Urethral Slings for Irradiated Patients With Male Stress Urinary Incontinence: A Meta-analysis

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OBJECTIVE To systematically compare success, cure and complication rates of urethral sling surgeries in stress urinary incontinence patients with and without a history of pelvic radiotherapy (RT).

MATERIALS AND METHODS We searched PUBMED, EMBASE, and Web of Science to identify relevant articles. The primary outcomes were the success and cure rates. The secondary outcomes included the rates of infection, urethral erosion, total complications, explantation, and satisfaction. Outcomes were analyzed using a random-effects model to calculate the unadjusted odds ratio (OR) in patients with a history of RT compared with those without prior RT.

RESULTS On pooled analysis, we found significantly lower odds of success (OR 0.68; 95% confidence interval [CI] 0.53-0.87, $P < .001$) and cure (OR 0.67; 95% CI 0.55-0.82, $P < .001$) in radiated patients than in nonirradiated patients. Subgroup analysis by type of sling showed significantly lower odds of success in Advance subgroup (OR 0.66; 95% CI 0.45-0.95, $P < .001$) and significantly lower odds of cure in Advance (OR 0.59; 95% CI 0.36-0.95, $P < .001$) and Atoms subgroups (OR 0.70; 95% CI 0.54-0.93, $P < .001$). We also found significantly greater odds of sling explantation (OR 2.93; 95% CI 1.62-5.29, $P < .001$) and infection (OR 3.06, 95% CI 1.03-9.07, $P < .001$) in radiated patients than in nonradiated patients.

CONCLUSION Patients with a history of pelvic RT have lower odds of success and cure and higher odds of infection and sling explantation than those without a history of pelvic RT. UROLOGY 180: 262–269, 2023.

Stress urinary incontinence (SUI) is a debilitating condition involving the loss of control over urination due to low urethral resistance. It affects 12%-17% of men in the United States.[1,2] SUI is especially common following radical prostatectomy, with rates as high as 40%.[3-5] Radiotherapy (RT) is frequently performed after prostatectomy, specifically in patients with adverse pathological features.[6] Furthermore, men with a history of pelvic radiation therapy are more prone to developing SUI.[7]

Contemporary procedures for treating postoperative SUI include the use of an artificial urinary sphincter (AUS), male urethral slings, and urethral bulking agents. The male urethral sling procedure involves the placement of a synthetic mesh to increase urethral resistance by compression or repositioning of the urethra to improve incontinence.[8] Patients with a history of radiation therapy are more prone to sling failure and complications such as sling erosion. This may be due to increased periurethral fibrosis or sphincter damage, which causes proportional intrinsic sphincter deficiency.[9,10]

Although the American Urologic Association (AUA) and Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU) guidelines suggest a preference for AUS over slings in patients with a history of pelvic radiation, male slings are gaining popularity owing to their convenient insertion, safety, and efficacy.[11,12] Male urethral slings have been shown to have success rates of up to 89%.[13,14] Furthermore, patients may favor slings as they enable a more physiological voiding process without the need to operate a manual pump.[15]

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However, there is disagreement in the available literature regarding the success and cure rates of sling surgeries in radiated patients compared to nonradiated patients. Hence, it is essential to have a clear understanding of the risks and benefits of urethral sling use in this population, so that these patients can be properly counseled prior to surgery.

In this systematic review and meta-analysis, we aimed to compare the success of male urethral slings in patients with a history of pelvic radiation to those with no radiation history. We will also evaluate the most common complications after male urethral sling surgery in the setting of radiation history, and how they compare to patients without a history of radiation.

MATERIALS AND METHODS

Search Strategy

Our systematic review and meta-analysis was performed using the standard protocol devised by the Meta-analysis of Observational Studies in Epidemiology (MOOSE).[16] Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) recommendations were followed to design the search strategies, selection criteria, and evidence report.[17] The International Prospective Register of Systematic Review (PROSPERO) protocol number for this study is CRD42022319363. We used the patient, intervention, comparison, and outcomes (PICO) strategy to answer our research question (Supplementary Table 1).

