



# Post-prostatectomy incontinence in patients with adjuvant radiotherapy: is there a therapeutic space for transobturator sling?

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## ABSTRACT

**Objectives:** Stress urinary incontinence (SUI) is a common sequela in patients undergoing surgery for prostate cancer, ranging from 4% to 31% in patients treated with robot assisted radical prostatectomy (RARP), and from 7% to 40% in patients undergoing radical retropubic prostatectomy (RP).

At this moment, only poor-quality studies evaluated the surgical techniques proposed for these patients; moreover, a limited number of studies evaluated both adjustable and non-adjustable slings, but no randomized trials are available. Nevertheless, it's important to highlight, that patients at high risk of local recurrence after RP will undergo adjuvant radiotherapy (RT), increasing the risk of postoperative complications and failure, if surgically treated for SUI. In this context few studies analyzed the outcome of post-prostatectomy sling positioning in patients treated with radiotherapy.

The aim of this narrative review is to summarize current data regarding outcomes after sling placement in patients with history of radiotherapy.

**Materials and Methods:** Outcome definition and measures, design of the studies, follow-up, numerosity and the type of sling used (Argus, AdVance/XP, InVance) are still heterogeneous.

Due to different follow-up and the low number of patients it is difficult to compare data.

**Results:** The larger study was a prospective multicenter paper, evaluating the outcomes of the Argus-T Sling, and documenting a 61.2% success rate in patients undergoing radiotherapy, with a higher risk of sling removal and urethral erosion.

**Conclusion:** At present, due to the lack of large prospective studies it is impossible to draw definite conclusions.

**Keywords:** Radical prostatectomy; incontinence; sling; radiotherapy

## INTRODUCTION

Stress urinary incontinence (SUI) is a common sequela in patients undergoing surgery for prostate cancer.

A systematic review focused on continence recovery after radical retropubic prostatectomy (RP) documented that incontinence rates at 12 months vary from 4% to 31% in patients treated with robot assisted radical prostatectomy (RARP),<sup>1</sup> and from 7% to 40% in patients who underwent RP.<sup>2</sup>

Unfortunately, incontinence represents an important burden for this kind of patients, with a significative influence on their quality of life.<sup>3</sup>

At this moment, there are no randomized trials comparing non-invasive and surgical therapies in male patients affected by SUI, and only poor-quality studies evaluated the several surgical techniques proposed for these patients.

A limited number of studies evaluated both adjustable and non-adjustable slings, but no randomized trials are available.

Argus adjustable system is a silicone device that makes it possible to regulate the tension of the bulbar sling, simply by tightening or releasing two silicone rings, with good results in terms of post operative continence, ranging from 92% to 100% in patients with mild incontinence.<sup>4-6</sup>

Nevertheless, it is important to highlight, that patients at high risk of local recurrence after RP will undergo adjuvant radiotherapy, increasing the risk of post operative complications and failure, if surgically treated with artificial urinary sphincter (AUS) for SUI.<sup>7</sup>

At present, only a few studies have evaluated the outcome of post-prostatectomy sling positioning in patients treated with radiotherapy.

The aim of our study was to evaluate the results of transobturator sling treatment in patients undergoing radical prostatectomy with adjuvant radiotherapy.

## MATERIALS AND METHODS

On January 2021 the PubMed database was searched using a combination of the following key words: (“radiotherapy”) AND (“male sling” OR “male slings”) AND (“urinary incontinence” OR “enuresis”) AND (“urinary sling” OR “urinary slings” OR “urethral sling” OR “urethral slings” OR “midurethral sling” OR “midurethral slings” OR “suburethral sling” OR “suburethral slings” OR “transobturator sling” OR “transobturator slings”).

We included all human research articles published in the last 15 years; case reports, reviews, editorial comments or letters to the editor were not included in our narrative review.

We sought also references arising from review articles.

The first search retrieved 85 articles.

The two authors reviewed the records separately and disagreements were resolved by consensus by both authors.

### Advance™ and AvanceXP™ and radiotherapy

Several studies with various designs evaluated the outcome of Advance or Advance XP positioning in patients undergoing radiotherapy (Table 1).

The AdVance sling (Boston Scientific, formerly AMS, Marlborough, MA, USA) was introduced in 2006 by Rehder and Gozzi<sup>8</sup> and is a retro-urethral tape positioned with a transobturator approach.

The rationale of this technique consists in a relocation of the proximal urethra in the pelvic floor, but without compression.

