Running Head: About the complications after male anti-incontinence procedures

Major Complications after Male Anti-IncontinenceProcedures: Predisposing Factors, Management and Prevention

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Keywords: artificial urinary sphincter; postoperative complications; prostatectomy; suburethral slings; urinary stress incontinence

ABSTRACT

PURPOSE: Significant post-prostatectomy incontinence (PPI) is a crippling condition and managed best through sling or artificial urinary sphincter (AUS) implantation. These procedures are often associated with complications requiring surgical intervention. The aim of our retrospective study was to evaluate the occurrence of major complications and identify risk factors.

MATERIALS AND METHODS: Between 2010 and 2018 ninety-one patients have been implanted with sling (22; 24.2%) or AUS (69; 75.8%) in our department. The cases where surgical revision was needed were examined regarding the etiology (mechanical failure (MF), urethral erosion (UE), urethral atrophy (UA), surgical site infection (SSI), combined reasons (COMB) and analyzed, using 16 possible perioperative risk factors.

RESULTS: Surgical intervention was carried out by 19 / 91 (20.9%) patients. (In 16 / 69 cases after AUS (23.1%), 3 / 13 after slings (23%)). The indication was in 6 (31.6%) cases MF, in 3 (15.8 %) COMB, in 4 (21.1%) UE, in 5 (26.3 %) SSI, in 1 (5.2%) UA. The type of reoperation was either explantation (12 / 19), system replacement (6 / 19), or cuff replacement (1 /19). Regarding the surgical intervention requiring complications only preoperative bacteriuria (*P* = .006) and postoperative surgical site oedema (*P* = .002) proved to be independent predictive factors.

CONCLUSION: Preoperative bacteriuria and surgical site oedema seemed to be good predictors for obligate surgical revision. Patients with AUS were more prone to have major complications. In most cases it was mechanical failure, infection or erosion. By reducing the frequency of these risk factors we might be able to decrease the amount of complications.

Keywords: post-prostatectomy incontinence, anti-incontinence surgery, implantation, sling, artificial urinary sphincter, complication

INTRODUCTION

Post-prostatectomy incontinence (PPI) is a frequent and often debilitating complication occurring mainly due to radical prostatectomy (RP) or other prostate operations (transurethral resection of the prostate– TURP or open prostatectomy – OP). May it be temporary or permanent, it can have a huge impact on the life quality, not to mention the financial burden the patient and the healthcare system has to carry.[(1)] The incidence fluctuates between 5 and 40 percent (depending on the definition), however the urine loss is often slight, and many of those affected will be continent again at the end of the first year.[(2)] Only a small fraction (about 7%) requires surgical intervention: suburethral sling (much like the female mid-urethral slings) or artificial urinary sphincter (AUS)

implantation.[3,4,5,6] Despite the long time it took to achieve relative safety, there are still numerous complications where we have to intervene.[5,6] Some of these problems can only be solved with replacement, some only with explantation. The revision rate between AUS (8 - 45 %) and slings (9,7 - 35 %) differs somewhat with AUS predominance.[7,8]

Our goal was to examine the frequency of major complications after male anti-incontinence procedures and to identify possible risk factors.

MATERIALS AND METHODS

Study Population – Between 2010 and 2018 ninety-one consecutive PPI patients have been operated in our department.

Inclusion and exclusion criteria – All of these implantees have been included in our investigation and there was no reason to exclude anyone of them. (Those, who were operated but could not receive implant due to intraoperative complications are obviously got not involved in our examination.) Data was collected retrospectively. Our patients of the study population (n = 91) were all Caucasian without significant diversity across demographic or comorbidity variables. Among the study population 71 (78%) patients had radical prostatectomy, 15 (16.5%) had transurethral prostate resection and 4 (4.4%) had open prostatectomy. (Only a fraction of these operations were performed at our clinic).

According to the 24h PAD test, 66 (72.5%) patients belonged to severe (over 400 mL/day), and 25 (27.5%) to the mild to moderate incontinence group (100 - 400mL/day).