Two authors (U.G. and B.A.) independently searched online databases including PUBMED, EMBASE, and Web of Science from inception to October 4, 2020, using a combination of Boolean operators ("OR," "AND") for medical subject headings and key terms including: "Radiotherapy," "Radiation therapy," "External beam radiation therapy," "prostate cancer," "Incontinence," "Sling," and "Slings". No filters were applied based on publication year, publication design, or language. Conferences, including abstracts, were searched for relevant information. A gray literature search was conducted using Google Scholar with a prime focus on the first 200 results. References of the included articles were manually searched for relevant studies. For studies published by the same authors or institutions, only the most recent or largest study was reported to have reduced the risk of repeated data. The full search strategy is provided in Supplementary Table 2.

Two authors (U.G. and B.A.) performed title and abstract screening and a full-text review. The inclusion criteria were as follows: (1) observational or experimental studies, (2) males who underwent urethral sling surgery of any type for SUI, and (3) parameters of success or complications mentioned separately for patients with and without RT.

Data Extraction

The following data points were collected: (1) baseline characteristics: age, follow-up duration, cause of SUI, type of sling (Argus, Virtue, ATOMS, Advance, Invance, Remeex, and Other), and history of RT; (2) primary outcomes: success and cure rates; and (3) secondary outcomes: rates of infection, urethral erosion, explantation, total complications, and patient satisfaction. Primary and secondary outcome data points were extracted from the spreadsheets. Discrepancies that arose during screening and data collection were resolved by consensus among the three lead authors and principal investigator (U.G., B.A., J.G., and B.B.).

Definitions and Endpoints

The primary outcomes of interest were the success and cure rates. The criteria for the success rate were either cured or improved. The cure rate included only patients who were cured. Definitions for cure and improvement in each study are provided in Table 1.

Quality Assessment

The quality of the included studies was assessed using the Newcastle-Ottawa scale.[18] A total score of 8-9 was considered high quality, 6-7 was considered intermediate quality, and 5 or less was considered low quality (Supplementary Table 3).

Statistical Analysis

Statistical analyses were performed using STATA version 17 (StataCorp, College Station, TX). A random-effects model was used to calculate the pooled odds ratio (OR). Statistical significance was set at an alpha value of $P < .05$. The estimated effect size was reported as a point estimate with a 95% confidence interval (CI). The Higgins I-squared statistical model was used to evaluate variations in outcomes of the included studies with values < 25%, 25%-49%, 50%-75%, and > 75%, corresponding to no, low, moderate, and high degrees of heterogeneity, respectively. Publication bias was illustrated using funnel plots and further explored using contour enhancement. Harbord's test was performed to assess publication bias.[19] Leave-one-out sensitivity analyses were conducted to assess the impact of excluding a single study on the primary outcomes.

RESULTS

The initial database search yielded a total of 899 studies. After excluding duplicates, 727 studies were included. The titles and abstracts were screened, and 551 articles were excluded. A full-text review of the remaining 176 articles was performed, and 27 studies consisting of 2569 participants (549 with a history of RT and 2020 without a history of RT) were included in the final analysis[10,15,20-44] (Fig. 1). The quality of the included studies was moderate to high on the Newcastle-Ottawa scale. The quality assessment findings of the included studies are summarized in Supplementary Table 3.

Baseline Characteristics

The baseline demographics and characteristics of the included studies are summarized in Table 1 and Supplementary Table 4. All included studies were observational, with 12 retrospective, 14 prospective, and 1 prospective and retrospective study. There were a total of 2569 patients, of which 21.4% had a history of RT while 78.6% did not have a history of RT. Among all the participants, prostatectomy was the most frequent cause of SUI. Other causes included transurethral resection of the prostate, unspecified endoscopic resection, focused ultrasound, trauma-induced sphincter insufficiency, adenomectomy, transurethral resection of the bladder, and radiation therapy. Sling types varied with Advance (nine studies), Invance (five studies), Argus (three studies), Atoms (five studies), Virtue (two studies), Remeex (two studies), and one study using another nonbranded type of sling. Satisfaction was

Table 1. Baseline characteristics of the included studies.

