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The use of male slings in the treatment of severe post prostatectomy urinary incontinence: a comparative study in patients with or without radiotherapy

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Abstract

Introduction: Urinary incontinence is a hostile complication following radical prostatectomy in patients with prostate cancer. The AUS achieves higher continence rates than male slings; however, its revision rates are not insignificant. The aim of this study was to investigate whether the Advance XP male sling could be an effective treatment option to improve quality of life in patients with severe post prostatectomy urinary incontinence, comparing patients with and without prior radiotherapy.

Methods: it was a prospective study assessing the satisfaction, social continence and urodynamic predictors of failure for patients who had undergone to male sling to treat PPI.

Outcomes: Fifty-eight patients with severe post prostatectomy urinary incontinence underwent Advance XP male sling. The overall satisfaction was almost 90%. Patients who had undergone RT presented lower abdominal leak point pressure and lower social continence, without any difference regarding satisfaction.

Conclusion: Advance XP sling represents a viable option to treat patients with severe urinary incontinence, reaching high satisfaction rates and social continence. Although prior radiotherapy decreases social continence outcomes, overall patient satisfaction remains acceptable.

INTRODUCTION

Urinary incontinence is an unpleasant complication following radical prostatectomy in patients with prostate cancer (1). Its reported prevalence varies widely, ranging from 2 to 65% (2–3). The use of male slings to treat post-prostatectomy urinary incontinence (PPI) has been increasingly studied as an alternative to artificial urinary sphincter (AUS), which is still considered the gold standard procedure (4). Although the AUS achieves higher continence rates than male slings, its revision rates are not negligible, comprising over 25% at 3 years (5).

The repositioning urethral male sling (MS) is a perineum mesh device that increases resistance to urinary outflow. It was originally developed to treat men with mild incontinence, defined as the use of 1–3 pads/day (4). Several studies have assessed male slings in the treatment of mild PPI.

Advance XP (Boston Scientific), is a repositioning urethral male sling that has demonstrated a mean subjective cure rate exceeding 71% after 4 years follow-up (6). Patients treated with AdVanceXP have an improvement in continence rate over 15%. Nevertheless, approximately 14% of patients fail to achieve good outcomes after surgery (6). These findings have been corroborated by additional studies(5, 7). Several factors have been identified as negative predictors of sling success, particularly prior radiotherapy and severe urinary incontinence (8).

The MASTER trial (9), a non-inferiority randomized controlled trial, compared the male transobturator sling with the AUS in men with bothersome urodynamic stress urinary incontinence after prostate surgery. The trial demonstrated that the male sling was non-inferior to the AUS in continence rates at 12

months (87.0% vs 84.2%). However, secondary outcomes favored the AUS, which showed greater symptom reduction and quality-of-life improvements.

It must be highlighted that the MASTER trial did not exclusively included patients with severe PPI (9), and its primary endpoint focused on continence rates rather than quality of life metrics. Currently, there is an increasing trend to value quality of life (QoL) instead of solely objective parameters (10), such as pads per day. This could influence the treatment outcomes and potentially redefine gold stand procedures to treat PPI. Although the AUS achieves higher continence rates, this does not necessarily translate into superior quality of life, as patients must manually operate the pump to void, face higher risks of mechanical failure, and may ultimately require additional surgeries. The risks, complexity and costs of the AUS are also limiting factors, particularly in developing countries. In this scenario, male slings may offer a more accessible means of improving QoL in patients with urinary incontinence.

The aim of this study was to investigate whether the Advance sling could be an effective treatment option to improve quality of life in patients with severe PPI, including those who had undergone prior radiotherapy (RT), at 12 months follow up.

Additionally, we assessed clinical and urodynamic features as predictors of success or failure among all patients and between groups.

MATERIAL AND METHODS

This was a prospective, observational and non-comparative study performed between March 2022 and February 2024, at a single center in São Paulo (Brazil). The procedures were done by a single surgeon.

All procedures were carried out in accordance with the Declaration of Helsinki (11). The study was registered and approved by the local ethics committee (CAAE: 84277724.0.0000.5432). Informed consent to participate was obtained from all of the participants in the study.

All patients were assessed using a strict protocol, including clinical evaluation, embracing comorbidities and stratification of urinary incontinence through 24-hour PAD test, the number of PADs used per day (PPD) and the Standing Cough Test.