Procedures – The following implants were used in our department: the AMS800® (69 pts) artificial urinary sphincter system (Boston Scientific, Marlborough, MA, USA), ATOMS® (13 pts) (A.M.I. GmbH, Feldkirch, Austria) and Argus® (8 pts) (Promedon SA, Cordoba, Argentina) transobturator adjustable sling systems, and the Surgimesh M-SLING® (1 patient) (Aspide

Médical, La Talaudière, France), a non-adjustable transobturator sling. The choice of which device to implant was based on the level of incontinence (AUS was usually used for more severe cases, slings for mild or moderate incontinence but patient's preference was taken into account as well. The operations were all performed by the same surgeon and assistant team. The follow-up time after the primary operation was avg 39 +/- 22.3 months (6 - 87 mo).

All operated patients had complete diagnostic assessment preoperatively: physical examination, urine test and culture, 24-h PAD test and urine loss ratio (urine loss during 24 hours/total daily urine production), uroflowmetry and post-void residual (PVR) urine measurement, upper urinary tract ultrasound, urodynamic investigation and urethro-cystoscopy. Bacteriuria was always treated with targeted antibiotic therapy before the operation and every patient received iv. antibiotics on the ward and for another 5 days per os after emission. If urine culture was negative, we automatically administered prophylactic cephalosporin. (If the urine culture was positive before the operation, the patient received preoperative, targeted antibiotic therapy. In these cases, no control culture has been done right before the implantation.)

Evaluations – The complications were classified by the following: infection (INF), urethral atrophy (UA) and erosion (UE), mechanical failure (MF) and combined causes (COMB: MF with UE). In our analysis we investigated all major complications that led to (obligate or optional) reoperation and looked for possible predisposing factors. We have examined the different types of anti-incontinence operations regarding the frequency of reoperations as well. A reoperation was obligate, if INF, UE or COMB type of complications made the intervention a must. It was optional if there was no imminent danger to the patient's health, but MF or UA made the continence to significantly deteriorate. In these cases, the surgical goal was to reinstate continence with a partial or total replacement.

The statistical analysis was performed as described in the following. For paired group comparisons, the nonparametric, 2-sided Wilcoxon rank-sum test (Mann-Whitney test) was applied. To analyze the potential impact of perioperative factors on reoperation we applied the Chi-square test. Factors occurred less than 5% in the study cohort, such as postoperative hematuria ($n = 1$), retention ($n = 2$) and fever ($n = 2$) were excluded, leaving 16 factors for analysis. All statistical calculations were done with the SPSS software package (24.0; SPSS, Chicago, USA). In all tests, P values < 0.05 were considered statistically significant. Multivariate analysis has been performed with the collected data.

Patients' characteristics, the examined perioperative parameters and their role as possible risk factors are demonstrated in Table 1. Table 2. shows the relation between the type of the anti-incontinence surgeries and the number of reoperations.

RESULTS

Surgical revision was necessary in 19 cases (20,9 %). In 16 (84,2%) Pts with the AUS, and in 3 Pts (23%) after ATOMS implantation. (With ARGUS or M-Sling there was no reoperation.) The elapsed time between implantation and reoperation was 14.2 months in average (0.5 - 43). The most common major complication was mechanical failure (MF) (6 / 19; 31.6%), followed by infection (INF) (5 cases; 26.3%). Urethral erosion (UE) was seen in 4 cases (21%). In 3 occasions a mechanical failure led to urethral erosion (COMB) (15.8%). In these cases the AUS could not becompletely deactivated after the implantation and it led to urethral erosion – these were categorized as combined complications. Urethral atrophy was seen only once (5.2%).(Figure 1.) Because of these unfortunate events we had to remove the implant (EXP) in 12 cases (13.2%). System replacement (REP) was carried out in 6 (6.6%) cuff change (CCH) in only one case (1.1 %). (Figure 2.) Based on the categories mentioned above, if we elicit the 9 (partly or totally)

mechanical complications from the whole „reoperated" population (19 cases), we end up with 10 cases (9 AUS, 1 ATOMS), where the root of the problem lay somewhere else.

Only preoperative bacteriuria and surgical site oedema proved to be an independent significant predictive factors in multivariate analysis (P = .025 and P = .012;) for obligate reoperations.(Table 1.) We recognize that surgical site oedema (or swelling) is a relative term that has no dimension;however, it is a well-knownphenomenon also presented as possible warning sign on the user's guide for AUS patients. (It was categorized as a "swelling at the surgical site" – probably due to hematoma, infection or dysfunctional lymph circulation – if itpersisted over 48 hours postoperatively or was much bigger in size than what is usually expectedafter these operations.)

