

Ente richiedente: U.O Urologia – ASL 4

Data: 18-7-2014

Male Sling ARGUS

Esaminata la Griglia presentata dal Richiedente si riportano le seguenti considerazioni:

1. La letteratura scientifica a sostegno della richiesta risulta carente sia quantitativamente (nr.1 articolo) che qualitativamente (trattandosi come correttamente riportato dal Richiedente di studio su serie di casi). *“BJU Int. 2006 Mar;97(3):533-9. An adjustable male sling for treating urinary incontinence after prostatectomy: a phase III multicentre trial. Romano SV1, Metrebian SE, Vaz F, Muller V, D'Ancona CA, Costa DE Souza EA, Nakamura F.”*
2. Ulteriore bibliografia presente (ad es. abstract presentati a congressi) sulla brochure informativa del device non è da ritenersi utile nella fase di assessment.

Vista la scarsità di evidenze scientifiche a supporto, è stata condotta un'ulteriore analisi della letteratura scientifica su Pubmed che ha prodotto i seguenti risultati:

- *Actas Urol Esp. 2009 Mar;33(3):309-14. Long-term results of a phase III multicentre trial of the adjustable male sling for treating urinary incontinence after prostatectomy: minimum 3 years. [Article in Spanish] Romano SV, Metrebian SE, Vaz F, Muller V, D'Ancona CA, de Souza EA, Nakamura F. CONCLUSIONS: Argus has demonstrated its efficacy in long- term follow-up. The social continence rate was about 80%. The important complication was erosion or infection.*
- *Urologe A. 2010 Apr;49(4):511-4. doi: 10.1007/s00120-010-2260-5. Adjustable systems for the treatment of male incontinence. [Article in German] Hübner WA.*
- *J Urol. 2011 Apr;185(4):1363-8. doi: 10.1016/j.juro.2010.11.075. Epub 2011 Feb 22. An adjustable sling for the treatment of all degrees of male stress urinary incontinence: retrospective evaluation of efficacy and complications after a minimal followup of 14 months. Bochove-Overgaauw DM, Schrier BP. CONCLUSIONS: The Argus adjustable male sling is a valuable adjunct in the treatment of all degrees of stress urinary incontinence. Complications are not uncommon but are mostly Clavien grade I to II. Patients report significantly improved continence and quality of life after treatment.*
- *J Urol. 2011 Aug;186(2):604-9. doi: 10.1016/j.juro.2011.03.131. Mid-term complications after placement of the male adjustable suburethral sling: a single center experience. Dalpiaz O, Knopf HJ, Orth S, Griese K, Aboulsorour S, Truss M. CONCLUSIONS: In our study cohort the Argus suburethral sling was associated with serious mechanical and infectious complications, and sparse functional results with negative impact on patient quality of life. Based on the results of this study significant changes are warranted in the sling system and in the implantation technique.*

Pertanto, per quanto presentato dal Richiedente e per quanto emerso in letteratura:

- non è possibile dare un parere esaustivo sul dispositivo in oggetto
- non è possibile delineare con certezza effectiveness e safety del dispositivo non disponendo di studi metodologicamente e qualitativamente adeguati
- non è possibile valutare un'efficacia comparativa di tali (o altre analoghe) sling vs. attuale gold standard di trattamento

Appaiono in tal senso condivisibili le conclusioni riportate nello studio: “*Continence and complications rates after male slings as primary surgery for post-prostatectomy incontinence: a systematic review. Arch Ital Urol Androl. 2013 Jun 24. Cerruto MA, D'Elia C, Artibani W.*”

CONCLUSIONS: Only a few number observational studies addressed review selection criteria. The pooled overall cure rates is high but there are no data concerning reliable pre- and postoperative prognostic factors affecting treatment failure and complications rates, thus it is not possible to have suitable criteria for a better patient selection. The statistically pooled results obtained should be interpreted with caution because of several limitations due to several study selection limitations: observational study design, few number of analysed studies, heterogeneity, lack of outcome definition and standardisation, between-study variability, high risk of bias.

Ed altrettanto quelle dello studio: “*The male sling for post-prostatectomy urinary incontinence: a review of contemporary sling designs and outcomes. BJU Int. 2012 Feb. Welk BK, Herschorn S.*” di cui si riporta abstract :

OBJECTIVE: To examine the outcomes and adverse events associated with novel male sling designs described in the last decade.

METHODS: A literature review was carried out using Medline, EmBase, Cochrane Registered Trials Database and the Center for Reviews and Dissemination Database.

RESULTS: Three principal slings are described in the literature. The bone-anchored sling has success rates of 40-88%, with some series having a mean follow-up of 36-48 months. It is associated with a mesh infection rate of 2-12%, which usually requires sling explantation. The retourethral transobturator sling has a success rate of 76-91% among three large case series with follow-ups of 12-27 months. There is a low reported explantation rate. The adjustable retropubic sling has a success rate of 72-79% with follow-ups of 26-45 months. Erosion (3-13%) and infection (3-11%) can lead to explantation.

CONCLUSIONS: Most male slings have a similar reported efficacy. Most case series define success as either dry or improved. True cure rates are lower. Mid- and long-term data are now available that indicate the male sling is a viable option for PPI. The use of male slings in severe UI, radiated patients, and non-radical prostatectomy patients is still unclear. Further study is needed to try and define criteria for the use of male slings, and to directly compare different procedures.

Conclusioni: Per quanto emerso si da parere negativo all'adozione del device in oggetto

Per la Commissione Regionale HTA:

Paolo Bruzzi

