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Systematic Review

Synchronous placement of penile prosthesis and artificial urinary sphincter: a systematic review with cumulative analysis

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Abstract

Radical prostatectomy is a life saving treatment for localised prostate cancer but may come with debilitating consequences, such as incontinence and erectile dysfunction. Penile Prosthesis Implants (PPI) are the gold standard of treatment for patients with refractory Erectile Dysfunction (ED) resistant to conservative management. Likewise, an Artificial Urinary Sphincter (AUS) is gold standard for those with refractory severe urinary incontinence. This systematic review with cumulative analysis assesses the efficacy and complications rates for synchronous placement of PPI and AUS as a single-stage procedure. Systematic literature review was performed using the US National Library of Medicine's life science database (MEDLINE) (2000 to May 2021), EMBASE (2000 to May 2021), Cochrane Central Register of Controlled Trials-CENTRAL (in the Cochrane Library-2021), Google Scholar and Individual journals. 5 studies were included for analysis, with total of 112 patients. The overall revision/replacement rate was 12.5% (n = 14). The revision rate for PPI alone was 4.5% (n = 5), for AUS was 6.5% (n = 9). The overall removal rate was 5.4% (n = 6). Removal rate for PPI alone was 0.9% (n = 1), for AUS was 1.4% (n = 3). There were only 2 case of dual prosthesis removal (1.4%). Our cumulative analysis has revealed that revision and removal rates for synchronous dual implants may be lower than previously believed. However, our review has highlighted the low quality of available data and stresses that more robust studies are required to validate the high satisfaction and low complication rates reported by small studies.

Keywords

Penile prosthesis implants; Artificial urinary sphincters; Erectile dysfunction; Severe urinary incontinence

1. Introduction

Radical prostatectomy is a life saving treatment for localised or organ confined prostate cancer, but may come with debilitating consequences. As high as 90% and 40% of patients undergoing such surgery can expect to suffer complications of Erectile Dysfunction (ED) and Severe Urinary Incontinence (SUI) [1, 2]. Penile Prosthesis Implants (PPI) are the gold standard of treatment for patients with refractory ED resistant to conservative management. Likewise, an Artificial Urinary Sphincter (AUS) is gold standard for those with refractory severe urinary incontinence. With careful
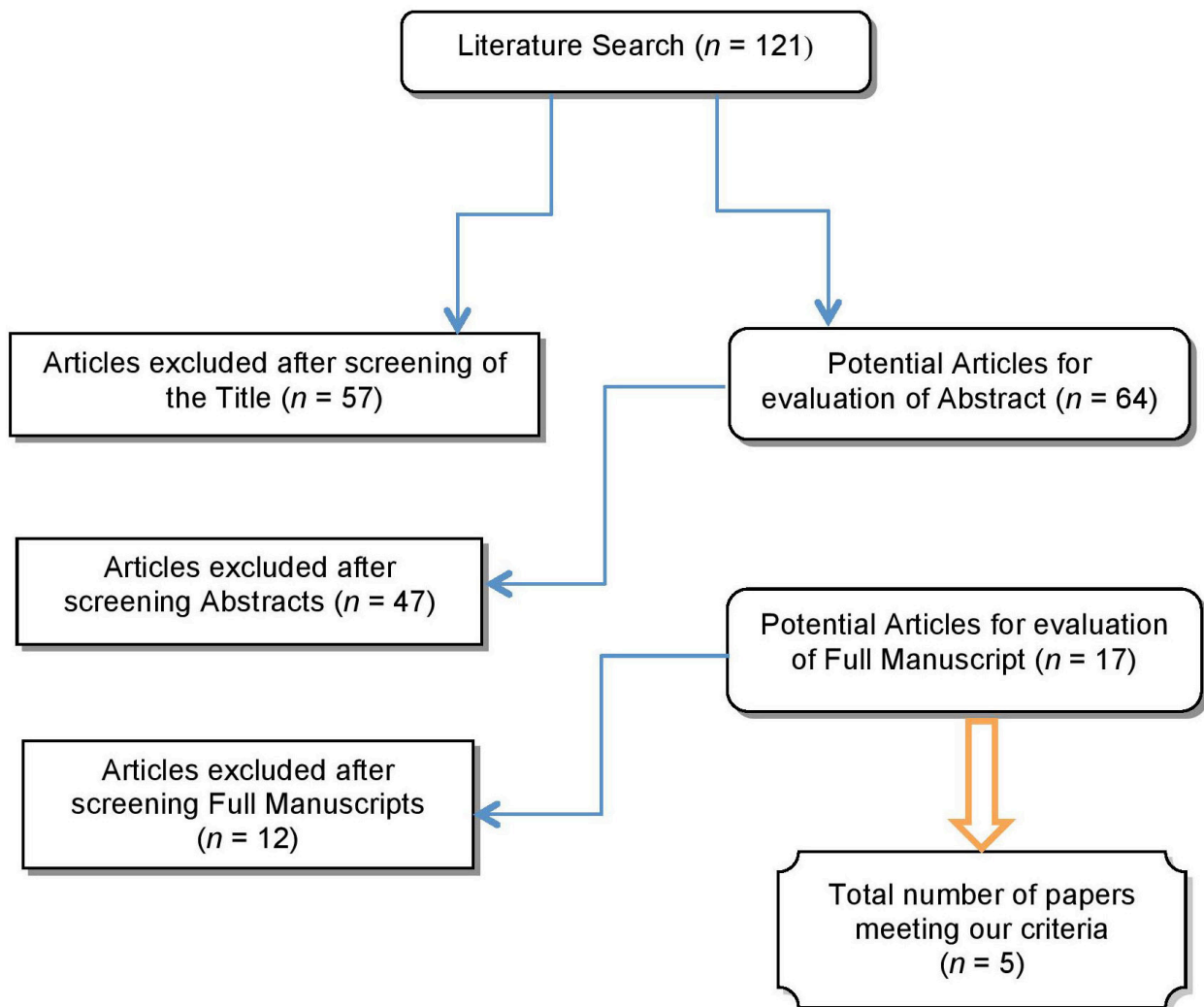