The type of the implant was also an important(although, not significant) predicting factor, since over 80 percent of our complications happened after AUS implantations and many of these were mechanical - a type of problem which usually occurs in a much lower number with slings.[9]

DISCUSSION

As we come across complications, we should always look for the origin even if the incidence does not differ much from the previously published data.[10] In our experience there are three ways to deal with this question. The root of the event can either be a mechanical problem, human error or the unlucky attributes of the patient. Since often there are combined reasons, it is not easy to decide which is which, although it is quite clear that failures arising from surgical inexperience counts to the expense of the surgeon, and mechanical failures can usually be blamed on the manufacturer.In our work, mechanical failure was the most common complication which represented the half of all cases (9 out of 19 – 47%) either as a single complication or as a part of

it. In contrast to others, however, we rarely saw erosion under the cuff (4 / 69). This difference (5.7 vs 10.7 - 10.8 %) may be related to the fact that others (like *McKibben*) used 3.5 – 4 cm cuffs, our average cuff-size was 4.5 cm.[11] *Bugeia* detected mechanical failures with AUS in 62 %, mostly due to the dysfunction of the pressure regulating balloon.[12] Urethral atrophy was only seen in a few cases, just like in our investigation (1 / 69). As we present in our study, the factors that showed a significant correlation with major complications required obligate surgical revision were the preoperative bacteriuria and the surgical site oedema which could be related to the patient's inadequate preparation giving us room to improve and change our routine.

When discussing major complications, it is also recommended to distinguish one from the other, based on the necessity of reoperation: i.e. the indication is obligate or imperative (the procedure is unavoidable) in case of acute infection or urethral erosion. Chronic infection, or skin erosion without signs of acute infection (around the pump, port or access kit) can be mended with exploration, debridement, total – or in some selected cases – partial exchange of the device. Evidently, we only turned to this solution, when the chronical, superficial skin (or subcutaneous) infection and consequential skin erosion did not reach the urethra, and the patient specifically requested the exploration and debridement, hoping that his continence will be preserved this way. (Even tough, because of the recurrent problems we later ended up removing the implant after all.) The other group of complications which require surgical attention is where malfunction appears in the form of recurrent incontinence: the main cause is usually a mechanical problem or urethral atrophy. (Here we have to add, that there is growing evidence that many of the cases which one could easily qualify as atrophy are not atrophies at all. In fact, it's only fibrous sheet (a.k.a. capsule) growing over the inner surface of the cuff that gives the impression of a urethral atrophy.[11,13]) In these cases the patient's health is not in imminent danger, but the deteriorating quality of life makes

the surgical intervention (replacement, or exchange) indisputably needed. In these cases, the (optional) replacement can be performed in a single operation. These types of complications (mechanical failures without any infection) were the most common in our experience (6 / 19) – four with AUSs and two with ATOMS slings. (Here we would like to add that AUS systems are notoriously more prone to suffer mechanical failures (in 12 - 53%) than any type of slings. This is partly due to their complex structure and partly to the fact that they have to be assembled on sight.[14,15]

The incidence comparison of complications between the patients operated early and late in the learning curve showed no significant difference. This is contradicted by a large study published in European Urology, which pointed out the extremely long learning process of AUS implantation but also called for structured, thematic, training-based surgical education to reduce the learning curve.[16] (In our case, we tried to reach the needed experience by accredited trainings and operating with practiced guest operators.) Our patients all received targeted or empiric antibiotic therapy however it looks like some patients (having had significant bacteriuria and treatment but no control urine culture before the operation) still suffer more complications. (Probably because the surgical site is still being contaminated through the non-sterile urine.) After what we learned we decided that to do another urine culture before the operation (even after the targeted antibiotics therapy), to see if we can improve our numbers. The other independent risk factor was the postoperative surgical site oedema (which is a relative concept, though we have tried to define the phenomenon above). In its development postoperative hematoma, diminished lymphatic drainage, or infection could all play a part to varying degrees. The possibility of this complication could be reduced by more precise surgical technique and hemostasis. Unlike *Hüsch et al*., we did not find preoperative irradiation to be an independent, predisposing risk factor for complications, however,

the role and significance of the independent risk factors we described are obviously enhanced in tissues where the circulation is damaged[17].