Author (s)	Type of Study	Median Age (Range)	Mean Age (y)	Median Follow Up (mo)	Mean Follow Up (mo)	Sling Type	Cure Parameter	Improvement Parameter
Siracusano 2017[20]	P	71 (50-86)		22 (1-59)		Argus	0-1 PPD	1-2 PPD or > 50% reduction in PPD
Torrey 2013[21]	R	68 (62-71)		17.3		Advance	No pads required	Decrease in number of PPD
Wright 2017[22]	R		69.3		ST 19.4 (2-52) LT 61.5 (33-92)	Advance	No pads required	1-2 PPD
Berger 2011[23]	R	67 (52-79)		22 (10-27)		Advance	No pads required	> 50% improvement in PPD or < 2 PPD
Clemens 1999[24]	P		68 (54-80)	9.6 (11-30)	11.9	Other	1 PPD (If > 1 PPD preoperatively) and 0 ppd (If 1 or less ppd preoperatively)	> 50% decrease in postoperative PPD
Doiron 2019[25]	R and P		70.5 SD 6.6	9 (4.5-13.5)		ATOMS	< 1 PPD	
Carmel 2009[26]	P		68 SD 6.3	36 (2-64)		Invance	Dry	1 PPD
Castle 2005[27]	R		71.6 (55-90)	18.1		Invance	≤1 PPD (If ≥2 pads preoperatively) and 0 pads (If 1 PPD preoperatively)	> 50% change in daily pad use
Fassi-Fehri 2007[10]	P		70 (48-81)	6 (1-22)		Invance	No further need for 1 PPD or further procedures	
Redmond 2020[15]	R		68.9 + − 6.6 (55-90)		19.6	Atoms	0 or 1 PPD	1-2 PPD and pad reduction > 50%
Shakir 2018[28]	P	67 (63-72)		64 (39-94)		Advance	Dry, with a pad test of 0-1 g	
Soljanik 2012[29]	P				20.8 (12-43)	Advance	No pads required or 1 PPD by precaution (dry)	≤1 PPD or pad usage reduced by ≥50%
Hubner 2010[30]	R		69.6 (51-84)		25.2 (1.2-54)	Argus	Dry rate	
Abdullah 2019[31]	R		67.8 + − 8.5		11	Virtue	0 or 1 PPD	Reduction of pads usage by > 50%
Angulo 2019[32]	R		69.7 + − 7		24.3 ± 14.2 (8-60) mo	ATOMS	Reduce leakage < 2 PPD	
Cornu 2009[33]	P		67.1 + − 6.8 (54-84)	13 (6-26)		Advance	Dry or 1 PPD for security	PPD improved > 50%
McCall 2016[34]	R	72 (64.5-77)		55 (30-69)		Virtue	Dry	PPD improved > 50%
Papachristos 2017[35]	P	67 (54-86)		52		Advance	Dry or 1 PPD for security	1-2 PPD or PPD improved > 50%
Alejandro Sousa-Escando´na 2007[36]	P	69 (58-81)		32 (16-50)		Remeex	Dry	1-2 PPD or PPD improved > 50%
Alessandro Giammò 2019[37]	R	73.7	73.6 (58.9-84.3)		20.1 mo (8.1-41.5)	ATOMS	Dry	2 or fewer pads and reduced by at least 50%
Rehder 2012[38]	P	68 (63-72)		39.0 (37.0-42.0)	40.1 + − 6 SD	Advance	0 or 1 security PPD	< 2 or 50% fewer pads than that at baseline

Table 1 (*Continued*)