The inclusion criteria were patients with severe urinary incontinence, defined by 1-hour PAD test > 75g or number of PADs per day used (PPD) > 4 or Standing cough test grade 3 or 4. Exclusion criteria included patients with moderate or mild PPI, neurological conditions, untreated urethral stenosis, bladder stones, active bladder cancer, active prostate cancer.

Baseline symptoms such as urgency and nocturia were also recorded. All patients underwent urodynamic studies prior to sling implantation, following the best practices recommended by the International Continence Society (12).

The parameters assessed included cystometric capacity (ml), presence and amplitude of detrusor overactivity (cmH2O), bladder sensivity and compliance (ml/cmH2O), abdominal leak point pressure – ALPP (cmH2O) and leakage volume. Pressure-flow studies were also perfomed in all patients.

All patients underwent a standard procedure involving the implantation of the male sling (Boston Scientific AdVance™ XP Male Sling System). The procedure initiates with bladder catheterization using a 14 Fr Foley catheter in the lithotomy position. A midline perineal incision was made to expose the bulbo espongiosus muscle, which was subsequently opened to reveal the sponge of the urethra and the central tendon of the perineum (CTP). The CPT was released until the proximal part of the bulbar urethra reaches approximately 3–4 cm of mobilization toward the membranous urethra. It must be highlighted that this urethral mobilization was one of the most critical steps of the surgery and the procedure proceeded only after achieving it.

Subsequently, the device was implanted. Sling passed along the summit of an imaginary triangle defined by the urethra, pubic bone and the corpora cavernosa. The mesh was fixed with an absorbable suture at the proximal bulbar urethra and tensioned until the bulbar urethra advance forward to bladder neck. Foley catheter was removed on postoperative day one, and patients were discharged after demonstrating a spontaneous voiding.

Postoperatively, patients were evaluated regarding their satisfaction with the procedure [Patient Global Impression of Improvement (PGI-I) - ranging from 0% – not at all satisfied – to 100% - totally satisfied], improvement in quality of life (QoL), as well as changes in PPD usage, severity of nocturia, and urgency.

The correlation between patient satisfaction after the procedure and all clinical and urodynamic parameters were analyzed. Patients with prior Radiotherapy (RT) were assessed separately after que initial analysis, to determine whether the outcomes were inferior compared to those patients without RT, according to previous evidence (13).

Statistical analysis

Statistical analysis was performed using JAMOVI software version 1.6. Categorical variables were assessed using Chi-square test (or Fisher test, when appropriated). Student's T-Test and Mann-Whitney U tests were performed as appropriate. To compare pre- and postoperative continence status in groups, the Wilcoxon signed-rank test was used

All values in the text and tables are expressed as mean ± standard deviation. Statistically significant results were P < or equal to .05

RESULTS

Fifty-eight patients were initially included in the study. After applying the exclusion criteria, 50 patients with severe PPI underwent repositioning urethral male sling. Twenty-five patients had undergone

radiotherapy. Baseline data are presented in table 1.

Table 1 – Overview of patient characteristics and preoperative parameters (mean ± standard deviation)

Age (years)	**Total (n = 50)**	**Non-radiotherapy group (n = 25)**	**Radiotherapy group (n = 25)**	**p (IC)**
	71.5 ± 6.66	**71.7 ± 6.72**	**71.2 ± 6.76**	**0.84 (-4.24–5.14)**
Time of incontinence (months)	61.7 ± 44.7	57.6 ± 53.3	67.1 ± 30.8	0.54 (-40–21.8)
BMI (Kg/m^2)	26.7 ± 3.35	27.6 ± 3.44	25.5 ± 2.92	0.06 (-0.16–4.13)
PPD	3.91 ± 2.45	3.95 ± 3.12	3.87 ± 1.19	0.92 (-1.6–1.8)
PAD test 1h	109 ± 85	103 ± 78.9	116 ± 94.8	0.65 (-73–46)
SCT	2.69 ± 1.08	2.55 ± 1.19	2.87 ± 0.95	0.39 (-1.06–0.43)
Urgency	60%	31.4%	28.6%	0.486
Hypertension	62.9%	40%	22.9%	0.313
Diabetes	40%	17.1%	22.9%	0.163
Treated uretral stenosis	5.7%	0	5.7%	0.09
Climaturia	5.7%	0	5.7%	0.09
Urodynamic				
ALPP (cmH2O)	125 ±49.1	145 ± 48.3	96.9 ± 35	**0.02** *(18.4–78.5)
Leak (ml)	336 ±143	365 ± 138	297 ± 146	0.16 (-29–166)
CC	368 ± 90.7	393 ± 83.6	332 ± 92.5	**0.05** * (-0.2–121)
Qmax (ml/sec)	19.2 ± 11.1	22.1 ± 13.2	15.4 ± 5.78	0.07 (-0.80-14)
PDetQmax (cmH2O)	24.9 ± 12.3	26.6 ± 13.2	22.6 ± 11	0.349 (-4.57-12.5)
PVR (ml)	16.7 ± 28	7.25 ± 16	29.3 ± 53.6	0.08 (-47-3.5)

