impact of preoperative variables and postoperative results on the DRS score mostly treated DRS as a dichotomous (present/absent) or trichotomous (mild/moderate/severe) categorical variable using chi-square or ANOVA testing. All statistical tests were 2-sided with $P < 0.05$ considered statistically significant.

Results

A total of 119 patients underwent either male urethral sling or artificial urinary sphincter placement for stress urinary incontinence between 2009 and 2020, at our institution. Following these operations, 41 (34.5%) of these patients were accessible for telephone follow-up. Mean follow-up was 65 months. Among the 41 patients, 46 total procedures were performed (13 male slings and 33 artificial sphincters), with 14 (34.1%) patients requiring additional procedures (AUS placement following male sling, AUS revision/explant) following their initial surgery. Of note, 11 (26.8%) men noted a history of pelvic radiation, while the majority of patients had a prior history of robotic-assisted laparoscopic radical prostatectomy (RALP). Of the 41

Table 1 Patient demographics and surgical data

Demographic and surgical data	Value
Age, month	796±105
Race	
Caucasian	33 (80.5)
African American	5 (12.2)
American Indian/Alaskan	2 (4.88)
Hispanic	1 (2.44)
Procedures	
Sling	13
Artificial urinary sphincter	33
Radiation	11 (26.8)
Etiology	
RALP	39 (95.1)
Trauma	1 (2.44)
Other	1 (2.44)
With additional surgery	14 (34.1)
Continent	3 (7.32)
Incontinent	
Mild	23 (56.1)
Moderate	13 (31.7)
Severe	2 (4.88)
Average PPD (pads)	2±1.56
Decisional regret	
Mild	29 (63.0)
Moderate	7 (15.2)
Severe	10 (21.7)

Data are presented as mean ± standard deviation or n (%). RALP, robotic-assisted laparoscopic radical prostatectomy; PPD, pad per day.

patients, 3 (7.32%) reported complete continence following surgery, with an additional 23 (56.1%) reporting only mild incontinence, requiring 1–2 pads per day (PPD). Post-procedural incontinence, irrespective of the procedure, yielded an average of 2 PPD. Demographic data are outlined in *Table 1*.

DR was gathered, calculated, and analyzed amongst the study population. Of the 41 patients undergoing a total 46 procedures, procedural DR was reported as follows: 29 (63%) were associated with none to mild regret, 7 (15.2%)

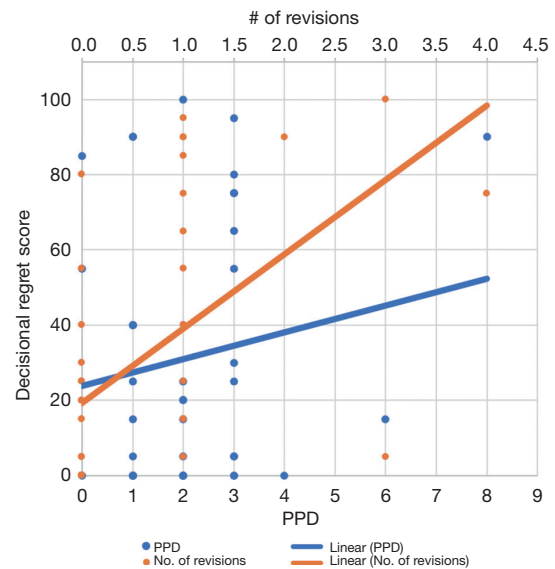


Figure 2 Decisional regret score with reference to PPD and number of surgical revisions. PPD, pads per day.

with moderate regret, and 10 (21.7%) with severe DR. Mean DR score across the cohort was 29.78. There were no significant differences in regret with age (in years) [40–59, 60–69, and >70, mean 26.5, 36.8, 29.7, $P=0.755$], complete continence [yes or no, mean 32 and 30.3, $P=0.44$], or pad per day usage [0–1, 2–3, 4+, mean 30.3, 31.6, 35, $P=0.098$] (see *Figure 2*). In addition, DR was found to be unrelated to race or time to follow-up.

