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EFFECTS OF RAZ -4 –DEFECT REPAIR AS SURGICAL TREATMENT OF CYSTOCELE AND/OR URINARY STRESS INCONTINENCE; LONG TERM RESULTS OF A LARGE COHORT STUDY.

Hypothesis / aims of study

Cystocele repair – especially anterior colporhaphy- with native tissues is known to have a high recurrence rate. Despite this knowledge anterior colporrhaphy is still being the most frequent treatment for anterior vaginal wall prolaps. Currently mesh implantation is being studied in an attempt to reduce the number of recurrences without compromising the functional outcome. In the USA and also in some centres the 4 defect repair as proposed by S. Raz has been performed for many years. In this repair native tissue, permanent sutures and a polyglactin mesh are used to repair 4 defects: urethral hypermobility, weakness of the cardinal and sacro-uterine ligaments, lateral support and the central cystocele.

Since many urologists and gynaecologists confuse this 4-defect-repair with the Raz-Pereyra colposuspension, this anterior wall repair has encountered a lot of resistance in the scientific community.

This retrospective study was performed to assess the functional outcome of the Raz-4-defect repair in a cohort of 443 consecutive patients.

Study design, materials and methods

In this retrospective study we included 443 patients undergoing Raz 4-defect-repair between 1999 and 2005. All procedures were performed as described by the group of Raz.[1]

Patient characteristics, i.e. age, parity, body mass index, previous gynaecologic surgery, and data about the surgical technique, concomitant surgical procedures, operating time, estimated blood loss, peri- and postoperative complications were collected from the hospital record files, and registered on standardised clinical record forms. We also registered whether patients had returned because of persistent or recurrent pelvic floor dysfunction and whether additional treatment had been given.

All 453 patients were send a validated questionnaire consisting of the following validated questionnaires: [1] urogenital distress inventory (UDI) to measure presence and experienced bother of prolapse and micturition symptoms, [2] defecation distress inventory (DDI) to measure presence and experienced bother of defecation symptoms, [3] impact incontinence questionnaire (IIQ) to measure experienced limitations due to pelvic floor symptoms and [4] short form 36 to measure generic quality of life. Five standardized questions to measure sexual wellbeing were added to this questionnaire.

Descriptive analysis of the data was performed using SPSS 14.0.

Results

Of the 443 patients, 8 patients had deceased, 6 patients relocated to an unknown address, 20 patients had difficulties to understand the questionnaire due to age and 4 patients could not answer the questions due to insufficient understanding of the language. Of the remaining 405 patients, 229 (response rate 52%) responded who were included in the further analysis.

The mean follow-up time was 47 months (range 10 – 93 months). The mean age of the responding patients was 70 years (range 29 to 93 years) when responding the questionnaire. Thirty-six (16%) patients had undergone previous prolapse surgery. A stage 3 or 4 cystocele was present in 161 (71%) of the patients before surgery. The most predominant symptom was feeling of prolapse in 175 (76%), stress incontinence in 33 (14%) and a variety other symptoms in 21 (9%).

In patients only undergoing Raz suspension, the average surgery time was 70 minutes (sd 10 minutes), average amount of blood loss 104 mL (sd 99 mL) and hospital stay 8 days (sd 2.4). Concomitant vaginal hysterectomy was performed in 121 (53%) patients, posterior vaginal wall repair in 45 (20%) patients and sacrospinous ligaments fixation in 7 (3%) of the patients. Half of the procedures was done by the urologist, the other half by the gynaecologist.

Complications during surgery occurred in 7 (3%) patients (1 bladder lesion, 3 bleedings > 500 mL), 1 ischemic hart disease, 1 ventricular fibrillation) and post-operative in 79 (34%) patients mainly consisting of bladder retention which occurred in 53 (23%) of the patients. Two (1%) required re-intervention due to bleeding, other postoperative complications where less serious.

At the first follow-up visit six weeks after surgery none of the patients had a stage 2 or more anterior or middle compartment prolapse. Four (2%) patients had a stage 2 or more posterior compartment prolapse. Prolapse symptoms were reported by 6 (3%) patients and stress incontinence by 21 (12%) patients.

During the follow-up period 76 (33%) patients visited the hospital because of pelvic floor dysfunction. Forty-one (18%) patients underwent repeated surgery. Laparoscopic sacro-colpopexy was performed in 24 (10%), laparoscopic rectopexy in 5 (2%), TVT in 7 (3%) and revision of the initial Raz procedure in 5 (2%).

Pelvic floor symptoms as measured by UDI and DDI after surgery can be found in the Table.

Symptom	missing	symptom present		bothered by symptom	
Prolapse symptoms					
Feeling or prolapse	11	47	(22)	26	(12)
Prolapse seen	15	28	(13)	19	(9)
Micturition symptoms					
Stress incontinence	12	100	(44)	23	(11)
Urge incontinence	15	89	(39)	39	(18)
Urgency	14	92	(40)	43	(20)
Frequency	9	89	(40)	40	(18)
Difficulty emptying bladder	12	85	(39)	27	(12)
Feeling of incomplete evacuation	11	88	(40)	23	(11)
Defecation symptoms					
Stool frequency < 3 times a week	17	27	(13)	11	(5)
Staining > 25% of time	21	89	(43)	50	(24)

Incorrect sensation of urge	19	85	(40)	33	(16)
Manual evacuation	22	28	(14)	22	(11)
Digital evacuation	18	56	(27)	32	(15)
Fecal incontinence for liquid stool	17	44	(21)	14	(7)
Fecal incontinence for solid stool	17	16	(8)	10	(5)

Data are mean (standard deviation)

Interpretation of results

The UDI and DDI questionnaires show that at long term follow-up one out of 10 patients is bother by prolapse symptoms. About 40% reports urge incontinence of which half reports to be bothered by this symptom. The same accounts for urgency and frequency. One out of 4 patients is bothered by frequent straining for stool and 15% is bothered by needing digital evacuation to empty the bowel.

Concluding message

This large study with long term follow-up shows that the Raz four-defect repair is, in experienced hands, a safe surgical procedure with an excellent short term outcome. The drawback of this technique however is the risk on rectocele and or enterocele formation (12%) requiring re-intervention and the risk on post-operative overactive bladder symptoms and defecation symptoms.

References

1 J Urol. (1999) 161; 587-94.

Specify source of funding or grant	**No funding**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**Retrospective study with only questionnaire of current situation. As this is non-invasive, we did not need IRB approval.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**