

COMPARISON OF THE EFFICACY AND SAFETY OF POLYVINYLIDENE FLUORIDE AND POLYPROPYLENE TRANSOBTURATOR TAPES: MID-TERM RESULTS FROM A COHORT STUDY.

Hypothesis / aims of study

Polyvinylidene fluoride (PVDF) has been proposed as an alternative to polypropylene (PP) for its use in suburethral slings. Owing to its biocompatibility and biomechanical properties it has been hypothesized that PVDF slings could be associated with less mesh-related complications such as erosions and urinary obstructions [1,2]. The aim of the present study is to describe and compare the effectiveness and complication rates of PVDF and PP transobturator suburethral tapes (TOT) in the mid to long-term follow-up.

Study design, materials and methods

A prospective cohort study was performed on women treated with a TOT procedure at a single institution between 2009 and 2013. Women with pure stress urinary incontinence or stress-predominant mixed urinary incontinence were eligible. Twenty-three women were operated on with a PVDF sling. A comparison group was randomly selected among all women treated with a PP sling during the same period in a 1:4 ratio (n=92). Postoperative follow-up was performed at six and twelve months and yearly thereafter. Outcomes were classified as cured, improved or failed defined by combined objective and subjective criteria. Failure incidence was analysed by the Kaplan-Meier survival functions and by a multivariate Cox regression model. Complications were also reported.

Results

Both groups were similar regarding their initial characteristics, such as age, body mass index, previous gynaecological surgery and associated prolapse surgery. The median follow-up was 51.5 months in the PP group and 55.6 months in the PVDF group. The survival functions showed a higher incidence of failures in the PP group, mostly because obstructive symptoms and de novo urge-incontinence (Figure). The survival estimates showed that the likelihood to be cured or improved is of 90.2%, 82.9% and 78.2% in the PP group and of 95.7%, 95.7% and 95.7% in the PVDF group at 1, 3 and 5 years of follow-up respectively, although these differences were not statistically significant (p=0.089). No differences in the incidence of failure were found (adjusted HR of failure of PP vs. PVDF = 6.00; 95% CI=0.79 – 45.40). Complication rates do not differ either between the two groups (Table). More cases of voiding dysfunction were observed in the PP group. Sling division was needed in eight women, all in the PP group. In six cases it was performed because of severe urge-incontinence along with an obstructive pattern that did not improve with medical treatment. In the remaining two cases it was performed because of severe obstructive symptoms. Of them, six women (75%) were regarded as cured or improved after the sling division.

Interpretation of results

In the present series, PVDF has shown a similar effectiveness and safety than PP. A higher number of obstructive events were observed in the PP group, although those differences were not statistically significant. This observation should be interpreted with caution because of the risk of bias owing to the design of the study.

Concluding message

There is a potential field of improvement with the TOT procedure by finding the best material for the slings. The potential benefits of PVDF over PP used in suburethral slings should be further evaluated.

Figure. Kaplan-Meier survival functions for the effectiveness of the slings. The steps indicate failures.

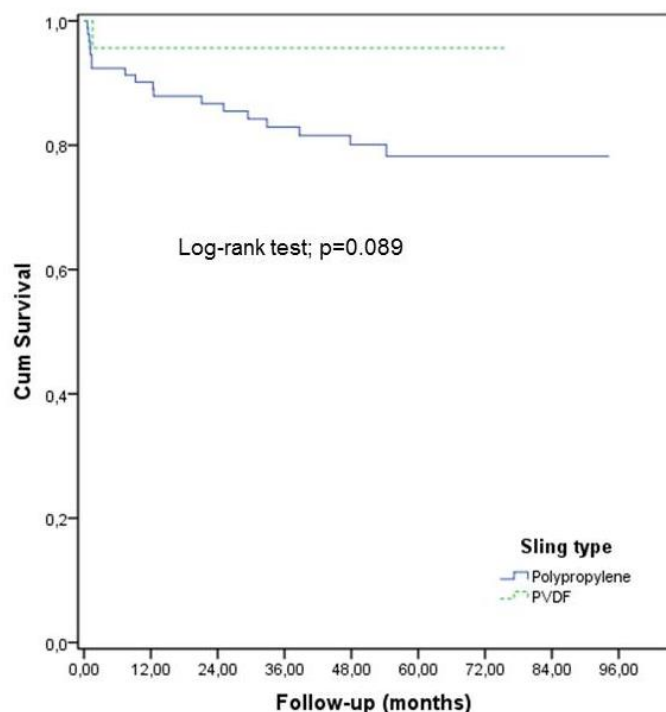


Table. Complications

Early postoperative	22 (23.9%)	3 (13.0%)	0.258
Cystitis†	2	0	
Temporary elevated PVRV	22	3	
Voiding difficulty requiring ISC	4	0	
Late postoperative	11 (11.5%)	1 (4.3%)	0.286
Repeated cystitis	7	1	
Urinary obstruction	4	0	
Persistent groin pain	1	0	
Tape erosion	0	0	
De novo urgency	16 (17.4%)	1 (4.3%)	0.115
Sling division	8 (8.7%)	0 (0%)	0.143

PVRV: Post-void residual urine volume. ISC: Intermittent self-catheterization.

References

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Disclosures

Funding: NONE **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Hospital Universitari Vall d'Hebron Clinical Research Ethics Committee **Helsinki:** Yes **Informed Consent:** Yes