Review article

Artificial urinary sphincter outcomes for post-radical prostatectomy urinary incontinence. A narrative review

Resultados del esfínter urinario artificial en incontinencia urinaria post-prostatectomía radical. Revisión narrativa

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Abstract

Urinary incontinence post-radical prostatectomy is a common complication that might negatively impact patients' quality of life. Treatments include medical and surgical options, being the insertion of an artificial urethral sphincter (AUS) the gold standard. The aim of this narrative review is to evaluate the outcomes of artificial urinary sphincter implantation for urinary incontinence developed post-radical prostatectomy with and without radiation, in terms of urinary continence and complications. The MEDLINE and Scopus search returned 477 articles. A total of eleven articles were included for qualitative analysis. A total of 707 men that met the inclusion criteria were included. The 22.6% of the men (160 patients) received pelvic external beam radiotherapy prior to the implantation of the artificial urinary sphincter. The overall continence success rate was defined by the use of pads. Some authors reported a success rate of 0 pads per day (PPD) or ≤ 1 PPD in the last follow-up. The complications included urethral atrophy, mechanical failure, revision and/or removal of the device, infection and erosion. Further prospective studies should be done to clarify continence concepts after the placement of an AUS and long-term complications.

Keywords: Stress urinary incontinence, urinary incontinence, prostatectomy, artificial urinary sphincter, radical prostatectomy, complications, outcomes

Citation: Corrales-Acosta E., Corrales M., Arenas-Aquino A. E., Melgarejo-García G. *Artificial urinary sphincter outcomes for post-radical prostatectomy urinary incontinence. A narrative review. Rev Mex Urol.* 2022;81(6):pp 1-13

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Received: September 30, 2021
Accepted: December 02, 2021

Resumen

La incontinencia urinaria posterior a la prostatectomía radical es una complicación común que puede afectar negativamente la calidad de vida de los pacientes. Los tratamientos incluyen opciones médicas y quirúrgicas, siendo la inserción de un esfínter uretral artificial (EUA) el estándar de oro. El objetivo de esta revisión narrativa es evaluar los resultados de la implantación de un esfínter urinario artificial para la incontinencia urinaria desarrollada después de una prostatectomía radical con y sin radiación, en términos de continencia urinaria y complicaciones. La búsqueda en MEDLINE y Scopus arrojó 477 artículos. Se incluyeron un total de once artículos para el análisis cualitativo. Se incluyeron un total de 707 hombres que cumplieron con los criterios de inclusión. El 22,6% de los hombres (160 pacientes) recibieron radioterapia pélvica externa previa a la implantación del esfínter urinario artificial. La tasa general de éxito de la continencia se definió por el uso de pañales. Algunos autores informaron una tasa de éxito de 0 pañales por día (PPD) o ≤1 PPD en el último seguimiento. Las complicaciones incluyeron atrofia uretral, falla mecánica, revisión y/o remoción del dispositivo, infección y erosión. Se deben realizar más estudios prospectivos para aclarar los conceptos de continencia después de la colocación de un EUA y las complicaciones a largo plazo.

Palabras clave:
Incontinencia urinaria de esfuerzo, incontinencia urinaria, prostatectomía, esfínter urinario artificial, prostatectomía radical, complicaciones, resultados

Introduction

Urinary incontinence (UI) post-radical prostatectomy (RP) is a common complication that might negatively impact patients' quality of life.

The incidence according to different series varies from 2% to 65.5%.[1] This wide range shows that UI definition is not well-stablished. Also, it could reflect that the post-surgical results are linked to several risk factors, such as radiotherapy prior to the AUS implantation.

Treatment for post-RP incontinence includes lifestyle modification, pharmacological management, and secondary surgical procedures, such as the insertion of an artificial urethral sphincter (AUS).[2]

The introduction of the AUS in the field of Urology was in 1972, when Scott successfully implanted it into a woman. Today it remains the "gold standard" surgical treatment option for UI.[3]

The evolution of the artificial urinary sphincter during the last decades has resulted in innovative and novel urinary devices,[4,5] in order to diminish the related complications such as infection, erosion and mechanical failure.