Author (s)	Type of Study	Median Age (Range)	Mean Age (y)	Median Follow Up (mo)	Mean Follow Up (mo)	Sling Type	Cure Parameter	Improvement Parameter
Onur 2004[39]	P		67		18	Invance		
Cerniauskiene 2020[40]	R	70 (55-84)		12		Argus		
Muhlstadt 2020[41]	P		69.4 + − 6.6 (46-84)		44 + − 30.9	Atoms		
Gallagher 2007[42]	P				15 (9-21)	Invance		
Leruth 2011[43]	P			24	28 (12-60)	Advance		
Kim 2015[44]	R	70 (53-84)			46 (12-89)	Remeex		

LT, long term; P, prospective; PPD, pads per day; R, retrospective; ST, short term.

measured using the Patient Global Impression of Improvement (PGI-I) in two studies, a global assessment questionnaire in one study, and unspecified in one study.

Primary Outcomes

In the pooled analysis, radiated patients had lower odds of success than nonradiated patients (OR 0.68; 95% CI 0.53-0.87, P < .001) (Fig. 2). Subgroup analysis by type of sling showed significantly lower odds of success in the Advance subgroup (OR 0.66; 95% CI 0.45-0.95, P < .001) (Supplementary Fig. 1). The odds of cure were significantly lower in radiated patients than in nonradiated patients (OR 0.67; 95% CI 0.55-0.82; P < .001) (Fig. 3). Subgroup analysis by type of sling showed significantly lower odds of cure in radiated patients with Advance (OR 0.59; 95% CI 0.36-0.95, P < .001) and Atoms slings (OR 0.70; 95% CI 0.54-0.93, P < .001) (Supplementary Fig. 2). Heterogeneity of the included studies was low.

Secondary Outcomes

On pooled analysis, the odds of sling explants were significantly greater in radiated patients than in nonradiated patients (OR 2.93; 95% CI 1.62-5.29, P < .05) (Supplementary Fig. 3). Radiated patients also had greater odds of infection than nonradiated patients (OR 3.06, 95% CI 1.03-9.07, P < .05) (Supplementary Fig. 4). There was no statistically significant difference in the odds of urethral erosion (OR 1.31, 95% CI 0.26-6.66, P = .743), total complications (OR 1.20, 95% CI 0.70-2.08, P = .449), or patient satisfaction (OR 0.75, 95% CI 0.54-1.04, P = .082) between the radiated and nonradiated patients (Supplementary Figs. 5-7).

Publication Bias

Funnel plots showed mild asymmetry in visual assessment, representing mild publication bias (Supplementary Fig. 8). Publication bias was assessed quantitatively using Harbord's test, which suggested no small study effect on publication bias (P = .066) (Supplementary Fig. 9). A sensitivity analysis based on the "leave-one-out" test showed no influence of any individual study on the pooled odds of success and cure (Supplementary Figs. 10 and 11).

DISCUSSION

Although previous systematic reviews have evaluated different types of urethral slings for SUI management in postprostatectomy patients, our systematic review and meta-analysis is the first to quantitatively compare the outcomes of urethral sling surgery for SUI in men with and without a history of RT.[45] In this systematic review and meta-analysis of 27 studies, we found statistically significant lower odds of success and cure of sling procedures in patients with a history of RT.

History of RT has been shown to affect the surgical and functional outcomes of sling surgeries. As a result, it is generally not recommended for patients with a history of RT to undergo sling surgery.[11] Despite this, there is a relative paucity of information on the efficacy of modern slings in this challenging population. Existing data on the subjective and objective outcomes of sling surgeries

