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A comparative study between 2 different grafts used as patches after plaque incision and inflatable penile prosthesis implantation for end-stage peyronie's disease

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ABSTRACT

Background: Although many grafts have been used for plaque incision with grafting (PIG) and penile prosthesis(PP) implantation, there is no evidence that favors 1 specific graft over another.

Aim: To compare fibrin-coated collagen fleece (TachoSil; Baxter International, Deerfield, IL, USA) with porcine small intestinal submucosa (SIS; Cook Biotech, West Lafayette, IN, USA) as grafts.

Methods: From January 2007 to January 2015, 60 non-randomized consecutive patients affected by end-stage

Peyronie disease underwent PIG and PP implantation (AMS 700CX; Boston Scientific, Marlborough, MA, USA). All patients underwent preoperative penile dynamic duplex ultrasound. All procedures were performed by the same surgeon. Patients were divided in 2 different groups according to the graft used to cover the albuginea defect. SIS was used for grafting in 34 patients (group A) and TachoSil was used in 26 patients (group B).

Outcomes: Overall hospital stay, operative time, 5-point Likert hematoma scale, visual analog scale, incidence of postoperative complications, and PP mechanical failure were selected as outcome measures. Functional outcomes were assessed through validated questionnaires (International Index of Erectile Function, Erectile Dysfunction Inventory of Treatment Satisfaction, and Sexual Encounter Profile questions 2 and 3) preoperatively and 3, 6, and 12 months postoperatively.

Results: The patients' median age was 63 years. No statistically significant differences were detected between groups for age and type and degree of curvature. Average follow-up was 35 months. No major intraoperative complications were reported. The average operative time was 145 minutes for group A and 120 minutes for group B. No statistically significant differences between groups were detected for postoperative complications. Only 3 patients developed a major postoperative complication requiring a 2nd surgical intervention: 1 patient in group A for

mechanic failure and 1 patient in group A and 1 in group B for inflatable PP infection. Multivariate statistical analysis showed no significant difference for all variables analyzed between the 2 groups, except for operative time, which was significantly shorter for group B.

Clinical Implications: TachoSil could represent a valuable option for grafting, considering its advantages in operative time and cost compared with SIS.

Strengths and Limitations: Long-term follow-up represents a strength factor. Main limitations are the nonrandomized nature of the study and the small number of patients.

Conclusions: TachoSil seems to represent an effective solution for grafting after PIG and PP implantation. However, additional studies are warranted to confirm our results.

INTRODUCTION

Peyronie's Disease (PD) is a wound healing disorder affecting the tunica albuginea of the corpora cavernosa.[1] Although the intralesional administration of collagenase of clostridium histolyticum (CCH) has recently shown its efficacy in reducing the degree of curvature in a selected group of patients [2], to date surgery represents the gold standard treatment.[1]

Penile prosthesis (PP) implantation is indicated in patients with medically refractory ED or in the presence of a concomitant ED and complex penile deformity.[3] Although curvatures $<20^\circ$ are deemed not to interfere with penetrative sex, in case of a significant residual curvature after PP implantation, an additional modelling procedure is able to correct most of penile deformities.[4,5] On the other hand, in case of complex penile deformities, patients are better served with a simultaneous PP implantation and plaque incision/excision and grafting (PIG).[6] Even though a vast variety of grafts have been proposed to cover the albuginea defect, strong scientific evidences supporting a specific graft over the others are still missing. [6,7]

Our aim is to compare the outcomes of fibrin-coated collagen fleece (Tachosil™) and porcine small intestinal submucosa (SIS™) as grafts to cover the albuginea defect in patients who underwent PIG and PP implantation for PD and ED.

MATERIALS AND METHODS

Study setting and patients

The clinical notes of 60 consecutive patients who underwent PP implantation and PIG for end-stage PD between January 2007 and January 2015 were retrospectively reviewed.

The inclusion criteria were: PD in chronic phase, ED and complex penile deformity (curvature $>60^\circ$, penile shortening, or calcified plaque). All patients underwent a preoperative penile

dynamic duplex ultrasound to assess the deformity, the degree of ED and the plaque characteristics. All the procedures were carried out by the same senior surgeon.