The aim of this narrative review is to evaluate the outcomes of artificial urinary sphincter implantation for urinary incontinence developed post-radical prostatectomy (RP) with and without radiation, in terms of urinary continence and complications such as urethral atrophy, mechanical failure, revision/removal of the prosthesis, infection and erosion.

Material and methods

We performed a literature review using the MEDLINE and Scopus databases with no time period restriction from inception until September 2021. This review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[6]

The keywords used were the following: "stress urinary incontinence", "urinary incontinence", "prostatectomy", "artificial urinary sphincter", "radical prostatectomy", and "complications". Boolean operators (AND, OR) were used to refine the search. The references mentioned in each included study were also reviewed. Additionally, no language restrictions were applied.

All patients that underwent an artificial urinary sphincter implantation for the first time for urinary incontinence developed post-radical prostatectomy (RP) with and without radiation were included. Case reports, posters, editorials, letters, comments were excluded; as well as reports including post prostatectomy incontinence caused by surgical techniques other than RP or incomplete data about overall success rate. The analysis was made by 2 authors (EC and MC).

Results

The MEDLINE and Scopus search returned 477 articles. After duplicate removal and full screened reports, a total of 11 articles were included for qualitative analysis (Figure 1). These included 7 retrospective single center study (RCSC), one retrospective multicenter study (RMS), one prospective multicenter study (PMS) and one cohort study (CS) (Table 1).