p value compares groups no radiotherapy vs radiotherapy; IC – Confidence Interval ;

t-student or Mann-Whitney test according to the distribution data ; % - percentage values – Chi-square or Fisher test, according to expected values

Note: Bold values refers to significant outcomes
BMI = body mass index ; PPD = pads per day ; SCT = Standing cough test ; ALPP = abdominal leak point pressure ; CC = Cystometric capacity ; PVR = Post void residual volume

The two groups were similar, although significant differences were observed between them regarding ALPP and cystometric capacity (CC). The group that had undergone RT presented lower ALPP and lower CC.

Overall satisfaction at 12 months follow-up in patients with severe urinary incontinence was high (mean 86,7±17.1%). There was no difference between groups regarding satisfaction [RT group 82.3% vs Non-RT group 90%, [p = 0.146 (-4.06,19.4), Mann Whitney test], as shown at table 2.

Table 2 – Outcomes at 12 months after repositioning male sling implanted (mean ± standard deviation)

PGI Satisfaction (%)	Total (n = 50)	Non-radiotherapy group (n = 25)	Radiotherapy group (n = 25)	p
	86,7±17.1	**90.6 ± 15.6**	**82.3 ± 18.4**	**0.146**
PPD	0.74 ± 0.74	0.55±0.60	1±0.84	0.108
Post-operative SCT	0.4 ± 0.73	0.35±0.74	0.46±0.74	0.570
Nocturia	0.68±1.11	0.6±0.99	0.8±1.26	0.78
Qmax (ml/sec)	15.9 ± 7.7	17.3±8.9	14±5.44	0.356
Urgency	31.4%	20%	11.4%	0.599

p value compares groups no radiotherapy vs radiotherapy ;

PGI – Patient Global Improvement ; PPD – Pads per day ; SCT – Standing Cough test ; Qmax – Peak flow on uroflowmetry

It was not found any difference after surgery in PPD used, post operative SCT or urgency between patients with or without RT, although patients with RT had lower ALPP preoperatively ($p < 0.05$), as show in Fig. 1.

Social continence (defined as the use of 1 PAD per day or less) was assessed and compared between patients with and without RT. Although satisfaction did not differ significantly between groups, it was

clear that social continence was significantly better in patients without RT, with statistical significance (p = 0.02, Mann Whitney test), as shown at Fig. 2.

A bladder capacity (CC < 300 ml) emerged as the main feature which predicts poorer outcomes, regarding higher rates of detrusor overactivity (p = 0.02), satisfaction (p = 0.02), early leakage volume (p = 0.02) and increased nocturia (p = 0.02), presenting statistical differences, as shown in table 3 (supplementary files).

DISCUSSION

There are several studies about male slings for the treatment of post-prostatectomy urinary incontinence (PPI), however most of them assess mild grade of incontinence. Although theses devices were developed to treat mild leakage, there is an increasing trend to extrapolate their use in patients with moderate to severe urinary incontinence (9, 14), due to good outcomes. This study represents the first prospective evaluation of the Advance XP male sling in patients with severe urinary incontinence, comparing patients with and without prior radiotherapy.