The AdvanceXP™ is an updated version of the AdVance, with increased sling arm length and an updated helical tunnelling needle shape.<sup>9</sup>

Thirteen studies evaluated the outcome of AdVance/AdVance in radiotherapy patients treated for post prostatectomy incontinence.

The majority of studies presented a prospective design,<sup>10-16</sup> and only one was a randomized study.<sup>15</sup>

All seven papers followed the patients for at least 13 months (range: 13–52 months) and the number of radiotreated patient included ranges from 3<sup>14</sup> to 24<sup>12</sup>.

Only two studies evaluated a cohort composed only by irradiated patients<sup>12,17</sup> and reported conflicting results.

The first prospective study was conducted in 2009 by Cornu et al.<sup>10</sup> on 17 irradiated patients, hypothesing an association between radiation and failure of the procedure ( $p=0.039$ ) and with 59% of cured/improved patients; these results were confirmed after one year, with a longer follow up, on 23 patients with a history of radiotherapy.<sup>11</sup>

Moreover, in a prospective study conducted on 24 (100%) irradiated patients, Bauer et al.<sup>12</sup> showed discrete outcomes with a 50% success rate and a cure rate of 25% obtained after 3 months; these outcomes were confirmed also at the maximum follow-up, in contrast with the data of a smaller series studied by the same author.<sup>13</sup>

Quality of life (QoL) and patient satisfaction were also improved by the procedure: the Urinary Incontinence Short Form (ICIQ-UI-SF) score was significantly decreased ( $p=0.008$ ), whereas the Incontinence Quality of Life Questionnaire (I-QoL) score increased ( $p=0.009$ ).<sup>12</sup>

**Table 1. AdVance/Advance XP studies**

Author	Year	Journal	Design	Patients	Irradiated	Follow-up	Outcome	Miscellanea
Cornu JN.	2009	Eur Urol	Prospective	102	17 (16.7%)	13	59% cured or improved vs. 85% in non-irradiated group	Radiation associated with failure ( $p=0.039$ )
Cornu JN.	2011	BJUI	Prospective	136	23 (17%)	21 (mean)	Failure trend associated with radiotherapy ( $p=0.0053$ )	No sling infection, erosion or explantation
Bauer RM.	2011	Urology	Prospective	24	24 (100%)	18	Success rate 50% (25% improved, 25% cured). 1-hour pad weight decreased significantly to 40 g ( $p=0.001$ ) and PPD used to 2 ( $p=0.001$ ). Median ICIQ-UI SF score decreased to 11.5 ( $p=0.009$ ) and I-QOL score increased to 72 ( $p=0.008$ ).	11 points satisfied
Bauer RM.	2011	BJUI	Prospective	137	17 (13.5%)	27	6/17 (35%) dry, 4/17 (23%) improved	Better outcomes for non-irradiated patients
Berger AP.	2011	Int Braz J Urol	Retrospective	26	5 (19%)	22	60% cured or improved; mean PPD decreased from 8.6 to 4.0. Cured: 1/5; improvement 2/5.	Radiotherapy associated with worse outcome ( $p=0.04$ )
Zuckerman JM.	2011	Can J Urol	Retrospective	27	27 (100%)	15.8 (mean)	70% benefit; PPD reduced from 4.2 to 1.1; 38% decreased efficacy	No erosions or infection; 2 intraoperative complications
Rehder P.	2012	Eur Urol	Prospective	156	11 (14.1%)	39	Cured or improved 54.6% vs. 65.6% in non-irradiated ( $p=0.0723$ )	One sling explantation
Collado Serra A.	2013	Urology	Prospective	61	3 (5%)	26	2/3 failure	No erosions
Torrey R.	2013	Urology	Retrospective	37	7 (19%)	17.3	No pad free vs. 63% in non-irradiated group; 2 (28.6%) were improved vs. 90.0% without prior RT; 71.4% no change or worse outcome vs. 10% without prior RT.	No RT: 22.5 OR in predicting the event of no pads or reduced pads postsurgery. QoL 1 (improved) 28.6% in RT group vs. 86.2% in no RT group ( $p=0.006$ ).

Table 1. Continued

Author	Year	Journal	Design	Patients	Irradiated	Follow-up	Outcome	Miscellanea
Habashy D.	2017	Neurourol Urodyn	Retrospective	80	12 (15%)	36	RT group: using an additional $1.03 \pm 0.42$ ( $p=0.019$ ) PPD. PGI score was $3.7 \pm 0.70$ ( $p=0.002$ ) --> no difference	Mid-term outcomes: return to baseline.
Wright HC.	2017	Can J Urol	Retrospective	52	18 (34.6%)	61.5 (only 16 men)	Greater improvement in EPIC scores and PPD use was seen in non-irradiated men	RT: less satisfied at both short and long term follow up. Diminished efficacy at extended follow up, more pronounced in RT.
Papachristos A.	2018	ANZ J Surg	Prospective	72	18 (21%)	52	69% improved vs. 84% in non-irradiated group	Irradiation: worse continence outcomes ( $p=0.02$ )

RT: radiotherapy; ICIQ-UI SF: The International Consultation of Incontinence Questionnaire – Short Form; QoL: Quality of Life; I-QoL: The incontinence quality of life questionnaire; OR: Odds ratio; EPIC: The Expanded Prostate Cancer Index Composite

Furthermore, in another prospective study conducted on 156 patients treated with AdvVance (22 with history of pelvic irradiation), the multivariate analysis conducted by Rehder et al.<sup>16</sup> showed that irradiation is not a predictor of the outcome ( $p=0.0723$ ).

The second study, conducted only on irradiated patients ( $n=27$ ), the largest series, with a retrospective design, showed a 70% success rate in the mid-term follow up of 15.8 months; unfortunately, about 40% of the patients showed a decrease in efficacy with time and four patients needed a new incontinence procedure.<sup>17</sup>

The conflicting outcomes due to radiation were confirmed also by the prospective studies of Collado et al.<sup>14</sup> (2/3 irradiate patients unsuccessful) and Papachristos (worse continence outcomes in irradiated patients;  $p=0.02$ ).<sup>15</sup>

Only a single randomized study was available in literature, comparing the outcome of the AdvVance and Argus slings in a series of 22 patients, with 3/11 irradiated patients in the AdvVance group; unfortunately, no information was provided with regard to the outcome of the irradiated patients.<sup>18</sup>

The retrospective studies showed conflicting results. These studies however included a small number of irradiated patients (range: 5–27). The first retrospective single center analysis, conducted in 2011 by Berger et al.<sup>19</sup> on 5/26 irradiated patients, demonstrated an unsatisfactory outcome (20% cure rate and 60% improving;  $p=0.004$ ) in the irradiated subgroup of patients in comparison with the non-irradiated one; these results were

confirmed in 2013 by Torrey et al.<sup>20</sup>, with no “pad free” patients after radiotherapy.

On the other hand, in 2011 Zuckerman et al.<sup>17</sup> reported a 70% benefit in a cohort of 27 irradiated patients, but with a decreasing efficacy in 38% of cases.

In 2014 Hoy and Rourke<sup>21</sup> conducted a retrospective analysis, comparing patients undergoing artificial urinary sphincter or advance placement, including also irradiated patients (3/76 in the sling group); unfortunately, no information about the outcome of these subgroups of patients was provided.

A recent retrospective study by Habashy et al.<sup>22</sup> on 12 irradiated patients confirmed the disappointing results of the previous series; at mid-term follow up, the patients treated with radiotherapy used on average the same number of pads per day as before the treatment, as confirmed by the PGI score.

The authors considered the radiotherapy independently predictive of a worse mid-term outcome.<sup>22</sup> On the other hand, Wright et al.<sup>23</sup> retrospectively analyzed a cohort of 18 patients receiving pelvic irradiation and documented a good overall satisfaction at short- and long-term follow up, although smaller with regard to the non-irradiated patients.

### InVance and Radiotherapy

The InVance suburethral sling (American medical system) is a non-adjustable rectangular polyester sling positioned under the bulbar urethra via a perineal incision, with the aim to obtain a bulbourethral compression (Table 2).

**Table 2. InVance studies**

Author	Year	Journal	Design	Patients	Irradiated	Follow-up (months; median)	Outcome	Miscellanea
Fassi-Fehri H.	2007	Eur Urol	Prospective	50	8 (16%)	6	75% incontinent vs. 16%	Radiotherapy is considered a bad prognosis criterion
Collado A.	2009	Arch Esp Urol	Prospective	27	3 (11%)	18	61% cure rate in the bad prognosis group (radiotherapy, 3 pads/day, bladder neck incision, urodynamic anomalies) vs. 100% in the good prognosis group	No erosion or explantation
Lanoë M.	2009	Prog Urol	Retrospective	84	12 (14.3%)	20 (mean)		Univariate analysis: incontinence due to a bitherapy including external radiotherapy is associated with treatment failure ( $p=0.031$ ). Multivariate analysis: bitherapy including radiotherapy is the so independent treatment failure risk factor ( $p=0.017$ ).
Carmel M.	2010	BJU Int	Prospective	45	12 (26.6%)	36		Success rate unaffected by radiotherapy ( $p=0.448$ )
Spie R.	2011	Prog Urol		106	24 (22.6%)	12.8	Continence: 52.6% vs. 63.2% ( $p=NS$ )	8.3% explantation vs. 4.8%; 45.8% vs. 25.6% transient perineal pain; no impact of previous radiotherapy on urodynamic parameters and continence

NS: not specified

Five studies evaluated the results of the InVance placement in irradiated patients.