FIG. 1. Flowchart for the article selection process.

pre-operative screening, patients that would benefit from both prostheses may be identified first-hand for single-stage synchronous dual implants. Initially, prosthetic placement was made through 2 incisions—scrotal and abdominal. The placement of dual prostheses through a single transverse scrotal incision was first described by Wilson *et al.* [3] and shows promising efficacy with low complications rates. To date, many of the studies analyse smaller cohorts, making the reported complication rates less reliable. This systematic review with cumulative analysis assesses the efficacy and complications rates for synchronous placement of PPI and AUS as a single-stage procedure. Only primary synchronous procedures were included, studies including revision surgeries were excluded due to the confounding increased complication rates.

2. Methods

2.1 Search strategy

A literature search of was performed with no limitations placed. Databases used: The US National Library of Medicine's life science database (MEDLINE) (2000–May

2021), EMBASE (2000–May 2021), Cochrane Central Register of Controlled Trials-CENTRAL (in the Cochrane Library-2021), Google Scholar and Individual journals.

The following search terms were used: Penile implant, penile prosthetic implant, Dual implant, Combination implant, Urinary sphincter, artificial Urinary sphincter, Artificial sphincter, simultaneous, dual, combined.

Medical Subject Heading (MeSH) phrases included:
- ("Penile Prosthesis" (MeSH)) AND "Urinary Sphincter, Artificial" (MeSH).
- ("Simultaneous" AND "Penile Prosthesis" (MeSH)) AND "Urinary Sphincter, Artificial" (MeSH).
- ("Dual" AND "Penile Prosthesis" (MeSH)) AND "Urinary Sphincter, Artificial" (MeSH).

