664

Mašata J[1], Martan A[1], Svabík K[1], Zvara K[2], Hubka P[1], Jedlickova A[3], Poislova M[3], El Haddad R[1]
1. *Dept. of Obst. Gyn., 1st Faculty of Medicine, Charles University Prague,* ***2.*** *Euromise Centre, AV and Charles University, Prague,* ***3.*** *Institute of Clinical Chemistry and Laboratory Medicine, Microbiology and Antibiotic Centre, 1st Faculty of Medicine, Charles University Prague*

EARLY POSTOPERATIVE INFECTIONS – COMPARISON BETWEEN PATIENTS USING SYNTHETIC MESH AND THOSE UNDERGOING TRADITIONAL PELVIC RECONSTRUCTIVE SURGICAL PROCEDURES.

Hypothesis / aims of study

Pelvic organ prolapse is a common problem affecting up to 50% of parous women Not all of them are symptomatic. For a long time traditional pelvic reconstruction surgical procedures were the only ones available. The long-term efficiency of those procedures varied, and re-operation rates of nearly 30% have been. This may be one of the reasons why synthetic meshes were introduced to pelvic reconstructive surgery. However, these new surgical procedure have brought with them new mesh-related complications such as erosion, pain syndrome, etc. Some of these complications - erosion, shrinkage and abnormal pain - can result from abnormal postoperative healing due to surgical site infection.

The aim of our study was to compare the incidence of infectious complications after reconstructive surgery using synthetic macro-porous polypropylene mesh and after traditional vaginal wall repair.

Study design, materials and methods

In this prospective observational study 99 women with symptomatic pelvic organ prolapse stage II or higher, using Pelvic Organ prolapse Quantitative (POP-Q), were included. All of them underwent surgical procedures between January 2007 and December 2008. The women were divided into two subgroups according to the type of procedure: 55 women underwent traditional vaginal wall repair (TR group) and 44 repair using mesh material (M group). Traditional repair was taken to include the mentioned anterior colporrhaphy with fascial plication, posterior repair with levator plication and - for patients with apical defect - Amreich-Richter procedure was added. Commercially available kits were used for mesh reconstruction.

One day before surgery a detailed history was taken, focusing especially on factors increasing postoperative infections (host-related factors such as poor nutrition, obesity, diabetes, impaired immunocompetence, and others). Pelvic examination was performed, and the character of the vaginal discharge was assessed (i.e. colour, smell, with or without addition of 10% KOH).

Measurement of vaginal pH was made with colour pH strip paper ph range 4.0 – 7.0 (Merck, Germany) using vaginal secretions obtained from the lateral pelvic wall; a sample of vaginal fluid was obtained from the upper lateral vaginal vault and spread onto two glass slides (for Gram and Giemsa stain) and after fixation sent to the laboratory for microscopic examination to ascertain the presence of asymptomatic infection, especially bacterial vaginosis, aerobic vaginitis, atrophic vaginitis and Trichomonas vaginalis infection. The presence of bacterial vaginosis (BV) was evaluated based on Nugent's criteria, while the presence of aerobic vaginitis was assessed using Donders' criteria.

Hemoglobin level and leucocyte count was also assessed one day before surgery.

Preoperatively all patients received prophylactic antibiotic Ampicilin + Sulbactam 1.5 g. i.v. (Unasyn, Pfizer, CR) or Clindamycine 900 mg (Dalacin Pfizer, CR) for patients allergic to penicilines, and a second dose 6 hours after the surgery; for Clindamycine the second dose was reduced to 600 mg. If there was any suspicion of infection further use of antibiotics was not restricted, and indication was left to the attending physician. Incidence of further antibiotic use was also compared in both groups.

After the procedure systemic inflammatory response parameters were monitored.

Infections with a systemic inflammatory response were monitored

Results

The two groups do not differ in basic demographic characteristics. Patients in the mesh group had a higher proportion of hysterectomies in their history (63.6% compared with 41.8%).

Neither do the groups differ in any other preoperative characteristics; e.g. presence of internal diseases, hypertension, diabetes type II, vaginal hormonal status, vaginal pH, presence of asymptomatic vaginal infection and blood count.

In the M group 9 patients underwent total prolift, while the rest had anterior or posterior prolift. In the traditional repair group 35 patients underwent anterior and posterior vaginal wall repair, the rest of the patients had one of these procedures; for ten patients the Amreich-Richter procedure was added. There is also no difference between the groups in terms of presence of concomitant hysterectomy (TR 19/34.5%, M 11/25%) and mean operation time. However, in the mesh group higher blood loss was noted based on post-operative haemoglobin drop. None of the patients required blood transfusion.

After reconstructive surgery using mesh material patients have a higher risk in the postoperative period of having febrile morbidity than patients who underwent traditional repair, OR= 3, RR=2.34, p=0.031 (Tab. 1). In the mesh group there was also a higher incidence of combination febrile morbidity with elevated CRP›50mg/L; OR=2.84, RR=2.32, p=0.046. CRP increase over 30 mg/L was more frequently present in the mesh group; p=0.005 (Tab. 1), but no differences in mean CRP levels were noted. In one case after the traditional procedure vaginal wound infection was noted; in contrast there were 5 cases after mesh repair. (OR = 6.80, RR = 6.25, CI = 0.76 – 51.56, p = 0.085). Incidence of further antibiotic use was also higher in this group, the difference is clinically significant but not statistically (Tab. 1). There was no difference in the occurrence of postoperative urinary tract infection. All infections were mild or moderate; in none of the patients was abscess formation or severe sepsis observed, and no readmission was noted.

Tab. 1 Comparison of post-operative infectious complication

	TR n/%	M n/%	p value*	OR	RR	CI 95%	
CRP›30	33/62.3	39/88.6	**0.005**		4.65	1.42	1.13-1.80

ATB	14/25.5	20/45.5	0.055	2.42	1.79	1.02-3.11	
FM	8/14.5	15/34.1	**0.031**	3.00	2.34	1.09-5.02	
FM+CRP›50	7/12.7	13/29.5	**0.046**	2.84	2.32	1.01-5.32	
Urine	6/10.9	6/13.6	0.762		1.29	1.25	0.43-3.61

*Fisher exact test
TR - traditional vaginal wall repair group, n= 55
M - vaginal wall repair using mesh material group, n=44
CRP – C- reactive protein
ATB - further antibiotic use
FM - febrile morbidity
FM – Febrile morbidity plus elevated CRP
Urine – positive urine culture (presence of colony - forming units ≥10^5)
OR- odds ratio
RR – relative risk
CI – confidence interval

Interpretation of results

There is no evidence of comparison of early infectious complication in patient using a mesh or those after traditional pelvic reconstructive surgery.

Because our study was not randomized, we were looking at all differences in factors which can increase the rate of postoperative infectious complications. The two groups do not differ in age, BMI, parity, presence of internal diseases (DM II, hypertension) or previous reconstructive surgery. The only difference was in the number in patients with hysterectomies in their history (there was a higher prevalence in patient who underwent mesh procedures)..

Available studies mainly deal with those mesh-related infections which occur later after surgery. The incidence of those infections ranged from 0% to 8%. Various Gram positive and Gram negative aerobic and anaerobic bacteria have been identified in this complication. Peri-operative bacterial colonisation and abnormal postoperative healing due to infection also may be one of the most important factors in the development of other mesh-related complications.

Concluding message

Reconstructive procedures using synthetic mesh are accompanied by higher incidence of early post-operative infectious complications.

Specify source of funding or grant	**This work was supported by IGA MZ CR, grant number NS10586-3/2009**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics committee of the General Teaching Hospital in Prague**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**