Figure 1. Flow chart of the literature review

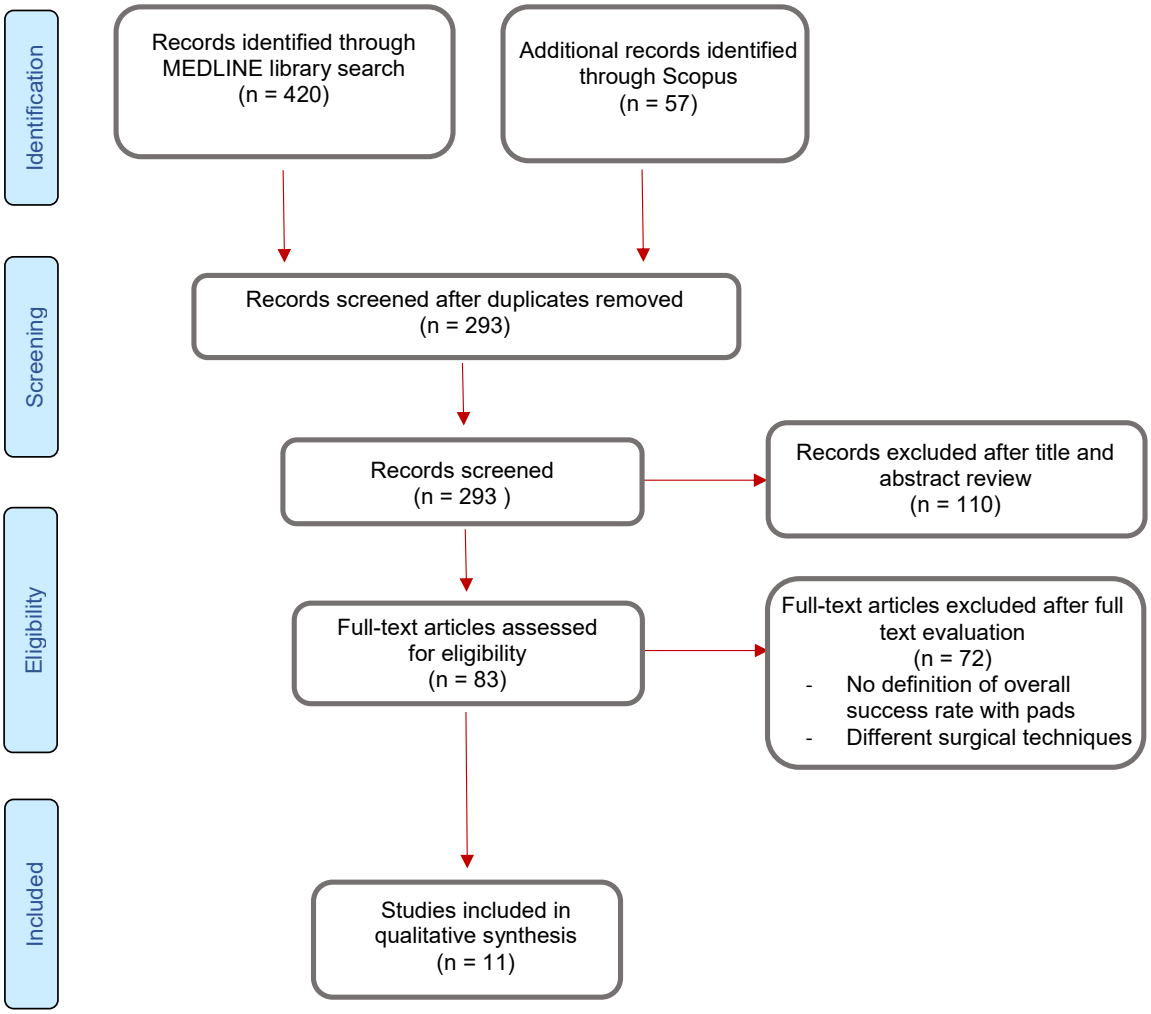

Table 1. Outcomes of AUS implantation for stress UI after radical prostatectomy

Study Design	*N*	*N with prior RT*	*Age (mean)*	*Mean length of follow-up (months)*	*0 PPD (%)*	*≤ 1 PPD (%)*	*Infection (%)*	*Cuff erosion or migration (%)*	*Infection and/or erosion (%)*	*Urethral atrophy (%)*	*Mechanical failure (%)*	*Revision and/or removal (%)*
Mottet et al., 1998, [15] PMS	103	N. A.	N.A.	12 – 36	53 (57.3)	74 (71.8)	N.A.	N.A.	12 (11.6)	N.A.	10 (9.7)	10 (9.7)/ (5.8)
O'Connor et al., 2007,[8], RSCS	29	11	77.6	60	7 (24)	24 (82.7)	N.A.	N.A.	2 (6.8)	1 (3.4)	N. A.	4 (14)/4 (14)
Trigo Rocha et al, 2008,[16], RSCS	40	0	68.3	53	20 (50)	16 (40)	3 (7.5)	5 (12.5)	N. A.	2 (5)	2 (5)	8 (20)
Sathianathen et at., 2014,[3], CS	77	27	72.2	21.2	N. A.	(87)	N. A.	N. A.	2 (2.6)	N. A.	N. A.	8 (10.4)/ 1 (1.2)
Hoy et at., 2014,[9], RSCS	48	7	68.1	42	N. A.	42 (87.5)	5 (10.4)	2 (4.1)	2 (4.1)	N. A.	N. A.	6 (12.5)
Serag et al., 2018,[10], RSCS	83	15	68.4	39	32 (38.5)	67 (80.7)	N.A.	N.A.	2 (2.4)	0 (0)	9 (10.8)	11 (13.25)
Lim et al., 2014,[7], RSCS	13	1	73.5	29.8	N.A.	10 (76.9)	1 (7.7)	0 (0)	N.A.	0 (0)	0 (0)	1 (7.7)
Kim et al., 2018,[11], RSCS	53	12	69.1	31	N.A.	44 (83)	3 (5.7)	8 (15.1)	N.A.	2 (3.8)	7 (13.2)	11 (20.8)
Sacomani et al., 2018,[7], RSCS	121	47	N. A.	62,4	82 (67.8)	106 (87.6)	N. A.	15 (12.3)	N. A.	5 (4.1)	1(0.8)	24 (19.8)/15 (12,3)
Sacco E et al., 2020,[13], RSCS	35	8	71	51.2	22 (62.9)	32 (91.4)	1 (2.9)	1 (2.9)	N.A.	0 (0)	0 (0)	1 (2.9)
Kretschmer et al., 2020,[14], RMS	105	30	70.1	38	N. A.	(48.4)	8 (7.6)	N.A.	12 (11.4)	3 (2.8)	1 (0.9)	29 (27.6)