121 papers were returned. 10 papers recorded original data for their centre's surgical outcomes. 5 of these were excluded. 1 paper was excluded on the basis that cases were grouped as dual prosthetic if the patient had synchronous operation, or if 2nd operation was completed within a year [4]. The outcomes were also grouped in this way and therefore could not be properly analysed to determine synchronous single-stage outcomes. Additionally, outcomes were grouped in a

way such that data extraction for cumulative analysis was not possible. The 2nd paper was excluded as it included two-stage procedures [5]. The third paper was excluded as the reporting style of outcomes made it unachievable to extract outcomes for complications and re-operation rates, therefore inability to include in cumulative analysis [6]. 2 further studies were excluded due to inclusion of revision operations [3, 7]. Therefore, 5 papers remained for inclusion [8–12]. The flowchart for study selection is detailed in Fig. 1.

2.2 Eligibility criteria

The purpose of this review was to establish the efficacy and complication rate of synchronous PPI and AUS insertion during a single-stage procedure. Inclusion criteria included single-stage synchronous implantation of dual prosthesis in primary candidates, i.e., not revision/replacement procedures. Minimum 12 month follow up period was required for inclusion. Studies that did not differentiate outcomes for single-stage or two-stage procedures were excluded. Studies that included patients undergoing revision/replacement of a prosthesis *in-situ* and/or the concomitant insertion of a second prosthesis were excluded.

2.3 Data extraction

The study period, number of patients, average age, average length of follow up, complications, revision/replacement rate, removal rate, surgical incision technique (i.e., single or double incision), comorbidities, radiation status, prosthesis type and indication for surgery were extracted. Additionally, outcomes for urinary and sexual function were extracted. Continence outcomes were recorded as mean pads used per day post-operatively. Sexual function was either recorded as IIEF(-5) or SHIM (Sexual Health Inventory in Men) score or qualitatively. This data was then tabulated in Microsoft Excel to allow for cumulative analysis of the results.

3. Results

Following literature search, 121 papers were identified. 5 studies remained which detailed original reporting of outcomes for synchronous PPI and AUS placement.

3.1 Included studies

In total, 5 studies were included for data extraction and cumulative analysis. The basic demographics and complications are detailed in Table 1 (Ref. [8–12]). Continence and sexual function outcomes are described below. 2 of the studies were based in the USA, 1 in Turkey, 1 in Spain and 1 in Italy. All studies included were retrospective observational studies. 4 papers only included patients that underwent simultaneous dual implantation of Penile Prosthesis Implants (PPI) and Artificial Urinary Sphincter (AUS) using a single transscrotal incision. 1 paper included patients that underwent dual implantation using single or double incision techniques as per Surgeon preference [10]. 94.6% (n = 106) of procedures were by single-incision technique.

3.2 Cumulative analysis results

In total, 112 patients were included for review. Average age of participants (median or mean reported) was included in 4 papers, with overall mean age 64 years old. Age range was reported in 3 papers, overall age range 49–80 years. Overall mean follow-up length was 28 months. The overall revision/replacement rate was 12.5% (n = 14). The overall removal rate was 5.4% (n = 6).

3.3 Indication for surgery

112 cases had indication for surgery mentioned, of which 111 (99.1%) were secondary to Radical Prostatectomy. 1 (0.9%) case was secondary to Radical Cystectomy.

3.4 Surgical technique

All patients had AUS and PPI placed as a single-stage procedure. In 6 cases, two incisions were made as per surgeon preference [10]. In all other cases (n = 106), a single transverse scrotal incision was utilised.

3.5 Continence and sexual function outcomes

Continence outcomes were identifiable for all 112 patients, as described in all 5 papers. 79 (70.5%) were reported as using an average (median or mean) 1 or fewer pads per day post-operatively. 33 (29.5%) were reported to use an "average" 1.3 pads per day post-operatively. 3 papers used validated questionnaire "International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI Short Form)" to further assess UI [10–12]. The average scores ranged from 18–20 preoperatively, to 2 post-operatively.

Sexual function outcomes were identifiable in 90 patients, as described in 4 papers. 62 out of 64 reported rigidity sufficient for intercourse post-operatively. 11 patients in 1 study had a median post-operative SHIM (Sexual Health Inventory in Men) IIEF(-5) score of 23, compared to a score of 3 pre-operatively. 15 patients in 1 study had mean IIEF score 70/75 post-operatively.

3.6 Safety of surgery

The 5 studies reported a total of 21 complications, as outlined in Table 2. This resulted in 14 incidences of revision/replacement surgeries and 6 incidences of prostheses removal. 17 complications were described. 4 complications were presumed on the basis of unexplained revisions or removal surgeries [9] and as such are tabulated as Complication: Not Mentioned (NM). The overall revision/replacement rate was 12.5% (n = 14). The revision rate for PPI alone was 4.5% (n = 5), for AUS was 6.5% (n = 9). The overall removal rate was 5.4% (n = 6). Removal rate for PPI alone was 0.9% (n = 1), for AUS was 1.4% (n = 3). There were only 2 cases of dual prosthesis removal (1.8%).

T A B L E 1. Characteristics of studies included for cumulative analysis.

Study	Country	Study period	Patients	Age, years, mean (range)	Follow up, months, average	Revision/ replacement (n)	Removal (n)	Complications (n)	Sexual function outcomes	Urinary continence outcomes
Kendirici et al. [8]	USA	2000–2003	22	64 (55–80)	17	AUS (3)	Nil	Urethral erosion (2), Reservoir migration (1)	NM	1 or less pads daily
Mancini et al. [9]	USA	2001–2006	33	67.8 (NM)	21.6	PPI (3) AUS (6)	AUS (1)	Subcuff atrophy (6), NM (4)	32/33 'rigidity sufficient for intercourse' post-op	Average 1.3 pads daily
Bolat et al. [10]	Turkey	Jan 2006–Mar 2015	11	58.3 (49–64)	61.3	PPI (2)	PPI + AUS (1)	Scrotal abscess (1), UTI (1)	IIEF-5 increased from 3 to 23 post-op	Median 1 or less pads daily. ICIQ-UI 19→2
Salamanca et al. [11]	Spain	Sep 2007–Oct 2011	31	66 (57–74)	28	Nil	AUS (2) PPI (1)	AUS reservoir migration (1), Urethral erosion (2), Distal corporal extrusion (1), UTI (1)	30/31 'rigidity sufficient for intercourse' post-op	Median 1 or less pads daily. ICIQ-UI 18→2
Rolle et al. [12]	Italy	NM	15	(NM)	12	Nil	PPI + AUS (1)	AUS infection (1)	IIEF 70/75	1 or less pads daily. ICIQ-UI 20→2
Total			112	64	28	14	6	21		

T A B L E 2. Prosthesis revisions and removals as a result of associated complications.

Complications, n (%)	Revision/replacement, n	Removal, n
Subcuff atrophy, 6 (4.9%)	AUS, 6	
Urethral erosion, 4 (3.3%)	AUS, 2	AUS, 2
NM, 4 (3.3%)	PPI, 3	AUS, 1
UTI, 2 (1.6%)		
AUS reservoir migration, 2 (1.6%)	AUS, 1	
Scrotal abscess, 1 (0.8%)	PPI, 2	PPI & AUS, 1
Distal corporal extrusion, 1 (0.8%)		PPI, 1
AUS infection, 1 (0.8%)		PPI & AUS, 1
Total = 21	14	6

3.7 Radiation status

4 of the 5 papers reported on radiotherapy (RT) status in different manners. Of the 3 complications observed by Kendirci *et al.* [8], 2 had previous RT, both of which suffered urethral erosion requiring AUS revision/replacement. 6/22 (22%) of their cohort total had RT. In Bolat *et al.*'s [10] study, 3/11 (27%) had RT; one of which ultimately had both devices removed due to infection and cuff erosion, he was the only patient to have device removal in their cohort [12]. Salamanca *et al.* [11] reported that the 3 patients that had device removal (urethral erosion (1) and distal corporal extrusion (2)) had history of radiotherapy. They did not specify whether other patients had undergone RT in the study. Rolle *et al.* [12] reported that the 1 patient that had dual removal of prosthesis had history of RT. Again, they did not specify whether other patients in their cohort had undergone RT. One paper did not comment on RT status at all [9]. Overall, 13/112 patients were reported as having undergone RT, of which 5 required prosthesis removal (2 dual prosthesis, 1 AUS, 1 PPI) and 2 required AUS revision/replacement.