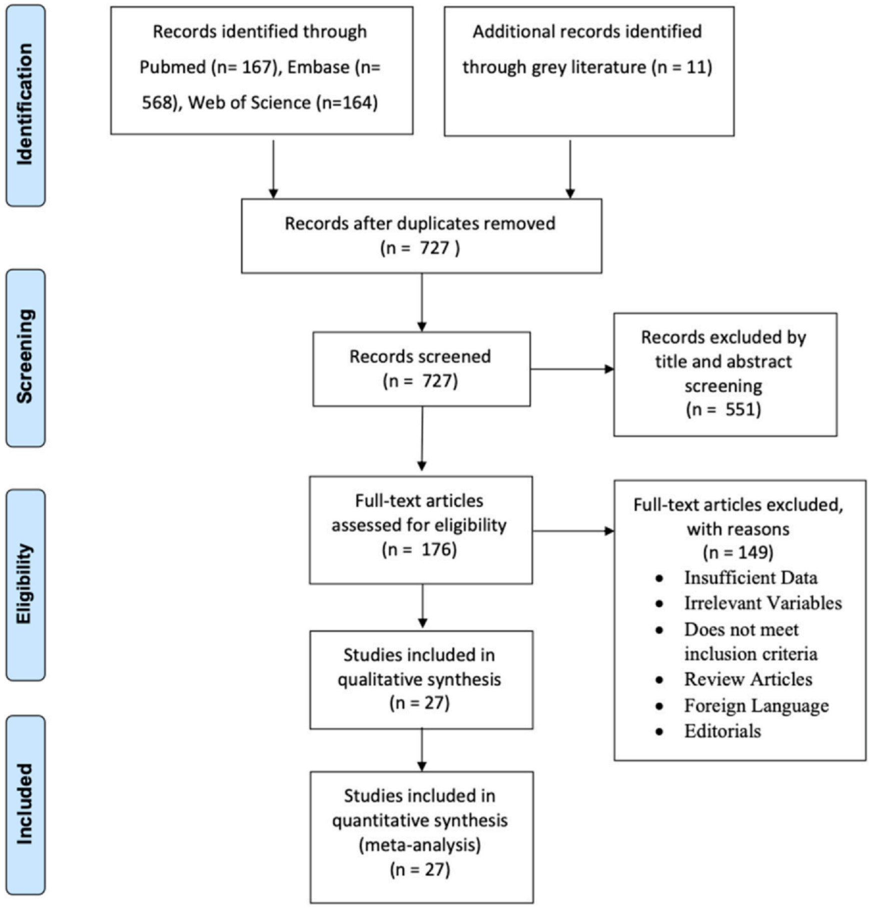

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flowchart of the search strategy for systematic review and meta-analysis. (Color version available online.)