Whereas most of the previous papers dealing with complications of male anti-incontinence operations involved only a handful of perioperative factors the current one has examined 16 parameters. Reconstructive male urogenital surgery with implants is more effective than with the use of autografts, however – just as with female patients, the surgical management of stress urinary incontinence and prolapsed surgery comes with a number of complications, which we aim to reduce in the future. [17,18]

Our study's obvious limitation is the low patient number. However, we tried to compensate this number with a large collection of assessed perioperative factors. Our initial results are promising and we intend to investigate our objectives further with a multicenter study, including measures designed to reduce complications mentioned in this study.

CONCLUSIONS

The rate of major complications after male anti-incontinence surgery in our department is in line with the international data. Among the male anti-incontinence operations the AUS implantation came with the most complications (requiring acute surgical revisions) but the difference has not proved to be significant. The leading indication for reoperation was the mechanical failure. Complications without the possible presence of mechanical failure were seen in only 10 pts (52.6 %).

Between these investigated perioperative factors, only the preoperative bacteriuria and the surgical site oedema could be identified as independent risk factors to predict major (surgical intervention requiring) complications with obligate necessity of surgical revisions. According to these findings we will alter our clinical protocol and do a preoperative control urine culture (just before the patient

gets admitted) after the targeted antibiotic therapy! Also, we will try to reduce the possible trigger factors leading to postoperative oedemas. These might help us reduce the number of reoperations and report about an improving complication rate in our follow-up publication.

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TABLES

Perioperative Parameters	**Value**	**Risk for Major (surgical intervention requireing) Complication**	**Risk for obligate intervention**	**Risk for optional intervention**
Age avg. +/-SD (yr)	69.3+/-5.83	.594	.991	.425
Elderly pts (>75yr) n(%)	21 (23.1)	.807	.943	.777
BMI avg.+/-SD (kg/m2)	28.6+/-3.75	.504	.8	.486
Etiology of MSUI		.549	.556	.937
RRP n(%)	41 (45.1)			
LRP n(%)	29 (31.8)			
PRP n(%)	2 (2.2)			
TURP n(%)	15 (16.5)			
OP n(%)	4 (4.4)			
Grade of Incontinence		.899	.837	.946
Severe n(%)	66 (72.5)			
Moderate n(%)	25 (27.5)			
Adjuvant Irradiation n(%)	18 (19.7)	.421	.626	.543
Operated anastomotic stricture n(%)	38 (41.7)	.432	.357	.944
Previous perineal operation n(%)	11 (12.1)	.178	.141	.853
Diabetes n(%)	21 (23.1)	.706	.101	.131
Bacteriuria n(%)	42 (46.1)	.248	.006 (.025[a])	.078
Prevoius anticoagulant th n(%)	40 (43.9	.222	.156	.951
Cuff size avg. (up-to) cm	4.5 (3.5-	.582	.728	.686

	6.5)			
Surgical Site Oedema (%)	16 (17.5)	.072	.002 (.012**)	.203
P.op. voiding diff. n (%)	7(7.7)	.655	.929	.427
Postop. UTI n (%)	6 (6.6)	.793	.794	.464
Postop. pain n (%)	7 (7.7)	.655	.929	.427

Table 1. The analyzed perioperative factors and risk analysis ($P = < .05$)

[a]Significant, independent predictive factor in multivariate analyses

Abbreviations: BMI: Body Mass Index, MSUI: Male stress incontinence, RRP: Retropubic radical prostatectomy, LRP: Laparoscopic radical prostatectomy, PRP: Perineal radical prostatectomy, TURP: Transurethral resection of the prostate, OP: open prostatectomy, UTI: Urethral tract infection

Comparison of the anti-incontinence surgeries	**n (%) vs n (%)**	**Risk for Major compl**	**Risk for obligate reop. requiring complications**	**Risk for optional reop. requiring complications**
AMS 800 vs. slings (ATOMS, ARGUS,M-Sling)	69(75.8) vs 22(24.2)	.377	.074[a] .169	.777
AMS 800 + ATOMS vs. simpler slings (ARGUS, M-Sling)	89(90.1) vs 9(9.9)	.104	.218	.362

