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PROLENE SOFT((GYNECARE) MESH FOR PELVIC ORGAN PROLAPSE SURGICAL TREATMENT: A PROSPECTIVE STUDY OF 264 PATIENTS.

Hypothesis / aims of study

The new Prolene Soft® (Gynecare) mesh is now available to augment surgery for pelvic organ prolapse. To date, little data is available on its effectiveness and possible complications, often related to mesh intolerance. The aim of this study was to state its efficiency and complications (granuloma formation, vaginal erosion and mesh shrinkage) at three months of follow up in five centers of gynaecologic surgery.

Study design, materials and methods

Since november 2002, 264 patients were include in a prospective multicentric study. All of them did benefit from a vaginal cure of genital prolapse by the use of Prolene Soft® mesh. Surgical protocol was standardized: Cystocele repair used anterior mesh anchored transversally between arcus tendineus with two arms each side through obturator foramen. Rectocele repair used posterior mesh anchored transversally between sacro-spinal ligaments. The mean age was 65.8 years old. 87.8% were menopausal. 27.3% had previous hysterectomy, 16.2% previous prolapse surgery and 10.8% previous stress urinary incontinence surgery. Simultaneous hysterectomy was performed in 47.1% patients. Simultaneous stress urinary incontinence surgery was performed in 41.4% patients, with TOT in 15.7% cases.

Organ prolapse recurrence, granuloma formation, vaginal erosion and clinically estimated mesh shrinkage incidences were noticed, during a mean of 3 months after surgery (Table 1).

Results

The results are summarized in table 2. Recurrent organ prolapse incidence ranged between 0% and 8% (mean of 4.2%). 95.8% of prolapse were considered as cured. De novo stress urinary incontinence incidence ranged between 0% and 11.8% (mean of 5%). Granuloma formation incidence ranged between 0% and 8.47% (mean of 4.17%). Vaginal erosion incidence ranged between 0% and 33.33% (mean of 16.67%). Mesh shrinkage incidence ranged between 7.69% and 35.59% (mean of 16.67%).

Interpretation of results

The results of this multicentric study had shown really satisfying functional results, with very low rates of recurrent organ prolapse and de novo stress urinary incontinence with a mean of only 4.2% and 5% respectively. In addition, variations concerning anatomical results are small between surgeons confirming that the technique is reproducible.

In opposite, large variation between surgeons in incidence of granuloma formation, vaginal erosion and mesh shrinkage is noticed in the study. Recent improvements in surgery consisting in short incisions of vagina seem to decrease occurrence of such complications. This hypothesis is confirmed by those significant variations in complication rates related to variations in the surgeon's technique.

Concluding message

Regarding functional results, the use of Prolene soft® (Gynecare) is a great improvement in organ prolapse surgery: this study confirm its superiority to the traditional techniques using autologous tissues. A great challenge is research in order to reduce complication rates: for exemple, new surgical procedures could decrease significantly granuloma formation, vaginal erosion and mesh shrinkage incidences.

Table 1: Operative data in each center (A,B,C,D or E).

	A	B	C	D	E	Total
Patients (n =)	51	59	30	39	85	264
Mean age (years)	64.5	69.2	69.9	65.2	63.1	65.8
Menopausal	95.2%	88.5%	87.1%	84.6%	83.5%	87.8%
Previous hysterectomy	17.7%	36.1%	29%	18%	31.8%	27.3%
Previous prolapse surgery	12.9%	24.6%	3.2%	5%	22.4%	16.2%
Previous urinary stress incontinence surgery	11.3%	19.7%	0%	2.5%	11.8%	10.8%
Simultaneous hysterectomy	43.5	23%	77.4%	51.2%	54.1	47.1%
Simultaneous urinary stress incontinence surgery	45.2%	55.7%	3.2%	66.6%	30.6%	41.4%
TOT	0%	29.4%	0%	10.3%	4.7%	15.7%

Table 2: Post-operative complication rates in each center (A,B,C,D or E).

	A	B	C	D	E	Total
Patients (n =)	51	59	30	39	85	264
Follow-up (Months)	3	3	4.96	3	3	3.2
Organ prolapse recurrence (%)	2,00%	5,10%	8,00%	0,00%	5.9%	4.2%
De novo urinary stress incontinence (%)	2,00%	0,00%	8,00%	0,00%	11.8%	5,00%
Granuloma formation (%)	5,88%	8,47%	6,67%	0,00%	1,18%	4,17%
Vaginal erosions (%)	17,65%	20,34%	33,33%	0,00%	15,29%	16,67%
Mesh shrinkage (%)	13,73%	35,59%	20,00%	7,69%	8,24%	16,67%