



Avoiding the cost of an Artificial Sphincter in Mediterranean Setting

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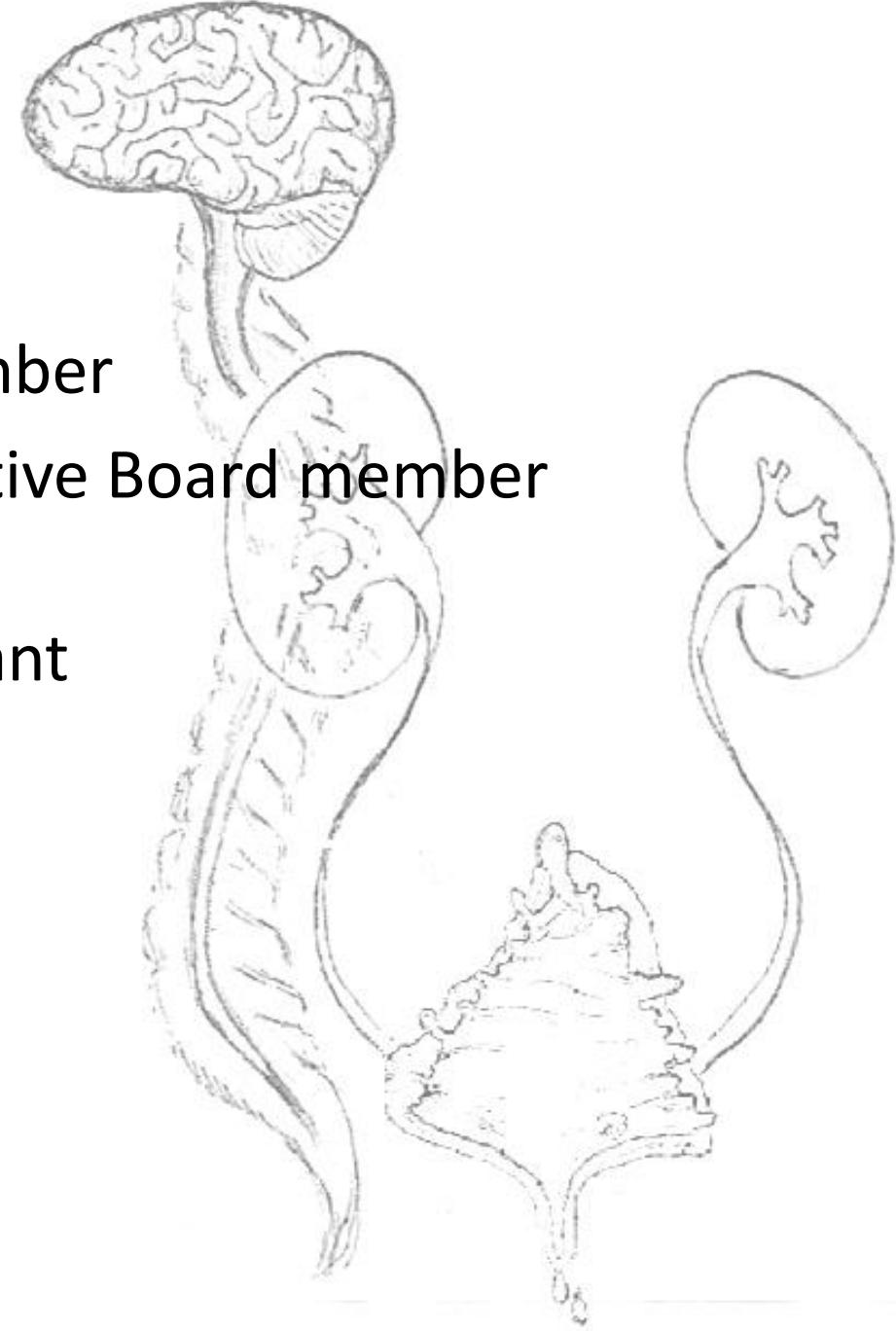
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Disclosures

- ICS: Neurogenic Promotion Committee member
- Hellenic Urological Association (HUA): Executive Board member (General Secretary)
- Coloplast: Advisory Board member, travel grant
- Ariti: travel grant
- Astellas: travel grant
- Lilly: travel grant
- Menarini: travel grant
- Pierre-Fabre: travel grant
- Ricordati: travel grant



Artificial Urinary Sphincter

- The artificial urinary sphincter (AUS) has historically been considered the gold standard for the surgical management of non-neurogenic stress urinary incontinence (SUI) in men.
- Twelve reports were identified, gathering data about 623 patients. Only three studies were prospective.
- Quality of evidence supporting the use of AUS in non-neurogenic male patients with SUI is low, based on heterogeneous data, low-quality studies, and mostly out-of-date efficacy outcome criteria.

Van der Aa F. The artificial urinary sphincter after a quarter of a century: a critical systematic review of its use in male non-neurogenic incontinence. Eur Urol. 2013 Apr;63(4):681-9.

After radiotherapy

- A continence rate of about 80% can be expected, while this may be lower in men who have undergone pelvic radiotherapy

Bauer, R.M., et al. Contemporary management of post prostatectomy incontinence. Eur Urol, 2011. 59: 985.

- Similar outcome

Gomha MA, Boone TB. Artificial urinary sphincter for post-prostatectomy incontinence in men who had prior radiotherapy: a risk and outcome analysis. J Urol. 2002 Feb;167(2 Pt 1):591-6.

- Patients who experienced complete continence after AUS implantation had a higher erosion risk
- One small series reported results of AUS implantation after failure of previous AdVance© sling, showing no difference in efficacy between secondary and primary implantation

Smith, P., et al. Hypercontinence and cuff erosion after artificial sphincter insertion: A comparison of cuff sizes and placement techniques. The Journal of Urology, 2011. 185: e538.

Lentz, A.C., et al. Outcomes following artificial sphincter implantation after prior unsuccessful male sling. J Urol, 2012. 187: 2149.

EAU Guidelines on Urinary Incontinence in Adults

F.C. Burkhard (Chair), J.L.H.R. Bosch, F. Cruz, G.E. Lemack,
A.K. Nambiar, N. Thiruchelvam, A. Tubaro
Guidelines Associates: D. Ambühl, D.A. Bedretdinova,
F. Farag, R. Lombardo, M.P. Schneider

4.3.5.5.3 Summary of evidence for compression devices in males

Summary of evidence	LE
There is evidence that primary AUS implantation is effective for cure of SUI in men.	2b
Long-term failure rate for AUS is high although device replacement can be performed.	3
There are conflicting data on whether previous pelvic radiotherapy affects the outcome of AUS implantation.	3
The usefulness of tandem-cuff placement is uncertain.	3
There is insufficient evidence to state whether one surgical approach for cuff placement is superior to another.	3
Very limited short-term evidence suggests that the non-circumferential compression device (ProACT®) is effective for treatment of post-prostatectomy SUI.	3
The non-circumferential compression device (ProACT®) is associated with a high failure and complication rate leading to frequent explantation.	3
The rate of explantation of the AUS because of infection or erosion remains high (up to 24% in some series).	3
Mechanical failure is common with the AUS.	3
Revision and re-implantation of AUS is possible after previous explantation or for mechanical failure.	3

AUS = artificial urinary sphincter; SUI = stress urinary incontinence.

4.3.5.6 Recommendations for men with stress urinary incontinence

Recommendations	Strength rating
Offer duloxetine only to hasten recovery of continence after prostate surgery but inform the patient about the possible adverse events and that its use is off label for this indication in most European countries.	Weak
Only offer bulking agents to men with mild post-prostatectomy incontinence who desire temporary relief of incontinence symptoms.	Weak
Do not offer bulking agents to men with severe post-prostatectomy incontinence.	Weak
Offer fixed slings to men with mild-to-moderate* post-prostatectomy incontinence. Warn men that severe incontinence, prior pelvic radiotherapy or urethral stricture surgery, may worsen the outcome of fixed male sling surgery.	Weak Weak
Offer AUS to men with moderate-to-severe post-prostatectomy incontinence.	Weak
Implantation of AUS or ProACT [©] for men should only be offered in expert centres.	Weak
Warn men receiving AUS or ProACT [©] that, although cure can be achieved, even in expert centres, there is a high risk of complications, mechanical failure or a need for explantation.	Weak
Do not offer non-circumferential compression device (ProACT [©]) to men who have had pelvic radiotherapy.	Weak

* The terms “mild” and “moderate” post-prostatectomy incontinence remain undefined.