Patients were categorized as having severe urinary incontinence, based on the 1-hour PAD test, the standing cough test or the daily pad usage. All of them underwent the repositioning male sling procedure, through a standardized manner, performed by a single surgeon. The mobilization of the urethra was insistently pursued, to achieve at least 4 cm of mobility. It was decided to reach this mobilization due to the mechanism of action of the urethral repositioning male sling. Only after that, the trocars were inserted, and the mesh was positioned. An unfavorable repositioning test has been identified as a predictor of failure after male sling procedure, according to a metanalysis involving 5696 patients (8)

In this study, the satisfaction after the procedure was very high (about 85%), with no significant difference between patients with or without RT in our study. Despite lower ALPP values in the RT group, the outcomes after the procedure were promising, with no difference regarding the two groups. These satisfaction rates are comparable to those reported on MASTER trial. The MASTER trial (9) demonstrated that patients with moderate to severe urinary incontinence (pad weight over 250g) reached 77% of satisfaction after the male sling procedure against 95% after artificial urinary sphincter procedure. Our findings were similar, suggesting that repositioning urethral male slings could be a cheaper alternative to artificial urinary sphincter, achieving good results. Even satisfaction is not so high as the achieved by AUS, patients improved their quality of life.

Regarding the social continence, patients with prior RT achieved inferior outcomes compared to those without radiation. Nevertheless, overall satisfaction remained similar. We can suppose the RT group reaches acceptable quality of life, with continence improvement, despite lower continence rates.

Favero et al (15) reported functional outcomes and patient satisfaction after AdVance and AdVanceXP at 5 years follow-up. The reported social continence was 66% and the satisfaction rate was 71%. These

outcomes were slightly inferior compared to our results, nevertheless It must be highlighted that 30% of their cohort received the old version of the device (AdVance) rather than the new one (AdVanceXP). The long term follow up could explain this difference, taking into account that the slings decrease their performance during the years. Furthermore, 23% of the patients had severe urinary incontinence also, but unfortunately, they did not mention the percentage of implantation of AdVanceXP in each population, according to grade of incontinence. Maybe, the group with severe urinary incontinence was undergone to the old version of de device.

Among potential predictors of failure or poorer outcomes on groups, we found out the cystometric capacity (CC) was the strongest urodynamic predictor which affected the results. Cystometric capacity was the most important predictor of early leakage, nocturia and overactivity, showing a linear correlation. Interestingly, CC can affect postoperative satisfaction more than ALPP or overactivity. These findings are consistent with previous studies. Lai HH et al (16) assessed the influence of preoperative overactive bladder on the continence outcomes of artificial urinary sphincter implantation and reported the rates and risk factors associated with the development of de novo and persistent overactive bladder after AUS surgery. They found that cystometric capacity lower than 200 ml increased overactivity bladder after surgery.

We believe our results highlight and urge new further large-scale and prospective studies to assess the efficacy of the Advance XP in patients with severe urinary incontinence. This is particularly important especially due to the higher costs of the artificial urinary sphincter in developing countries, where AUS is not easily available. We attribute our favorable results to surgical technique, especially due to the urethral mobilization through the release of the central tendon of the perineum, a critical and essential step during the surgery to achieve continence postoperatively.

There are several limitations in our study, such as the short follow-up and relatively small sample size. However, these were mitigated by a homogeneous population. All patients suffered from severe urinary incontinence and according to our knowledge, it was the first study to assess implantation of Advance XP in this grade of incontinence, with no variations.

CONCLUSION

Advance XP sling can represent a viable option to treat patients with severe urinary incontinence, reaching high satisfaction rates and social continence. Although prior radiotherapy decreases social continence outcomes, overall patient satisfaction remains acceptable. Further studies can investigate whether sling can become a more accessible way to treat moderate-severe urinary incontinence.

Abbreviations

ALPP
Abdominal leak point pressure
AUS

Artificial urinary sphincter
BMI
body mass index
CC
cystometric capacity
CPT
Central tendon of of perineum
MS
Male sling
PPD
PADs used per day
PGI
Patient Global Improvement
PPI
post–prostatectomy urinary incontinence
PVR
Post void residual volume
Qmax
Peak flow on uroflowmetry
QoL
Quality of life
RT
Radiotherapy
SCT
Standing cough test

Declarations

Ethics approval and consent to participate - The study was registered and approved by the local ethics committee (CAAE: 84277724.0.0000.5432). An informed consent to participate was obtained from all of the participants in the study.

Consent for publication - Not Applicable

Availability of data and materials – data are stored in redcap of our institution, following the rules of our local ethical committee. It can be assessed on the website https://redcap.epm.br/redcap_v17.1.2/index.php?pid=2265. Data are protected and only the researchers can assess this information, nevertheless anyone can consult upon requesting, as long as they provide a valid reason.

Competing Interests – there is no confliction interest.