Table 2. The association between the reoperations and the type of the anti-incontinence surgery. [a]p only for acute obligate reoperation. *(P = < .05)*

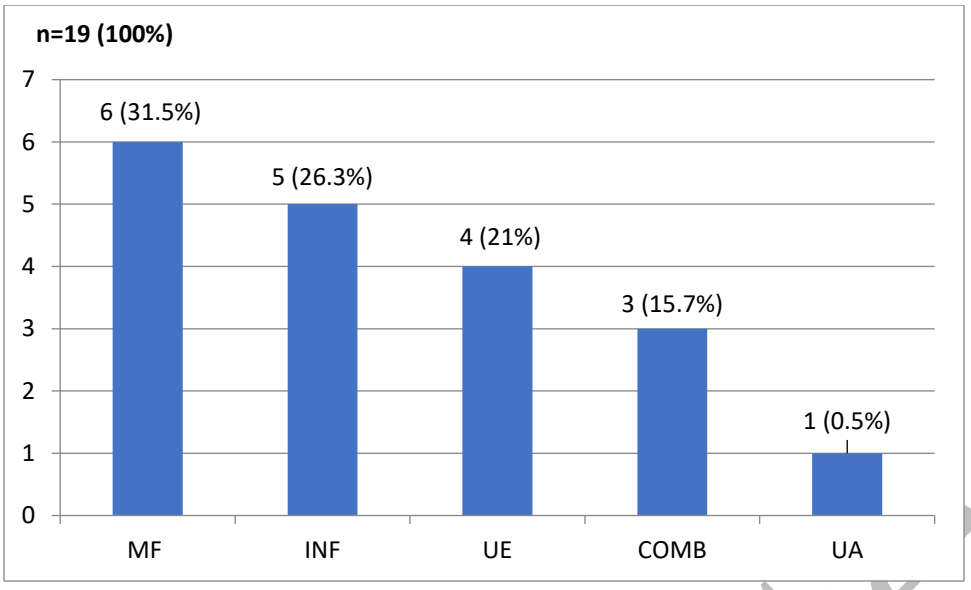

Figure 1. Complications and their incidence (MF: mechanical failure, SSI: surgical site infection, UE: urethral erosion, COMB: combined reasons, UA: urethral atrophy

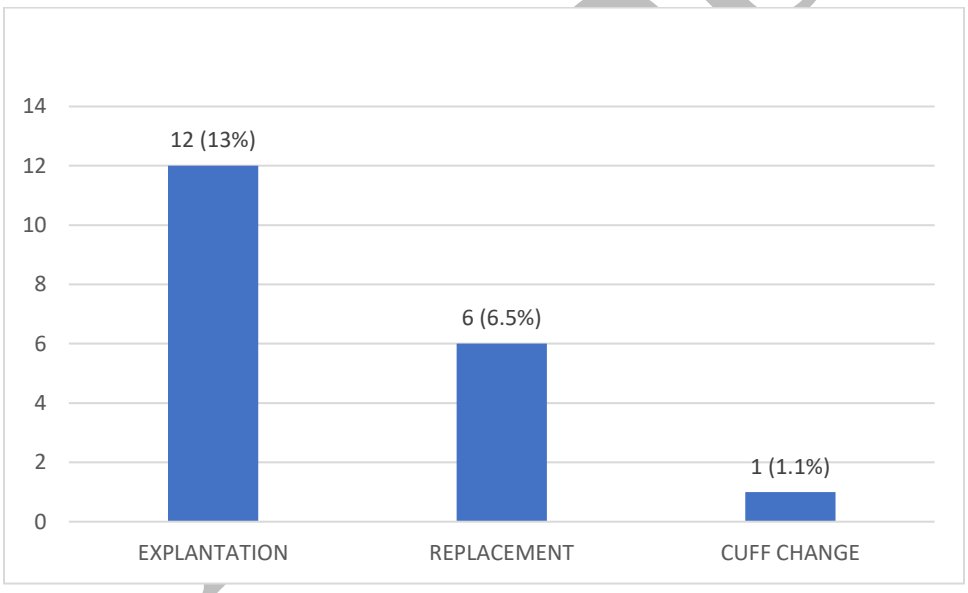

Figure 2. Types and incidence of reoperations (n = 19)