

SYSTEMIC AND LOCAL INFLAMMATORY RESPONSE IN COLLAGEN VS. POLYPROPYLENE TAPES FOR STRESS URINARY INCONTINENCE: IS THERE ANY DIFFERENCE?

Hypothesis / aims of study

In the last years the use of vaginal slings for treatment of female stress urinary incontinence (UI) has evolved in the search for new materials for tapes. The recent collagen tape seems to be promising, as animal studies show that this material reduces host local inflammatory response, declining complications usually associated to polypropylene tapes, as fibrosis or erosion.

The aim of this study was to evaluate immediate systemic and late local inflammatory response to polypropylene macroporous monofilament vs. porcine acellular collagen cross-linked trans-obturador tapes.

Study design, materials and methods

Assuming that marked inflammatory response occurs in 70% of patients after polypropylene tape and that we expected to obtain a two-third reduction in that response by using a porcine acellular collagen tape, and considering a significance level of 95% and statistic power of 80%, we needed twenty-one patients in each group, in a total of 42 patients.

Forty-two patients with stress UI were blindly randomized for surgical treatment with polypropylene (PT) or porcine collagen (CT) trans-obturador tape.

All patients had blood samples for C Reactive Protein (CRP) and white blood count (WBC) in the previous day and 24 hours after surgery. A local biopsy (3cm, right or left, para-urethral parallel to tape in obturator foramen direction) was performed 90 days after surgery and analysed for local inflammatory markers (polymorphonuclear cells, mononuclear cells, giant cells and neovascularization) and local collagen reaction (collagen amount, composition and organization). Each parameter was considered individually and in combined scores.

Median values of CRP, WBC and local inflammation and collagen scores were computed. Paired Mann-Whitney test was used to compare acute changes in systemic inflammatory markers and independent samples Mann-Whitney test to compare local inflammation and collagen scores between groups.

Results

No differences were found in age between groups. Median CRP levels previous to surgery were higher in PT group (0.3mg/dL vs. 0.4mg/dL, $p=0.01$). After surgery no differences were seen between median CRP levels (1.5mg/dL vs. 1.4mg/dL, $p=0.64$). Median CRP rise was 1.2mg/dL in CT group vs. 0.8mg/dL in PT group ($p=0.26$). WBC previous to surgery were non significantly higher in PT group ($6.88 \times 10^3/\mu\text{L}$ vs. $7.86 \times 10^3/\mu\text{L}$, $p=0.09$). Median increase in WBC was $0.84 \times 10^3/\mu\text{L}$ in collagen group and $-0.06 \times 10^3/\mu\text{L}$ in polypropylene group ($p=0.06$).

One patient refused local biopsy in pos-operative follow up and in one case biopsy did not reveal sufficient material for analysis, so 40 cases were left to statistical analysis.

Median score for local mononuclear response was higher in PT group (2.0 vs. 1.0, $p=0.39$). Median individual scores for neovascularization and collagen organization, composition and amount were not different between groups. Combined score for local inflammation was non significantly higher in PT group (0.32 vs. 0.13, $p=0.30$) and collagen combined score was similar in both groups (6.5 in PT group vs. 6.4 in CT group, $p=0.70$).

Interpretation of results

Levels of systemic inflammatory markers were higher in polypropylene group before surgery. No significant change was observed in CRP levels, and a trend to higher rise in WBC was found in collagen group. Systemic inflammatory response was similar in both groups, although collagen group revealed a tendency to a more marked response.

Local inflammatory response at 90 days, although not statistically significant, was higher in polypropylene group, especially mononuclear response, but no differences were found in local collagen response between both groups.

Concluding message

These results seem to be in agreement with recent studies in animal models, which show that even though systemic inflammatory response to porcine acellular collagen tapes is more intense, local inflammatory response is less significant, allowing a more *natural healing* and lower complication rate. A more favorable collagen host response wasn't proven by this study.

A larger sample and a longer follow-up of patients are needed to completely understand tapes behavior and their long term implications.

Specify source of funding or grant	None
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Comissão de Ética da Maternidade Júlio Dinis
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes