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FRENCH MULTICENTER RANDOMIZED STUDY COMPARING LAPAROSCOPIC SACROPEXY AND VAGINAL MESH SURGERY IN CYSTOCELE REPAIR: A PRELIMINARY ANALYSIS OF ANATOMICAL AND FUNCTIONAL OUTCOMES IN PROSPERE RCT.

Hypothesis / aims of study

Cystocele is a frequent and invalidating type of genital prolapse in women. Sacrocolpopexy using synthetic mesh is considered the surgical gold standard, and the laparoscopic approach (LSC) has supplanted the open abdominal route because it offers the same anatomical results with a lower morbidity. The use of mesh during vaginal repair (VRM) may have many advantages: easiness to perform, shorter operative time and recovery [1]. At the present time only one RCT has compared LSC and VRM [2]. The French HAS (Haute Autorité de Santé) as the UK health department have highlighted the need of comparative study to properly evaluate risk and benefit ratio of surgery including mesh procedures. A French national multicentre randomized study, including centres with experience of both vaginal and laparoscopic approach was designed for comparison of the safety, functional and anatomical results of both approaches. We present here the preliminary results of functional and anatomical outcomes.

Study design, materials and methods

PROSPERE RCT is a randomized multicenter controlled trial conducted in 12 participating French hospitals referral centers for pelvic reconstructive surgery. Inclusion criteria's were: patients aged 45 to 75 years old, with cystocele ≥ stage 2 of the POP-Q classification. Exclusion criteria's were a previous surgical POP repair, and inability or contra-indication to one or the other technique. Both LSC and VRM surgery have been standardized using a consensus Delphi method. For LSC, the mesh must be fixed to the promontory by stitches; peritonisation of the mesh was recommended. For vaginal repair, the mesh must be suspended by four arms, and treatment of apical prolapse is systematically associated.

Hysterectomy is not systematic, and performed at the discretion of the operator and the patient. The placement of a posterior mesh is left to the operator's choice. The concomitant treatment of urinary incontinence is at the discretion of the operator and the patient, using sub-uretral synthetic sling when performed. Manufacturers of mesh kits did not provide the products used in this trial and had no involvement in the study design nor funding.

The estimated number of subjects required, based on the primary endpoint, the complication rate Morbidity (Dindo Classification), was 131 patients per group, 262 patients in total. Randomization process was performed centrally online with balanced blocks of four patients, stratified by center and by the existence of an active sex life.

Post-operative Site-specific POP-Q measurement were performed at 6 weeks and six months by independent observer blinded to randomization group. Functional outcomes were assessed using patient administered French validated questionnaires (PFDI-20, ICQ-SF, PFIQ7, EQ-5D; and PISQ-R).

Analyses were performed in intention-to-treat. Categorical end points were analysed with the use of Fisher's exact test, Continuous endpoints were evaluated with the use of analysis of covariance (ANCOVA), with group and baseline values for the dependent variable entered as independent variables in a model.

Results

Between October 2012 and April 2014, 925 patients have been assessed for eligibility, and 663 have been excluded (332 not meeting inclusion criteria, 208 declined to participate, study not proposed in 175) leaving 262 patients randomized in the study (n = 130 in the LSC and n = 132 in the VRM). After randomization, 1 patient in the LSC and 4 in the VRM declined to participate. There was no lost to follow-up during the study period, leaving 129 in the LSC and 128 in the VRM for analysis. The groups were comparable in terms of age, BMI, number of deliveries, menopausal status, hormonal replacement therapy, smoking, previous hysterectomy and previous stress urinary incontinence surgery. Both groups were similar in extent of prolapse at POP-Q sites in both groups. At baseline the PFDI-20 score showed a slight but significant difference between groups (100.8 ± 54.3 for LSC versus 87.5 ± 46.2 for VRM; p=0.035). There was no difference in the rate of pre-operative sexually active patients (LSC n=81 (62.3%), VRM n=72(54,5%), p=0,202).