In all cases a 3-pieces inflatable PP (AMS 700 CX®-Boston Scientific) was implanted. Patients were then subdivided in 2 different groups according to the graft used to cover the albugineal defect. In group A, SIS (Cook) was used as graft. Whereas, Tachosil (Baxter Healthcare Corporation) was used in group B.

Main outcome measures

Overall hospital stay, operative time, a 5-point Likert's haematoma scale, VAS scale, the incidence of postoperative complications and PP mechanical failure were selected as outcome measures. A haematoma >1 according to the Likert's scale, recurrent penile curvature (>20°), PP infection or PP mechanical failure were considered as postoperative complications. Functional outcomes were assessed through validated questionnaires (IIEF, EDITS, SEP-2 and SEP-3) preoperatively and 3,6 and 12 months postoperatively.[5]

Statistics

STATA statistical software package (v.14) was used for the analysis (p value <0.05). Non-parametric tests, and linear regression (ANCOVA) with relevant covariates and a variable for group was conducted.

Surgical Technique

A standardized surgical procedure was carried out in all patients.

Once the penile shaft was completely degloved through a subcoronal incision, the neurovascular bundle was extensively mobilized through two para-urethral incisions to gain the maximum length as possible. After the induction of an artificial erection, the point of maximum curvature on the convex side of the shaft was identified and marked on the albuginea. A double Y relaxing albugineal incision was performed. The size of the albugineal defect was measured and the graft shaped accordingly. Then PP was inserted through a traditional penoscrotal incision. The SIS graft, oversized by 30%, was sutured to the edges of the tunical defect with a 4-0 PDS running suture (*figure 1a*). In group B instead, the Tachosil, that not need to be sutured, was oversized to obtain 1 cm overlapping of the patch's edges on the tunica albuginea. (*figure 1b*). A bilateral closure of Buck's fascia was performed for haemostatic purposes. An indwelling urinary catheter, a suction drain and a compressive dressing were left in place for 24 hours. Patients were discharged on oral antibiotics for 1 week. The cylinders were left semi-inflated for 2 weeks and deflated in clinic afterwards. Patients were advised to start cycling the device daily. Sexual activity was encouraged 6 weeks postoperatively.

RESULTS:

Patients Characteristics

Patients characteristics were summarized in *Table 1*. No statistically significant differences were detected in-between groups.

Surgical Outcomes

The surgical outcomes were summarized in *table 2*. The procedure resulted to be significantly shorter in group B. No significant differences were reported for both intraoperative and postoperative complications.

Functional Outcomes

Functional outcomes were summarized in *Table 3a-3b*. No significant differences in-between groups were detected in postoperative IIEF. None of the covariates analysed by a linear regression influenced the results (ANCOVA F value=1.8).

DISCUSSION

A simultaneous PIG and PP implantation represents a valuable option to address complex PD deformities. [6] However, an ideal graft has not been identified yet.[6,7] Graft materials can be classified in: synthetic, autologous and extracellular matrix (ECM).[8,9] Each material has its own advantages and drawbacks in terms of availability, antigenicity and cost effectiveness. Contrary to the other categories, ECM are not associated with donor site morbidity, limited availability and immunogenicity.[7,9] ECM tissues are acellular and they induce a minimal antigenic reaction. They act as bio-scaffolds being replaced by surrounding tissues within a few months. [7] Additionally, Tachosil has self-adhesive properties compared to SIS and this feature translates in a significant reduction of the operative time.[9] Considering that local fibrosis and graft retraction are among the most commonly reported undesirable effects of ECM, to minimize the risk of contracture, it is recommended to oversize by 30% the SIS graft compared to the defect. On the other hand, Tachosil should overlap the albugineal defect of at least 5 mm.[10] Finally, the cost of Tachosil is lower compared to SIS in our institution.

Our study demonstrated that Tachosil may represent a reliable and cost-effective option. Surgical and functional outcomes resulted comparable to the SIS. Indeed, Tachosil® showed a clear advantage in reducing operative time as well as a reduced cost.

Conclusions are limited by the non-randomized nature of our study, the lack of validated PD questionnaires and the small number of patients in our series. Prospective and randomized studies are warranted to confirm our preliminary results.

Conclusion

Tachosil® may represent an effective solution to cover the albugineal defect after PIG and PP implantation.

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