ACT[©] = artificial compression device; AUS = artificial urinary sphincter.

The choice of artificial sphincter

- Degree of incontinence
- Previous incontinence surgery
- Patient dexterity
- Expectations from surgery
- Economics

Patients preference

- All patients recommended to have a sling chose a sling (mild to moderate incontinence)
- 75% recommended to have an AUS had an AUS (severe incontinence)
- In case that there was offered a choice (moderate to severe incontinence): 92% chose a sling

Kumar A, Litt ER, Ballert KN, Nitti VW. Artificial urinary sphincter vs male sling for post-prostatectomy incontinence - what do patients choose? J Urol 2009;181:1231-5.

Real life situation - Greece

Radical prostatectomies more than 3000/year

Implanted sphincters

- 2018 - 24 pieces
- 2017 - 15 pieces
- 2016 - 12 pieces
- 2015 - 10 pieces
- 60% in public setting
- 40% in private (20% private insurances / 80% self-paid)

Real life situation - Greece

- Cost of AUS (AMS 800): ~9500 Euro
- Additional cost for the surgical procedure
- Reimbursement by the health care system ~3000 Euro (surgery + implant)
- Only 3 academic centers can offer artificial sphincter implantation under public insurance cover
- Cost of a male sling (Advance): ~ 2800-3500 Euro
- Condom catheters are full reimbursed by the health care system
- Pads are advertised and easily accessed (and are self-paid)
- External compressive devices are rather cheap



Real life situation – AUS implantation

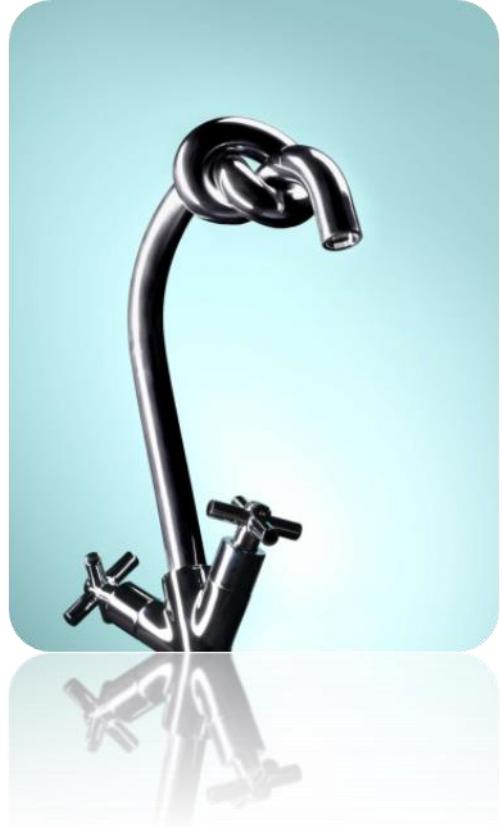
- Italy (300 – 400/per year)
 - Reimbursement: 50% covered by the patient. At the end of 2019 it is expected to cover totally by the state
- Spain (~300/per year)
 - Reimbursement: 40% covered by the patient.

Evaluation

- Bladder diary
 - Control the fluid intake, bladder capacity, incontinence episodes
- Pad test
 - Quantitative evaluation of incontinence
- Urodynamics
 - Exclude detrusor overactivity
- Cystoscopy
 - Evaluation of a “vital” sphincter
 - Exclude strictures

Conservative management target

- To improve continence
 - From severe to moderate
 - From moderate to mild
- Can PFMT be a valid option?
- Can a male sling replace the need of a sphincter?



Thank you so much