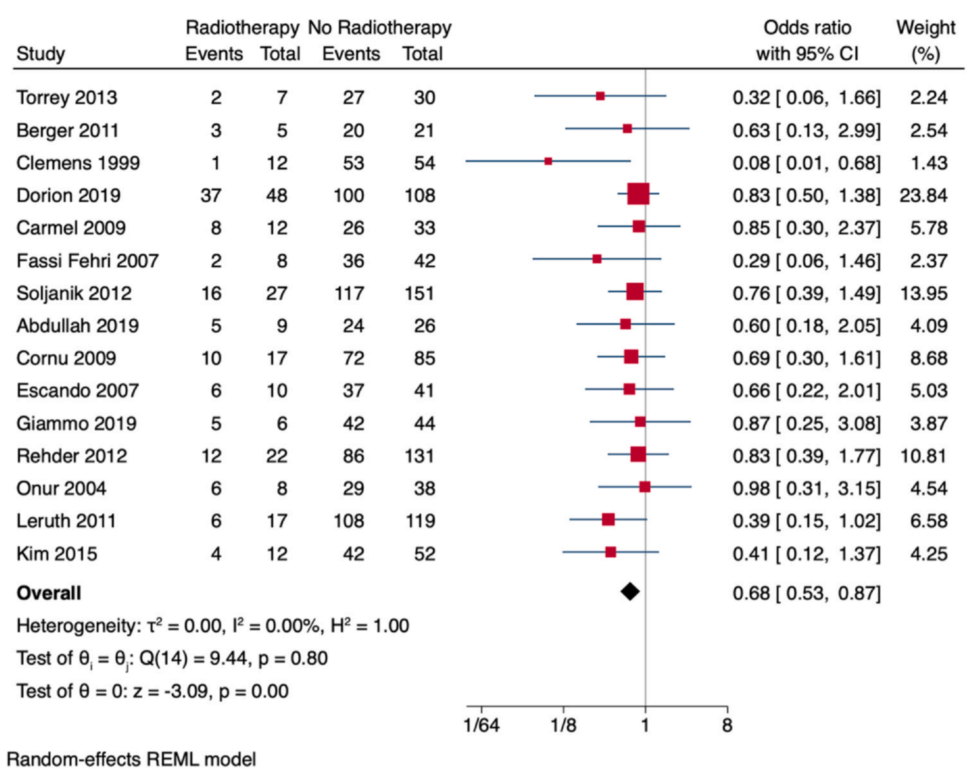

Figure 2. Forest plot comparing success rates in radiated and nonradiated patients. (Color version available online.)

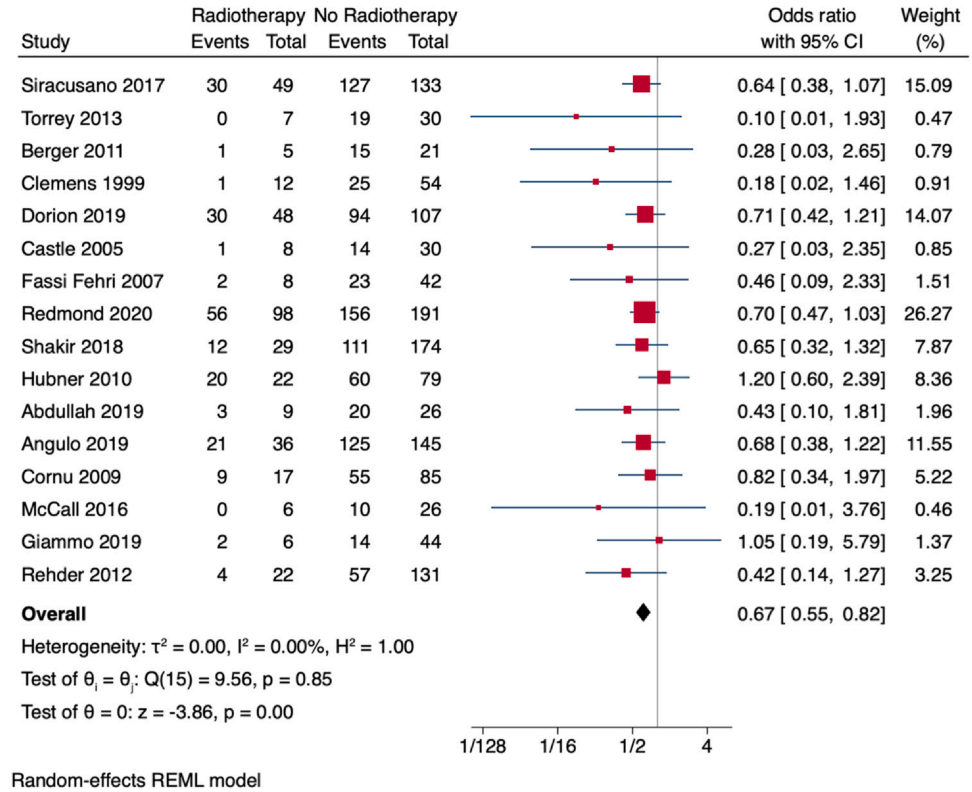

Figure 3. Forest plot showing odds of cure in radiated patients compared to nonradiated patients. (Color version available online.)

in radiated patients are conflicting. Even though most groups have reported poor outcomes in radiated patients, others demonstrated no significant impact of radiation on postoperative cure rates.[21,24,28,30,37] Cornu et al reported significantly lower success rates in radiated patients than in nonradiated patients (59% vs 85%).[33] A single-arm observational study revealed good short-term success rates in patients with prior RT, with worsening outcomes in 38% of patients on long-term follow-up.[46]