N: Number of patients; N with prior RT: Number of patients with prior radiotherapy; PPD: Pads per day; CS: Cohort study; PMS: Prospective multicenter study; RSCS: Retrospective single center study; RMS: Retrospective multicenter study; NA: Not available

A total of 707 men that met the inclusion criteria were included, being the study of Sacomani *et al.*[7] the largest of them all with121 patients.

The 22.6% of the men (160 patients) received pelvic external beam radiotherapy (RT) prior to the implantation of AUS [3,7–14]. Mottet *et al.*[15] did not mention this medical history, and Trigo Rocha *et al.*[16] excluded patients with prior RT.

The mean age of the studied data was from 68.1,[9] to 77.6.[8] Mottet *et al.*[15] did not mention the mean age of their series, and neither did Sacco *et al.*[13]

The mean length of follow-up in months was from 12,[15] to 62.4.[7]

The overall continence success rate was defined by the use of pads. Some authors reported the improve of the incontinence after the implantation of the AUS with the use of 0 pads per day (PPD) or ≤ 1 PPD,[15] in the last follow-up. The men with better improvement rates of incontinence after the colocation of the AUS were described by Kim M *et al.*[12] with the definition of patients using ≤ 1 PPD.

As for complications, the first article published by Mottet *et al.*[15] in 1998 reported complications such infection and erosion in 12 patients (11.6%), and mechanical malfunction in 10 patients (9.7%) that led to revision in all of the cases. This PMS stablished a complete replacement rate of 5.8%.

Almost a decade later, in 2007, O'Connor *et al.*[8] described in a RCSC the need of AUS revision in 4 patients (14%), and the sphincter removal in 4 patients (14%). The complications included urethral atrophy in 1 patient (3.4%) and 2 patients had cuff erosion.

A year later, Trigo Rocha *et al.*[16] made another RSCS. The complications included 3 (7.5%) cases of prosthetic infections, followed by erosion. In total, 5 patients (12.5%) suffered from erosion of the device. Other complications described were urethral atrophy in 1 patient and mechanical failure in 2 patients. The surgical revision rate was 20%.

In 2014, Sathianathen *et al.*[3] reported complications that consisted in infection and erosion in 2 patients (2.6%), revision of the AUS in 8 patients (10.4%) and removal in 1 patient (1.2%).

The same year, Hoy *et al.*[9] made a RCSC. The AUS complications included infection in 5 patients (10.4%), migrated cuff in 2 patients (4.1%) and erosion in 2 patients (4.1%). There were more serious complications that required removal/revision in 6 patients (12.5%).

Also, in 2014, Lim *et al.*[11] described in a RSCS the AUS complications including infection in 1 patient (7.7%) and revision required in 1 patient (7.7%) for cuff change.

In 2018, three RSCS were published. In the first one, Serag *et al.*[10] reported the complications including 9 mechanical failures (10.8%), 2 implant infections (2.4%) and 0 cases of urethral atrophy. The reoperation rate was 13.25%.

In the second article, Kim *et al.*[12] reviewed the complications that were infection in 3 patients (5.7%), erosion in 8 patients (15.1%), mechanical failure in 7 patients (13.2%) and removal of the AUS in 11 patients (20.8%).

The last RSCS mentioned in 2018 was published by Sacomani *et al.*[7] where they described that revision occurred in 24 patients (19.8%) due to malfunction (1 case), urethral atrophy (5 cases), urethral erosion (15 patients), among other causes. The removal was necessary in 15 patients.

