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LAPAROSCOPIC SACROCOLPOPEXY USING POLYPROPYLENE OR PORCINE SMALL INTESTINE MUCOSA DERIVED COLLAGEN MATRIX(SURGISIS): A CONTROLLED STUDY.

Aims of Study

Vaginal vault prolapse can be successfully cured by sacrocolpopexy but this procedure requires an implant to fix the vault to the sacrum. Excellent cure rates with synthetic implants have been obtained, but there is an inherent risk for infection or erosion. Typically erosion rates of 2.7 % for completely abdominal procedures have been reported, which rise up to >30 % when the vagina is opened (Visco, 2001). Recently collagen matrix derived from porcine small intestinal mucosa (SIS, Cook) was introduced as an alternative material to synthetic fabrics in fascial repairs. It is a non-cross linked product which is completely remodelled by the recipient within three months, theoretically offering ideal biocompatibility. Therefore patients presenting with local infection may be treated conservatively and the material may in general be less prone to erosion. This would mean that the surgeon may be less reluctant to open the vagina at the time of sacrocolpopexy. There are however no clinical data available on efficacy with this novel product. We conducted a clinical study in patients requiring sacrocolpopexy and compared outcomes with a similar number of historical controls.

Methods

In 25 consecutive patients scheduled for laparoscopic sacrocolpopexy we used SIS. They were compared to 25 identical procedures by the same surgeon, were polypropylene mesh (PR) was used. These controls were actually the 25 consecutive patients preceding the 25 cases, acting as unselected historical controls. In our hospital, sacrocolpopexy is since 5 years primarily done by laparoscopy using a four port technique. We use at least 9 Ethibond (Johnson & Johnson: J&J) sutures (3 anterior, 3 to the vault and 3 posterior) to fix the implant to the vault, and more when dissection is larger or associated surgery is done. The vault is then suspended tension free by stapling the implant with an EMS endostapler (J&J) to the upper presacral area. We do *not* associate by definition a Burch type colposuspension, and traditionally we tried to avoid to open the vagina, so also in the PR group. In contrast, in SIS patients with a large cystocele, we repaired the latter vaginally prior to the abdominal part of the operation. All operations were performed under prophylactic antibiotics (single shot cefazolin 2000 mg & metronidazole 1500 mg). Mean outcome measures were operation time, blood loss, postoperative febrile morbidity and signs of infection, intra- or postoperative complications, anatomical and subjective functional result. All patients were assessed 12 weeks and 6 months after the operation and thereafter yearly. Since the study was concluded only 6 months ago, 40% of the SIS-patients have not completed their one year follow up.

Results

In the SIS group there were more associated vaginal prolapse procedures (3 cystoceles – Table), while in the PR group the vaginal procedures were limited to a TVT (table). One patient had a large vaginal erosion defect prior to the surgery, the lesion being excised and sutured primarily (SIS group). Operation time was over 170 min, but varied greatly according to the dissection required and associated procedures such as rectopexy. In both groups there was one conversion because of extensive adhesions. There were no intra-operative complications, except for one bladder perforation. We decided at that time to deal with this by primary closure through laparotomy (PR group). No transfusions were given and measured blood loss (haemoglobin drop) was comparable in both groups. There was one severe postoperative complication, eventually even with failure. This patient from the SIS group was readmitted with bowel obstruction. At laparotomy a bowel loop was found entrapped retro-peritoneally, between two sutures covering the implant area to the right of the sigmoid. The surgeon did release several vault suspension sutures at that time. She recovered well from this re-intervention but developed recurrent vault prolapse only 2 weeks later, milder than initially and not asking for repair (so far). In the SIS group, there were two mild infections in

the operative field at the level of the vaginal vault. The first patient had low grade fever 8 weeks postoperatively and on examination we saw a suture through the vagina. This and another nearby vaginal suture were removed to drain a collection. She also had antibiotics per os and recovered completely without recurrence. The second patient had mild signs of local infection without collection 6 months postoperatively, which were treated with antibiotics per os. In the PR-group there was one patient with an infection and erosion, failing to respond to conservative therapy and later successfully cured by trimming the eroded area by vaginal route.

Table:

	Polypropylene group	SIS group
Age (yrs, mean +/- SD)	61.8 +/- 9.3	67.1 +/- 10.3 **
Associated surgery: vagina opened laparoscopic rectopexy	 1 (TVT) 4	 3 cystocoele repairs, 1 defect 1
conversions	2	1
Bloodloss (mL)	211 +/- 140	44 +/- 26 **
Haemoglobin drop (g%)	- 2.28 +/- 0.92	-1.45 +/- 0.50
Skin to skin time (min)	205.9 +/- 42	169 +/- 43
Subjective cure	25/25	25/25*
Anatomical failure	0/25	1/25*
Intervention for *de novo* stress incontinence	0/25	0/25
Follow-up (mean+/-SD, months) <12 months (%)	36 +/- 12 100 %	12.88 +/- 3.2 ** 40 %
* one obvious anatomical recurrence; ** significant (P<0.05)		

Conclusions

Laparoscopic sacrocolpopexy is a lengthy operation and associated with low bloodloss and perioperative morbidity. The number and nature of associated vaginal procedures were different between the two groups as well as the age of the patients in the SIS group. This may reflect a bias in the selection of patients. Two infectious complications occurred in the SIS group; in both the vagina was opened at the time of the operation. They could however be treated conservatively, while in the PR group one infection remotely in time, and later erosion failed conservative therapy and required re-intervention. There was one recurrence in the SIS group. It is possible that it is not directly related to the material used. The patient needed emergency laparotomy because of bowel entrapment, at what time suspension sutures were released. No other vault prolapse recurrences were seen in neither groups. For the SIS group the follow up period was shorter, however for all patients longer than the 3 months it reportedly takes to remodel the product.