Funding - the study developed includes only patients treated inside the Brazilian public health system. There were not any additional costs involved.

Authors' contributions

Lebani, Bruno Rodrigues* (*corresponding author) - conceptualization, Methodology, Investigation, Data Curation, Formal Analysis, Writing – Original Draft, Visualization, Project Administration

Baungratz, Monaliza Marizete - Methodology, Investigation, Data Collection, Writing – Review & Editing.

Barcelos, André da Silva - Methodology, Investigation, Data Collection, Writing – Review & Editing.

Glina , Felipe Placco Araújo - Methodology, Investigation, Data Collection, Writing – Review & Editing.

Sacomani, Carlos Alberto Ricceto – Supervision, Methodology, Critical Revision of the Manuscript.

Pinto, Eduardo Remaile da Silveira - Supervision, Methodology, Critical Revision of the Manuscript.

Skaff, Milton - Supervision, Methodology, Critical Revision of the Manuscript.

Zequi, Stenio - Supervision, Validation, Critical Revision of the Manuscript.

Almeida, Fernando Gonçalves - Conceptualization, Supervision, Validation, Writing – Review & Editing, Final Approval of the Manuscript.

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Figures

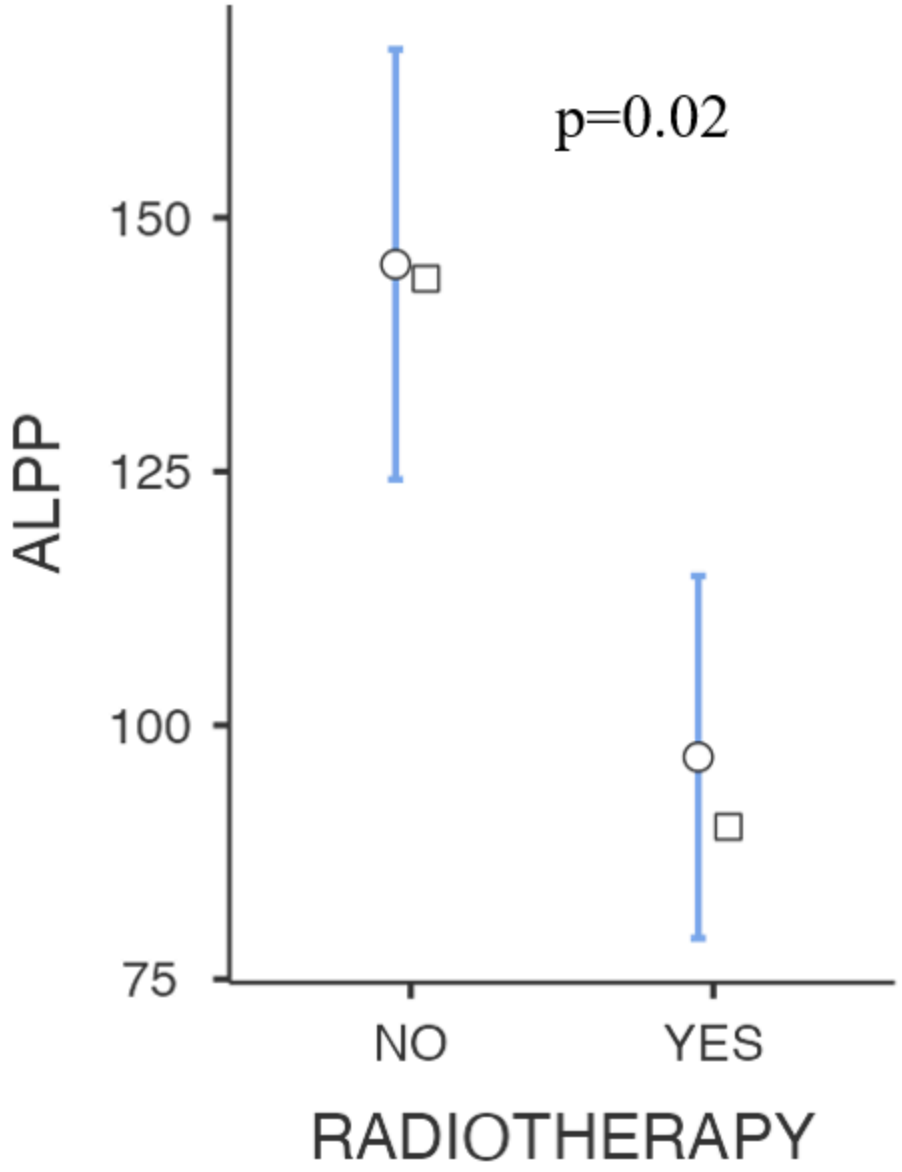


Figure 1

ALPP vs Radiotherapy group and No Radiotherapy group p value compares groups no radiotherapy vs radiotherapy.