3.8 Comorbidities

Only 2 of the 5 papers reported patient co-morbidities. One paper described Diabetes Mellitus in 32% (n = 7), Hypertension in 27% (n = 6) and Peyronie's disease in 4% (n = 1). Another paper reported Diabetes in 27.2% (n = 3), "Cardiovascular risk factors" in 63.6% (n = 7). The meaning of "cardiovascular risks" was not elaborated on. The authors did not correlate the reported outcomes with comorbidities in either paper. The remaining 3 papers did not comment on patient comorbidities.

3.9 Penile prosthesis type

3 studies used exclusively Penile Prosthesis Implants (PPI) and 2 papers offered patients either Malleable Penile Prosthesis (MPP) or PPI [10–12]. Overall, 99 had PPI and 13 had MPP. In Bolat *et al.*'s [10] series, the 1 patient with several complications had PPI. In Rolle *et al.*'s [12] series, the 1 patient that had dual device removal following sphincter infection did not have penile prosthesis sub-type disclosed. There is insufficient data collected in this review to evaluate whether PPI versus MPP carry different complication rates.

4. Discussion

We agree that synchronous placement of PPI and AUS as a single-stage procedure is an efficacious solution for concomitant severe ED and SUI, with acceptable complication and re-operation rates [13]. These are comparable to single PPI and AUS implants [14–17]. Improvements in the prosthetic devices, such as those impregnated with antibiotics, has helped to reduce worrisome complication rates. In 1982, Graham *et al.* [18] first reported their series of dual implants using the Kauffman prosthesis, with a near 100% revision rate. Parulkar and Barrett [5] had greater success with their series, with high satisfaction for continence and sexual function

outcomes. However, 33 of the 60 patients required 1 or more of their prostheses revised, with an average of 0.98 corrections per patient. Of note, their paper was not included for our cumulative analysis study due to no distinction between patients undergoing single-stage versus two-stage procedures.

Many studies analyse a relatively small cohort of patients and therefore complications and revision rates have typically been deemed less reliable. The overall revision/replacement rate from the cumulative analysis was acceptable at 12.5% (n = 14). Revision rate for AUS alone was 6.5%, with subcuff atrophy as the most common reason for AUS failure; as reported by previous studies for sole AUS implantation [19]. Of note, reported infection rates were low. A potential explanation is that with each operation brings an increased risk of introduction of bacteria with prostheses; therefore a synchronous single-stage operation reduces this risk.

Removal rate for PPI alone was surprisingly low at 0.9% (n = 1); it has been reported as high as 11.3% by Patel *et al.* [4]. Unfortunately, this larger cohort study was unable to be included in our review due to the grouping of outcomes for single-stage synchronous dual prostheses with two-stage procedures, whereby the second prosthesis was implanted within a year. Due to the grouping method the outcomes could not be analysed and extracted for cumulative analysis. Had they not been grouped in this way the additional 139 single-stage patients would have doubled our cohort and would have been a valuable addition to our cumulative analysis.

The overall prosthesis removal rate was low at 5.4% (n = 6). Of the 112 patients included for analysis, only 2 had dual implant removal (1.8%). In the series by Bolat *et al.* [10], a patient had a PPI infection requiring 2 revision surgeries at 43 and 48 months post-op synchronous implantation. This was further complicated by the development of a scrotal abscess with concurrent cuff erosion. The decision was then made for dual explantation. In Rolle *et al.*'s [12] study, a patient underwent 2 urethrotomies for recurrent urethral stricture, which resulted in a sphincter infection and later dual prosthesis removal. Bolat *et al.* [10] had the most substantial follow up period with median 61.3 months, whereas Rolle *et al.* [12] had the shortest at 12 months. The extended follow up period with Bolat *et al.*'s [10] study allowed for reporting of 2 failed revision surgeries and failed antibiotic therapy, resulting in the ultimate decision to remove both devices. This highlights the importance of extended follow up reporting to determine reliable long-term complication rates. It is emphasised that studies with short follow up period are more likely to demonstrate lower revision and removal rates, due to the lesser time for time-dependent complications such as erosion to develop, and potential failed revisions resulting ultimately in device removal.