31 different surgeons performed the interventions. In the LSC group, there was 1 conversion to laparotomy and 7 (5%) to vaginal surgery, but in all of them an anterior mesh was placed. An anterior mesh was placed in 126 (98%) of patients in the VRM group. The rates of hysterectomy and SUI surgery were respectively 14% and 37,2% in LSC, and 10,9% and 26,6% in VRM group (p=NS).

At six month follow-up, there is a significant reduction in extent of prolapse at POP-Q sites, including Aa, Ba, C, Bp, and Ap in both groups as compared with preoperative assessment. There was also a significant and important improvement in symptom severity and quality of life scores. At six month follow-up anatomical and functional outcomes were similar in both groups (Table).

Outcome Measure	LSC group n/N (%)	VRM group n/N (%)	OR [95% CI]
No with Point Ba < -10 mm	71/117 (60.7)	85/122 (69.7)	0.67 [0.82-6.08]
No with Point C < -10 mm	108/114 (94.7)	105/118 (89.0)	2.23 [0.82-6.08]
No with Point Bp < -10 mm	92/116 (79.3)	101/122 (82.8)	0.80 [0.42-1.53]
No Prolapse stage 0 or 1	50/117 (42.7)	62/122 (50.8)	0.722 (0.43 to 1.20)
No with Symptom of vaginal bulge	11/120 (9.22)	8/123 (6.50)	0.689 (0.27 to 1.78)
No of Sexually active patients	67/117 (57.3)	71/122 (58.2)	1.039 (0.62 to 1.74)
No with Dyspareunia	26/62 (41.9)	24/69 (34.8)	0.738 (0.36 to 1.50)
No with Improvement (PGI-I)	108/118 (91.5)	113/123 (91.9)	0.956 (0.38 to 2.39)
	mean (95% CI)	**mean (95% CI)**	**mean difference [95% CI]**
PFDI score	28.1 (22.7-33.4)	27 (21.7-32.3)	1.07 (-6.48 to 8.62)
POPDI subscale	6.1 (4.1 to 8.0)	6.1 (4.2 to 8)	-0.06 (-2.80 to 2.68)
DDI-8 subscale	10.4 (8.6 to 12.2)	9.6 (7.8 to 11.4)	0.87 (-1.69 to 3.42)
UDI subscale	11.4 (8.4 to 14.4)	11.5 (8.5 to 14.5)	-0.9 (-4.34 to 4.15)
PFIQ-7 score	8.49 (4.59 to 12.4)	10.5 (6.658 to 14.4)	-2.028 (-7.52 to 3.47)
EuroQoL5D scale	79.5 (76.2 to 82.8)	82.2 (79.0 to 85.5)	-2.75 (-7.36 to 1.86)
FSFI score on sexually active patients	19.0 (16.9 to 21.0)	20.7 (18.7 to 22.7)	-1.699 (-4.54 to 1.14)
ICIQ-UI SF score	2.75 (2.01 to 3.50)	2.58 (1.83 to 3.32)	0.177 (0.88 to 1.23)

At the present time, 84 % of patients have completed the one year follow-up and 100% will be available in the next months and will be presented at the congress.

Interpretation of results

This study is a pragmatic multicenter RCT with experienced operators in both surgical approaches. At 6 months follow-up, anatomical results show minimal and non-significant discrepancies between sites specific evaluation. There is a significant improvement in functional symptoms and quality of life after surgery, with no difference between groups. Even though the delay after surgery is only 6 months, 58% of patients are sexually active post operatively, and there is no difference in dyspareunia rates between groups.

These results should be interpreted with caution as the follow-up is only 6 months, but they may demonstrate that LSC and VRM offer same anatomical and functional results. Longer follow-up with evaluation of complications and re-interventions is mandatory.

Concluding message

The completion of this study should meet daily clinical problem about POP surgery. It will help to better determine the respective indications of LSC and VRM, currently based on surgical practice and subjective choice.

References

1. Maher C, Feiner B, Baessler K, Adams EJ, Hagen S, Glazener CM. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev. 2010;4:CD004014
2. Maher CF, Feiner B, DeCuyper EM, et al. Laparoscopic sacral colpopexy versus total vaginal mesh for vaginal vault prolapse: a randomized trial. Am J Obstet Gynecol 2011;204: 1.e1-1.e7

Disclosures

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