Sacco *et al.*[13] published their RSCS in 2020. The reported complications were infec-

tion in 1 patient (2.9%), erosion in 1 patient (2.9%), surgical revision in 1 patient (2.9%). Only 2 patients (5.7%) required explantation of the device.

Lastly, in 2020, Kretschmer *et al.*[14] performed a MCS. The complications described were infection in 8 patients (7.6%), erosion in 12 patients (11.4%), urethral atrophy in 3 patients (2.8) and mechanical failure in 1 patient (0.9%). The explantation rates were 27.6%.

Discussion

The artificial urinary sphincter (AUS) remains the device with the longest experience and the largest body of evidence. Therefore, it is the gold standard for treatment for moderate/severe post prostatectomy incontinence (PPI),[17] and it has a high success rate (greater than 80%).[18] Multiple series have published the outcomes after placement of the AUS, but outcome criteria and definitions differed for most of the studies.

Continence outcomes

The functional outcomes have not been well-established to calculate continence. The pad count-based definition is the most used in AUS literature and in clinical practice.[13] It is possible that the definition of PPD in the studies are similar, but it is still heterogeneous.

Kretschmer *et al.*[14] defined continence as the use of up to a unique single daily "safety" pad representing in the study a continence rate of 48.4% but referred in the results this usage as a dry pad.

The continence rate in all the studies was recorded by the definition of the use of 0 pads per day (PPD) or ≤ 1 PPD, but some studies used the definition of continence success only with the use of ≤ 1 PPD.

Sathianathen *et al.*[3] reported one of the highest success rates of continence (87%) in irradiated patients by measuring pad usage /24 hours and defining success with a "social continence" (defined as requiring 0-1 pad/24 hours).

A success rate of >80% has been reported. These results are even more pronounced considering the strict definitions of success used in most AUS studies (0–1 pad/d).[19] Among the 707 patient's follow-up patients, the improved rates were computed between 40%-91%. Nevertheless, in all the studies mentioned a high overall satisfactory outcome, and it is considered the primary end point of the treatment.

Sacomani *et al.*[7] had the biggest population in the study and is the second study with the highest success rate, 87.6% (106 patients), of which 82 patients (67.8%) reported a 0 PPD use, but in the methodology they mentioned these patients claimed that they used pads only on certain occasions, such as intense physical activity.

The patient desires to be completely dry (especially with an expensive device implanted), but the AUS might fail to provide total continence in all subjects. Dry rates (0 PPD) were reported in only six studies, in total 216 patients (30%).

It is now widely recognized that a minimum follow-up of at least 1 year is mandatory for the evaluation of efficacy in the field of urinary incontinence;[17] in our review all the studies had started the evaluation after 12 months of the AUS implantation. The lack of standardized definition and objective tools may change the

real estimation of improvement after AUS implantation. Also, the end points should always be reported alongside improvement rate with a clear definition given for improvement or success rate.

Complications

Urethral atrophy

Urethral atrophy is a well-known late complication after AUS implantation, suspected when stress urinary incontinence recurrence occurs with a functional mechanical device. It is the most common cause for surgical revision and cuff replacement. In this review, this complication was reported in 5 articles and it occurred in 13 patients (1.88%). Most of the articles did not report the timing of the complication.

Several surgical techniques have been developed with the goal of protecting the damaged urethra. One technique has been to wrap the urethra with xenograft material to increase the urethral circumference. Rahman *et al.*[19] reported 5 patients with a history of cuff erosions who underwent repeated AUS placement augmented with small intestinal submucosa, and calculated that 4 (80%) of them had surgical and functional success as they were dry and had the sphincter still in place at a median follow-up of two years.

Another approach introduced in 2010 was cuff downsizing using 3.5cm cuff to address the issue of incomplete coaptation in patients with urethral atrophy, becoming a good alternative for the traditional methods such as cuff relocation or urethral bulking using xenograft.[20] However, it is still controversial if this represents more risk of erosion than larger cuff.[21]

Finally, Guralnick *et al.*[22] described trasnscorporal cuff placement as a salvage technique to improve outcomes in the revision setting for patients with urethral atrophy or those in high risk of developing an adverse outcome.