Fassi-Fehri et al.<sup>24</sup> prospectively assessed the short-term results (median follow up: 6 months) in 8/50 patients with history of radiotherapy who had undergone InVance positioning after prostatic surgery or pelvic trauma. The incontinence rate was 75% vs. 16.3% in the irradiated and non-irradiated group of patients, respectively, defining the radiotherapy as a “bad prognostic criterion”.<sup>24</sup> The data of Fassi-Fehri were confirmed by the small series of Collado et al.<sup>25</sup>

At a mid-term follow up of 18 months, the three irradiated patients, included in the “bad prognosis group” (history of irradiation or bladder neck incision, 3 pads/day, urodynamic abnormalities), showed a lower cure rate in comparison with the patients included in the “good prognosis” group (61% cure rate in bad prognosis group vs. 100% in good prognosis group,  $p=0.03$ ).<sup>25</sup>

The author concluded that InVance positioning is an adequate procedure for patients with mild-moderate incontinence, without urodynamic abnormalities and who have not undergone radiotherapy.<sup>25</sup>

Even in 2009, Lanoe et al.<sup>26</sup> highlighted as history of radiotherapy could be the sole independent treatment failure risk factor ( $p=0.017$ ).

On the other hand, Carmel et al.<sup>27</sup> and Spie et al.<sup>28</sup> showed promising results at mid- and long-term follow-up.

A history of radiotherapy did not adversely influence the cure rate of 12/45 patients prospectively evaluated by Carmel et al.<sup>27</sup> ( $p=0.448$ ), and the data regarding a larger series of Spie et al.<sup>28</sup> ( $n=24$  irradiated patients compared with 82 non irradiated ones) are supporting these evidences.

### Argus and Radiotherapy

The Argus-T is a re-adjustable radio-opaque cushioned system with silicone foam suburethral sling device, which make it possible to adjust the sling tension effectively not only during surgery but also in the first few days after surgery.<sup>4</sup>

Only three studies evaluated the success rate of patients undergoing Argus or Argus T implantation after radiotherapy (Table 3).

The retrospective series by Hübner et al.<sup>29</sup> showed good results in irradiated patients, with 20/22 dry patients at mid-follow up (18 months) and only two explantations of the sling.

With regard to the prospective studies, the data of the 2-center evaluation by Bauer et al.<sup>30</sup> on 13 irradiated patients confirmed the results of Hübner et al.'s<sup>29</sup>; at a long-term follow up of 28.8 months, the risk analysis did not show differences in patients that received radiotherapy ( $p=0.581$ ), with regard to the number of pads used and I-QoL and ICIQ-SF scores.

In contrast, Siracusano et al.<sup>4</sup> conducted the largest prospective study on the Argus-T device in irradiated patients. Forty-nine patients with a history of radiotherapy for prostate cancer were treated with the Argus sling and followed for a median follow up of 22 months and evaluated with the Visual Analogue Scale (VAS) score for continence and a QoL score.

The overall success rate was 86.2%, but only 61.2% of irradiated patients showed successful results.

Moreover, the irradiated patients were more likely to undergo sling adjustment or sling removal and postoperative complications ( $p=0.04$ ,  $p=0.002$ ,  $p=0.01$ ). Nevertheless, the irradiated patients, too, showed a significant overall reduction of daily pad number and an improvement of their QoL ( $p<0.0001$ ).<sup>4</sup>

**Table 3. Argus studies**

Author	Year	Journal	Design	Patients	Irradiated	Follow-up (months; median)	Outcome	Miscellanea
Hübner WA.	2011	BJU Int	Retrospective	101	22 (21.8%)	18	20/22 dry	Two erosions and one infection; two explantations of the sling
Bauer RM.	2015	Urology	Prospective	42	13 (30.9%)	28.8	PPD use: 6.3 to 2.7; 24 h pad weight: 315 g to 130 gr; IQoL score: 6.9 to 90.8 ICIQ-UI SF score: 15.9 to 3.9 risk analysis: no difference with and without radiotherapy ( $p=0.581$ )	Two explantations
Siracusano S.	2017	Urology	Prospective	182	49 (26.9%)	22	Success rate 61.2%; significant overall reduction of daily pad number and an improvement on their QoL ( $p<0.0001$ )	Irradiated patients: high percentage of sling adjustment or sling removal and post-operative complications ( $p=0.04$ , $p=0.002$ , $p=0.01$ )