Patients with a history of pelvic radiation were noted to have significantly higher DR to those who did not (radiated versus non-radiated, DRS 45.5 and 26.2, $P=0.056$). Of additional significance was the choice of anti-incontinence procedure. DR was significantly higher in the male sling cohort compared to those who underwent AUS (49 vs. 21.8, $P=0.011$). The most significant factor, though, with regard to statistical significance and impact on DRS, was the need for surgical revision (see *Figure 2*). Fourteen (34.1%) of the 41 patients required an additional procedure, prompting a DR score of 55 (19.1 in those not requiring revision), with a P value of 0.00042. DRS breakdown and analysis are presented in *Table 2*.

Discussion

We present a novel application of the decisional regret scale in men specifically undergoing anti-incontinence procedures and found that the majority of men reported

Table 2 DRS score by patient characteristics

Characteristic	No.	Mean ± SD	t-test (P value)
Race, n (%)			
Caucasian	33 (80.5)	34.85±35.52	
African American	5 (12.2)	12.00±14.40	
American Indian	2 (4.88)	37.50±53.03	
Hispanic	1 (2.44)	0	
Radiation			
No	30	26.17±29.17	1.62 (0.056)
Yes	11	45.45±44.35	
Anti-incontinence procedure			
AUS	29	21.79±30.80	2.38 (0.011)
Sling	10	49.00±34.30	
Revision			
No	27	19.07±27.07	3.62 (0.00042)
Yes	14	55.00±35.52	
Complete continence (Always ≤1 PPD)			
No	16	30.31±34.08	0.15 (0.44)
Yes	25	32.00±35.30	
PPD			
0	34	6.67±43.11	0.489
1	13	26.54±32.56	
2	10	18.50±30.28	
3	12	42.50±35.45	
4+	3	35.00±48.22	
Time to follow-up (month)			
0–12	5	31.00±2.83	0.965
13–24	6	33.33±3.54	
25–36	4	22.50±57.12	
37–48	3	41.25±97.12	
49–60	3	36.25±7.12	
61+	20	26.74±80.56	

DRS, decisional regret scale; SD, standard deviation; AUS, artificial urinary sphincter; PPD, pads per day.

minimal regret, regardless of the procedure they had undergone. The most significant regret was noted in men requiring multiple procedures to achieve desired results.

Based on prior literature, overall patient satisfaction

scores following AUS placement for PPI is relatively high with an average pad per day usage of 0–1 (6). Litwiller *et al.* conducted a study on 50 patients with severe incontinence on satisfaction and defining successful outcomes of PPI following AUS placement; 90% of patients reported satisfaction with the AUS, and 96% would/had recommend(ed) the procedure to a friend (15). These findings proved interesting, as postoperative continence was not 100% but relative overall improvement was most significant in defining success to the patients (15). Similarly, Trigo Rocha *et al.* prospectively evaluated the efficacy of AUS placement for PPI, with focus on the impact of UI on quality of life, amongst other factors, and found that there was an overall significant reduction in pad count, 4.0±0.9 to 0.62±1.07 diapers per day, as well as a significant reduction in incontinence negatively affecting quality of life (16). The modern male sling, like the AUS, has also achieved satisfactory results from patients' perspectives with notable successful outcomes (17–19). A nonconcurrent study by Chua *et al.* on long-term durability of transobturator slings revealed 150/215 (69.8%) of patients maintained treatment success, though only 44.7% noted complete continence. Success was gauged by >50% improvement and overall satisfaction without further procedures needed (17). Likewise, Abramowitz *et al.* used an incontinence grading scale (IGS) to try and quantify success post-sling placement for PPI and determined that though the scale alone was not predictive of surgical success/failure, there was an 85% subjective success rate based on patient-deemed improvement in continence (18).