Mechanical failure

Mechanical failure of an AUS can occur within one of the sphincter components, in the tubing, or in one of the connections such as dislodged pump or reservoir, cuff leakage and failure in tubing kink. In this review, mechanical failure rate was reported in six studies, with 30 patients, representing only 4.2%. The life expectancy of the device is 7–10 years. The incidence of mechanical dysfunction has decreased significantly following the introduction of the narrow-back cuff in 1987.[5]

Mottet *et al.*[15] had concluded a 9.7% mechanical failure rate, but they had a long follow-up study that was roughly 4 years. The mechanical failures were dislodged pump (2/10), cuff leakage (2/10), cuff proven too large (2/10) and dislodged reservoir (2/10).

In the study by Serag *et al.*[10] on 84 patients with an average follow-up of 39 months, nine included mechanical failures (10.8%) without specifying their type. Additionally, they performed a Kaplan-Meier analysis for mechanical failure-free survival, estimating a rate of 89.9% at 5 years, but at 10 years the mechanical failure rates increased, which could be related to life expectancy of the device. The median of the mechanical failure in this study was 18 months.

Kim *et al.*[12] monitored their patients for 10 years and they found that most complications occurred within the first 48 months following

the insertion of AUS. In fact, mechanical failures were reported on seven patients (13.2%).

Due to the retrospective nature of the studies, the mechanical failure rate might be underestimated, but the number of mechanical failures has decreased substantially with advances in AUS design.

Revision and removal

Revision surgery is often required for worsening incontinence, erosion, urethral atrophy, infection, or mechanical dysfunction. Reintervention rate provides an overview of complications that occur following AUS implantation needing invasive treatment, and they should be regarded as an important end point.[17]

Serag *et al.*[10] reported that 13.25% (11/83) had to undergo a revision or a reoperation of the AUS implantation; 9 by mechanical failures due to malfunctioning device and 2 by device explantations due to infections. The revision-free estimated survival rate of this study was of 86.75% at 5 years and at 10 years it will increase due to device failure.

Revision or removal are due to different causes. Mottet et al. [15] reported non-mechanical revisions and mechanical malfunction revisions. Surgical revision was necessary in 22 patients (21%). Of them, 12 patients (11.65%) underwent infection and erosion (non- mechanical revisions) of the prosthesis. Out of these 12 patients, 6 suffered complete removal of the AUS device and the other 6, partial removal (cuff replacement), mainly for urethral erosion. The other 10 patients had mechanical malfunction and after the revision 9 were corrected successfully and only in one patient the device had to be removed.

Reintervention rate should be an essential secondary outcome criteria, because of the global patient satisfaction with the AUS device; although reintervention, probably will not have an impact on the final incontinence outcome.

Improvements are needed to minimize the number of reinterventions due to mechanical failure, erosion, infection, and urethral atrophy. Less invasive management of these complications should also be considered.

Infection

In this review, the infection of the device is considered the most common complication after an AUS placement. The rate of infection ranged from 2,4 % to 10,4%. This event is usually presented prior to erosion, atrophy or failure.[9,13]

In a previous review by de Cógáin *et al.*[23] they found that the InhibiZone® coating did not demonstrate a significant benefit to improve the infection rates, and the evidence of the use of perioperative antibiotic (single shot or longer prophylaxis) resulted limited. However, Hofer and Gonzalez,[24] confirmed that strict perioperative antibiotic prophylaxis and sterile surgical technique seem to be crucial for acceptable surgical outcomes, but it has not been established the antimicrobial or the duration. It is also recommended a careful postoperative follow-up upon initial signs of sphincter deactivation.[22] Due to the lack of evidence, antimicrobial prophylaxis regimens still vary significantly between institutions.[24]