The findings are supportive of the synchronous dual implant as a safe and time effective alternative to two-stage procedure. Often AUS is first placed to allow familiarisation with the device, before later inserting PPI if appropriate. We agree that the low complication rates and re-operation rates

observed in this cumulative analysis should encourage the strategic questioning and examination of patients to assess for suitability for synchronous dual implantation [20, 21].

This review was limited in several ways by the available literature. Firstly, by the low quality of selected studies and absence of randomised control studies in this field. Due to the relative rarity of the dual implant, furthermore as a single-stage procedure, the study cohorts are typically small for these retrospective studies, therefore reporting of revision and removal rates are very variable.

The cumulative analysis performed in this systematic review adds to the known literature by summarising these complication rates across a larger overall cohort. Statistical meta-analysis was not performed due to the heterogeneity of reporting outcomes, particularly with regards to the radiation status of patients and whether complications were associated with RT status. The validity of the cumulative outcomes for people that had history of RT is likely inaccurate, due to the heterogeneity of reporting between studies for number of patients that had undergone RT and whether all reported complications were correlated with RT status.

A further limitation is the bias when relying on the self-reporting of complications. One study reported incidences of revision/removal of prostheses without explanation of why [8]. Therefore, the overall complication rate has been reflected, but the sub-grouping of particular complications will have been diluted. If, for example they had all been attributed to infection, this would have largely influenced the overall infection rate. The non-standardisation of which outcomes are reported and disclosed in the published literature is a major limitation of this review.

The lack of co-morbidity reporting removes the possibility for statistical analysis of certain conditions being associated with certain outcomes, such as the known increased risk of PPI infection with diabetes mellitus [22]. For example, if the 3 studies that did not report co-morbidities, had indeed reported that no patients in their studies had diabetes, or that very few did, this known confounding factor could explain the observed lower revision and removal rates established in our cumulative analysis.

Not all studies reported on sexual function outcomes, those that did used different outcome reporting strategies. 2 used validated screening tools (IIEF and IIEF-5) and the other, a qualitative questionnaire. This limited our ability to perform statistical analysis for outcomes. Similarly, for urinary continence outcomes, all patients post-operatively were said to have use 1.3 pads or fewer per day. Not all studies used validated UI screening tools, limiting the review of UI pre and post-operatively.

The length of follow up time ranged from 12 to 61.3 months. The shortest study only reported 1 complication of infection requiring dual prosthesis removal. The lack of long-term follow up studies, allowing for time-dependent complications such as erosion, is also a limitation of this review.

5. Conclusions

This systematic review has highlighted the lack of high quality data supporting the reported safety of dual placement of PPI and AUS as a single-stage procedure.

Our cumulative analysis revealed revision and removal rates may be lower than previously believed. Additionally, functional satisfaction is high and supports the strategic questioning of patients pre-operatively to ensure they are considered for dual prostheses if appropriate. The vast majority of surgeons in this review adopted a single-incision technique, supporting its use. The quality of the evidence remains limited due to heterogeneous nature of the outcome reporting, the high satisfaction and low complication rate still have to await more robust studies.

Abbreviations

PPI, penile prosthesis implants; AUS, artificial urinary sphincter; ED, erectile dysfunction; MeSH, Medical Subject Heading; IIEF(-5), International Index of Erectile Function(-5); SHIM, Sexual Health Inventory in Men; MPP, Malleable Penile Prosthesis; NM, Not Mentioned; SUI, severe urinary incontinence.

Author contributions

OMA and AA conceived the idea for systematic review and performed literature search; SJ analysed the data and wrote the paper; JH edited first draft; RT and AY edited final draft.

Ethics approval and consent to participate

Not applicable.

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Conflict of interest

The authors declare no conflict of interest.

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