The reasons for lower success and cure rates in radiated patients are uncertain. It has been postulated to be a direct effect of radiation leading to "sphincter damage" and "proportional intrinsic sphincter deficiency."[9] Others have proposed that it may be due to increased periurethral fibrosis attenuating urethral compression rendering urethral function less effective.[10]

We performed a subgroup analysis to determine the impact of sling type on primary outcomes. When the results were stratified by the type of sling used, we observed significantly lower success rates in the radiated patients in the Advance group. There were also significantly lower cure rates in radiated patients in the ATOMS and Advance groups. This heterogeneity could be explained by the higher power of these subgroups, possibly owing to the higher popularity and availability of these slings.

Our analysis illustrated significantly increased rates of explantation and infection in radiated patients at follow-up compared to their nonradiated counterparts. Siracusano et al previously reported higher rates of infection and explantation in radiated patients than in nonradiated patients who received Argus slings.[20] Similarly, Redmond et al also found higher rates of explantation in radiated patients than in nonradiated patients who underwent ATOMS sling.[15] Due to the limited number of included studies and variation in the type of slings used, our results for complications should be interpreted with caution. Urethral erosion did not significantly increase in the radiated patients in the cumulative analysis. Again, this may be limited by the low power of the analysis. Obliterating endarteritis and tissue atrophy due to radiation could lead to vascular compromise, increasing the risk of erosion or sling failure.[47] The increased rate of infections may have been a result of multiple coexisting factors, including age, prior surgery, or diabetes. These factors were not accounted for in most included studies. Our analysis was limited to other commonly reported complications of this procedure such as urinary retention, bleeding, persistent pain, and hypercontinence. This may be due to insufficient data in studies that failed to outline complications separately in radiated and nonradiated patients.

Finally, the differences in satisfaction rates were not significant between radiated and nonradiated patients. This may be because of the lower power of the cumulative analysis. Previously, Wright et al reported lower satisfaction rates in radiated patients vs nonradiated patients on short-term follow-up (64% vs 95%).[22] They demonstrated a further decline in statistically significant satisfaction rates on long-term follow-up (33% vs 80%). Differences in follow-up durations at which satisfaction rates were measured and differences in methods of measuring these rates limit the interpretation of our finding.[22,25,32,35]

LIMITATIONS

Our study was limited by the absence of randomized clinical trials for quantitative analysis. Only observational studies that met the inclusion criteria were included. Several studies were removed from the analysis due to insufficient data on outlining outcomes separately for radiated and nonradiated patients. The overall sample size for the pooled analysis of both primary and secondary outcomes was low. The role of other factors, such as age, initial incontinence severity, and sling type, could not be fully evaluated due to insufficient data in the included studies. Differences in the definitions of primary outcomes among the studies limit the interpretation of our findings. The use of pads per day as a marker of incontinence instead of accurate objective measures such as 24-hour pad urine weight, limited our analysis. Moreover, we had insufficient data to perform subgroup analyses for the different sling types.

CONCLUSION

Our results suggest that radiation history should be a critical consideration in preoperative counseling and patient selection to manage postoperative SUI. With lower success and complication rates of urethral sling surgeries in irradiated patients, AUS may be a practical alternative to sling surgery in this population. Further studies are needed to elucidate the role of radiation factors, including dose, time from radiation, and the effect of radiation on the success and complication rates of various sling types. Randomized clinical trials comparing standardized outcomes in radiated and nonradiated patients undergoing sling surgery are needed to acquire accurate data on the efficacy and safety of these procedures in this population.

Author Contributions

All authors contributed to the design and full-text review for the manuscript. UG analyzed the results and wrote the manuscript. BB supervised this project.

Declaration of Competing Interest

The authors have no conflict of interest to declare.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.urology.2023.07.022.

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