It is important to remark that it is not common to have an infection in the absence of cuff erosion. Most patients presenting an AUS infection probably have an underlying

cuff erosion, which is not evident until the cuff site is examined by urethroscopy with the cuff open. However, many cuff erosions will not be associated with infection, although if the AUS removal is delayed, eventually an infection could appear.[17]

Erosion

Erosion is another major complication associated with AUS, also guiding to complete or partial removal of the device. The rate of erosion in our literature review showed a decreasing trend in newer studies. The studies with fewer urethral erosion rate excluded neurogenic bladder pathologies; nevertheless, we conjecture that the presence of an overactive bladder or any kind of neurogenic bladder could worsen the rate of urethral erosion. Many erosion events happened later in the time of follow-up, suggesting that the longer follow-up the more adverse events can be appropriately captured.[21]

Sacomani *et al.*[7] evaluated long-term outcomes and complications, such as urethral erosion. After more than five years of follow-up, they reported this complication in 12.4% of the total population, 80% of which occurred in patients who had been irradiated. Some studies,[3,25] have speculated that previous radiotherapy may elevate the risk of urethral atrophy and increase the chance of cuff erosion, but this information is not conclusive. Rivera *et al.*[26] quantified through a retrospective study with 489 patients the risk of erosion, and it did not significantly vary between the irradiated group and the non-irradiated group.

Despite the rate of erosion has significantly decreased using the narrow-backed cuff, an increase of the pressure balloon or a larger cuff could raise the risk of subsequent cuff erosion with potential loss of prosthesis. However, there is a lack of evidence with longer time of follow-up

History of radiation

Sathianathen *et al.*[3] found the incidence of infection (3.4 vs. 0%), erosion (3.4 vs. 2.0%), and revision surgery (10.3 vs. 12.5%) did not differ significantly between the irradiated group versus the non-irradiated group. However, major complications were seen only in the irradiated group and consisted of one infected prosthesis requiring explantation, and one drainage of scrotal hematuria. O´Connor et al. found that the patients who required cuff downsizing presented urethral atrophy produced by radiotherapy.[8] Sacomani *et al.* calculated that 12 out of 15 (80%) who had artificial urinary sphincter erosion received radiation previously.[7]

Manunta et al. established that a secondary impairment of the urethral blood supply and urethral atrophy can occur as a consequence of hypovascularity caused by radiotherapy induced fibrosis even if the bulbar urethra is not in the irradiated field.[27] Likewise, the patients who were undergone pelvic irradiation likely presented and stiffness urethra due to decreased elasticity and fragility resulting in devaluation of long-terms outcomes.[12] The literature does not expose a clear increase of the complications or a deterioration in the continence rate. Nevertheless, according to the International Continence Society, patients receiving radiotherapy should be notified that they constitute a high-risk group with increased adverse effects such as cuff erosion.[28]

Limitations

Another problem is that most of the early publications did not report standardized data on complications in order to compare with data with other research groups.

The time of follow-up varied in the different studies making difficult to compare the long-term complications.

The majority of the literature reviewed was retrospective data. This type of studies cannot give precise information about inclusion criteria as neurogenic bladder measured by urodynamics or discuss the surgeon's learning curve or experience at the time of surgery.

Since some complications will occur over time, the results may show a higher incidence of complications in longer follow-up studies.

More systematic reviews are needed to improve understanding of the efficacy and complications of the AUS.

Conclusion

Urinary incontinence post radical prostatectomy is an expected event that diminish the quality of life of patients. The placement of an artificial urinary sphincter remains the gold standard treatment but this procedure is not free from complications, which include urethral atrophy, mechanical failure, revision and/or removal of the device, infection and erosion. The continence outcomes criteria and definitions are not well-stablished in the literature. There are also several risk factors that can contribute to these complications as the history of radiotherapy.

Further prospective studies should be done to clarify continence concepts after the placement of an AUS and long-term complications.

Financing:

No sponsorship was received to write this article.

Conflict of interest:

The authors declare no conflicts of interest.

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