I-QoL: The incontinence quality of life questionnaire; ICIQ-UI SF: The International Consultation of Incontinence Questionnaire – Short Form, QoL: Quality of Life

## DISCUSSION

The surgical treatment of male urinary incontinence after radical prostatectomy is still a complex issue today, although guidelines in this regard have existed for several years. In the context of stress urinary incontinence stabilized one year after radical prostatectomy of stress incontinence is now feasible. In this way patients with milder degrees of incontinence and without bladder dysfunction are usually candidates for artificial urinary sphincter placement or sling surgery with overlap success rates [European Association of Urology (EAU) guidelines]. In particular, using the sling would result in a lower risk of surgical complications<sup>3</sup> while in case of severe incontinence the AUS shows a more predictable success profile with respect to using the sling.

In this context minimally invasive approaches, such as robotic surgery, urinary incontinence represents up today an important post-operative complication, causing a devastating reduction in the quality of life that is added to the sequelae caused by radiotherapy.

In these patients, the resolution of incontinence is still problematic, because there are still no satisfactory degrees of recommendation for surgery.

In particular, the artificial urinary sphincter is more widely used, but radiation may be a risk factor for an increase in complications<sup>7</sup>, and on the other hand, the slings generally have a lower success rate, if compared with patient with no history of radiotherapy. In this regard, the review of literature that we carried out shows that the transobturator sling is still considered as being little effective, therefore, to facilitate our analysis, we discussed the “suspensive sling” which refers to the Advance system and the “compressive sling”, which refers to the InVance and Argus-T devices, separately, since the above reported devices are the most used for the transobturator approach in patients suffering from UI after adjuvant RT.

The rationale of the Advance sling is the relocation of the sphincteric unit in the pelvic floor, which means a suspension of the bulbar urethra. This relocation would allow a resumption of sphincter activity when the sphincter is intact and the suspension of the bulbar urethra is possible. The satisfaction of these two conditions is essential to restore continence.

In the majority of cases, the authors reported a limited success compared to patients without adjuvant radiotherapy<sup>14,15,17,19,20,22</sup> and, at same time, the number of radiotreated patients who underwent the placement of the Advance device is too small to suggest a possible cause of failure.<sup>10-23</sup>

In this way, we believe that sphincteric unit and bulbous urethra fibrosis could contribute to limit the success of this

device, because the pelvic floor is fixed and not susceptible of suspension.

Nevertheless, to date the only negative prognostic factor in patients undergoing this implant is related to the presence of a preoperative detrusor overactivity.<sup>22</sup>

In this regard, the experience with InVance is very limited and the only currently available device within the compression system is offered by the Argus-T sling, with results in the mid/short-term. This latter device is not very effective in patients who are radiotreated compared to non-radiotreated patients and in the largest series<sup>4</sup> the number of readjustments was higher than those performed for non-radiotreated patients, with a consequent disadvantage in terms of costs/benefits.

In literature, nowadays none of the transobturator devices is effective in treating urinary incontinence in a post-radical prostatectomy patients undergoing adjuvant radiotherapy. In this context, we currently only have empirical solutions aimed at treating patients who did not have any benefit from the use of the transobturator sling. Usually, the use of bulking agents as well as the use of a transcorporeal artificial sphincter could represent the only two possible surgical solutions. In particular, with regard to bulking agents, we do not have reliable data in the literature, while for the use of transcorporeal AUS, the results to date are contradictory as the studies are exclusively of a retrospective type, the population that underwent this type of surgery is extremely small and data on radiation field exposure are not available.<sup>31</sup> In conclusion, suspensive and compressive devices do not seem to offer satisfactory outcomes in this group of patients, since the possibility of continence recovery is in any case low.

## CONCLUSION

Only long-term randomized longitudinal studies will allow us to understand if a sling can be a valid alternative to the artificial sphincter that at present represents the only reliable possibility for these patients.

At the moment, due to the lack of large prospective studies, it is impossible to draw definite conclusions.

## ETHICS

**Peer-review:** Externally peer-reviewed.

## Contributions

Concept: S.S.; Design: D.F.; Data Collection: D.F.; Analysis and Interpretation: C.D.; Literature Search: F.R.; Writing: S.S.

## DISCLOSURES

**Conflict of Interest:** No conflict of interest was declared by the authors.

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