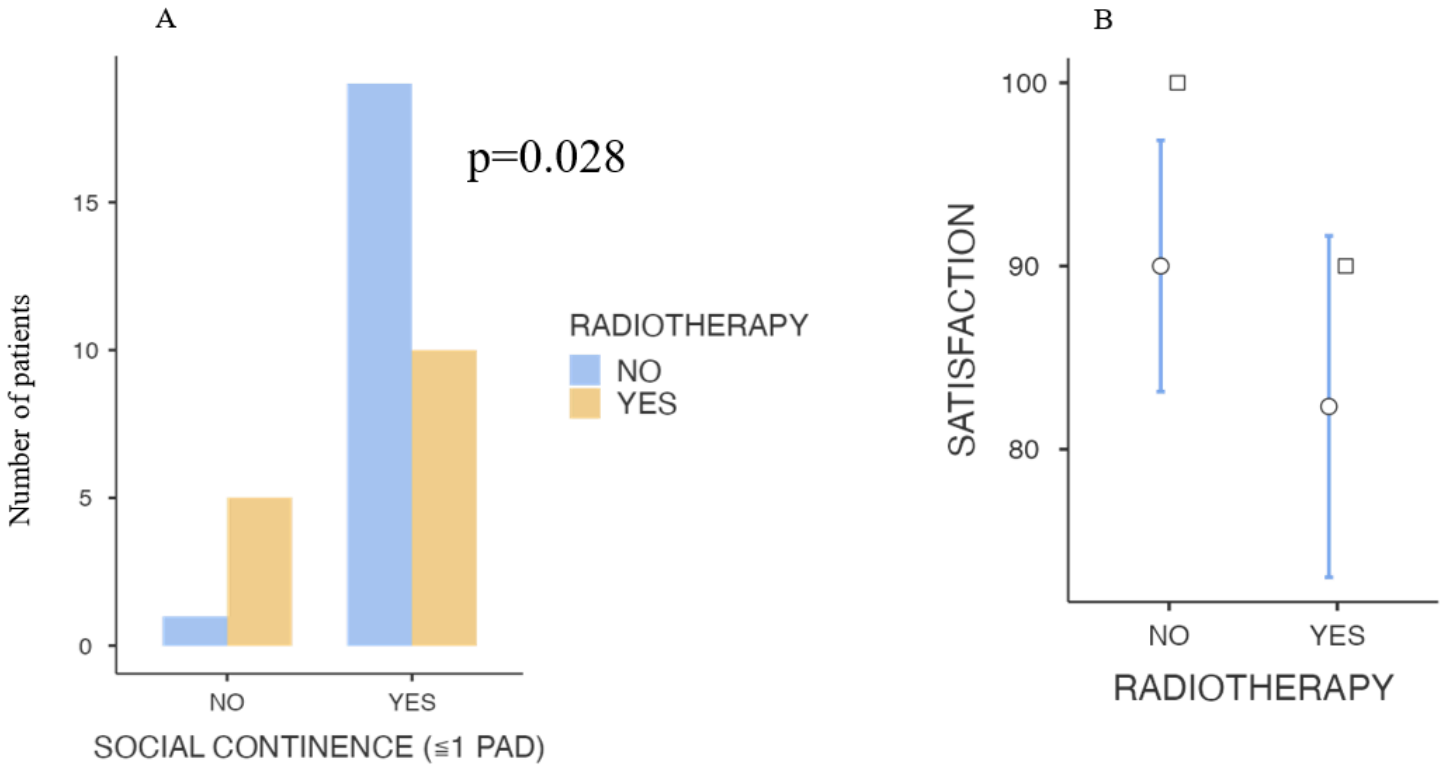


Figure 2

A – Social continence in patients with and without Radiotherapy ; B – Satisfaction (Radiotherapy vs No Radiotherapy) ; p value compares groups no radiotherapy vs radiotherapy.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table3Supplementaryfile.docx