Though prior studies have evaluated and demonstrated high subjective patient satisfaction and success rates following both male sling and AUS placement, there has been a paucity of objective data validating the results. Therefore, using the decisional regret questionnaire, we found that there is a direct correlation between specific patient demographics/factors and higher decisional regret scores regarding anti-incontinence procedures. In our study, 11/41 (26.8%) patients underwent pelvic radiation prior to AUS/sling placement and reported significantly more decisional regret. Likewise, the choice of anti-incontinence procedure (irrespective of the degree of UI), as well as the need to undergo a revision/explantation of the initial procedure, resulted in significantly higher decisional regret. Given that AUS has a relatively high revision rate approaching 25% in some patients (20), we feel that our findings may represent a lapse in pre-operative counseling, or patient understanding regarding risks of procedure and

overall long-term expectations. Moreover, the subset of patients that opted for AUS placement after previously placed sling showed the highest degree of decisional regret. Each of these findings is particularly important in operative patient selection and preoperative counseling, as the patient's expectations and definition of surgical success may potentially be incongruent with actual surgical success. We interestingly found that post-operative pad per day usage was not correlated with decisional regret. This finding would appear to indicate that even patients who did not have the intended pad per day outcome still had low levels of regret.

Though the decisional regret scale was recently studied in older men undergoing SUI treatment (both conservative and surgical), our study focuses on its application solely in the surgical setting. It has also been studied in prostate cancer, hypospadias, and surgery for pediatric fecal incontinence. Morris *et al.* evaluated treatment decisional regret among men with prostate cancer and found that 12% of patients experienced treatment regret, despite favorable treatment outcomes. Increased regret was associated with unexpected treatment side effects on daily life, which resulted in lower patient satisfaction (9). van Engelen *et al.* assessed parental decisional regret following surgical treatment in young males born with hypospadias and discovered that 50.5% of parents (11.3% moderate-strong) reported decisional regret, which was unrelated demographic or medical variables; instead, parents' decisional conflict and patient's psychosocial behavioral problems directly correlated with regret (11). Consequently, our results and prior applications of DRS can differ from patient satisfaction, in that patients may report satisfactory surgical results, but high decisional regret could have prohibited them from undergoing the chosen procedure due to complications, multiple interventions, or discordant expectations.

With regard to recent application of the DRS in older men undergoing treatment for SUI, similar findings were noted in that the majority (78%) of patients reported none to mild decisional regret associated with their chosen treatment (13). However, Hampson *et al.* reported statistically significant DR amongst patients with concomitant depression, lower rating of shared decision-making, and higher current incontinence scores (13). Though comorbidities and shared decision-making were not patient characteristics evaluated in our study, degree of incontinence did not correlate with higher decisional regret,

an important and novel finding. In addition, the need for surgical revision was also highlighted as a statistically significant finding and was not reported in Hampson's study. Though the two studies display similarities in the method by which they were conducted, DRS utilized, and overall purpose, the difference in results (predictors of higher decisional regret) and sole focus on surgical treatment options in middle to older aged men sheds new light on SUI treatment counselling.

We recognize that our study is limited by a relatively small sample size, particularly attributed to overall participation in survey. Further investigations utilizing the DRS questionnaire at follow-up visits may prove more inclusive, including those who declined to participate in the research consent over the phone due to time constraints and/or misunderstanding of provided information. This limitation was mitigated by the fact that the participants who completed questionnaires represented a diverse cohort based on surgery type and severity of SUI. Future studies need be prospective in nature to capture more respondents. Administration of DRS at follow-up visits may also standardize time to follow-up, with DRS administered at set time periods to assess for any variability with increasing time from surgery. For future studies, one may consider conducting a survey on symptom bother, both pre- and post-operatively, and compare these findings to overall decisional regret. Differentiation amongst pad usage, i.e., liners versus diapers, may also prove interesting in determining surgical success, patient-viewed success, and treatment regret.

Conclusions

The DRS has recently been applied to older men undergoing anti-incontinence treatment for male stress incontinence, but our study focuses on its application in middle age to older men solely undergoing surgical therapy. As expected, the majority of men had minimal regret with a subset that had significant regret—history of radiation, multiple revisions/explant, and those who elected for sling but later required AUS. However, we interestingly found that persistent post-operative incontinence did not correlate with degree of decisional regret. These results further highlight the importance of patient selection and pre-operative counseling in patients undergoing elective procedures for male SUI.

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Footnote

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Ethical Statement: The authors are 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. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the University of Oklahoma Health Sciences Center Institutional Review Board (IRB No. 11596) and individual consent for this retrospective analysis was obtained through telephone.

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