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THE HYSTERECTOMY IS REALLY NECESSARY TO TREATMENT OF UTERINE PROLAPSE TO THE MENOPAUSE WOMEN? A RANDOMIZED COMPARISON OF HYSTEROPEXY VERSUS HYSTERECTOMY FOR THE TREATMENT OF UTERINE PROLAPSE USING POLYPROPYLENE MESH

Hypothesis / aims of study

The objective of this study was to compare the anatomical results and the impact of quality of life after the Vaginal Hysterectomy (VH) or Hysteropexy (HP) with the use of Type I polypropylene mesh to treatment for uterine prolapse in the menopause women.

Study design, materials and methods

This prospective randomized experimental study was carried out at two University Urogynecology referral Centers, between June 2006 and July 2008: 31 menopause women suffered of uterine prolapse were divided into two groups according to a computer-generated randomization table at the time of surgery:

- Group VH: 15 women underwent vaginal hysterectomy and correction of apical prolapse with the use of a synthetic monofilament polypropylene mesh
- Group HP: 16 women without hysterectomy, keeping the uterus, underwent correction of apical prolapse with the use of a synthetic monofilament polypropylene mesh

Inclusion criteria: Menopause women between 50 and 80 years old, with diagnoses of POP-Q stage III or IV (ICS). Exclusion criteria: women suffering from cervical or uterine cancer, suffering from ovarian tumors, chronic diseases with high surgical risk, rectal prolapse and previous correction of prolapse genital with implants, presence of vaginal or urinary infections, compromised immune system or any other condition that could compromise the renal function and / or upper urinary tract obstruction as women submitted to prior radiation or hormonal systemic therapy .

The pelvic statics was evaluated according to recommendations of International Continence Society (ICS), according to the POP-Q system and with the Pelvic Organ Prolapse Quantification Index (POP-Q-I)[1] at the first visit and follow-up (1, 3, 6 and 12 months post operative). The POP-QI quantifies directly the prolapse continuously. This way, comparing the results only by anatomical measures of dispersion and median (Mann-Whitney test). This system quantifies the prolapse from zero to one, for each point, where zero means absence of prolapse, while one corresponds to the maximum prolapse possible.) . The Mann–Whitney's and Kolmogorov Smirnov test were used where appropriate. The sample size was calculated based on the 1.8-cm standard deviation published [2] for point C using Student's t test, with a statistical power of 80% for a difference of 2 cm between groups and a significance level of 5%. Minitab® 15.1.1.0 (Minitab® Inc., USA) was used for sample size calculation. Using those parameters, the calculated sample size was 14 patients per group, which we increased to 15 in order to avoid a loss of power due to attrition during follow-up. A validated Portuguese version of the King's health questionnaire (KHQ) was used to assess pelvic floor symptoms and quality of life, because the PQOL was not yet validated in Portuguese in time of this study. To diagnose occult SUI, all patients, symptomatic or not, were subjected to urodynamic using the recommendations of the ICS. The patients, who had preoperative diagnosis of SUI, underwent surgical correction for sling transobturator with mesh type I polypropylene. The surgical time (minutes) was evaluated by a stopwatch and the volume of intra-operative blood loss (mL), which was measured by a disposable plastic surgical aspirator coupled to a collector graduated. All patients were operated on the use of antibiotic intravenous prophylaxis, using one metronidazole 500 mg and cefazolin sodium 1.0 g the first one at the beginning of the surgery and the second one four hours after the first one.

Results

Median follow-up was 12 months on both groups. No difference was observed on complication rates and functional outcomes. Operation time was 120 minutes to VH group, versus 58.9 minutes to HP group (longer in VH group, $p < 0.001$) and intraoperative blood loss was 120 mL on group VH versus 20 mL to group HP (greater in group VH, $p < 0.001$). No difference was observer on anatomical cure rates (Point C median after surgery equal -4,433 to VH group and equal to -4,156 HP group). Objective success rate was 86.67% to VH group and 75% to HP group (p=0,667) at 12 months of follow-up,

Interpretation of results

The anatomical results were similar between the two groups. The patients' quality of life with uterine prolapse, treated with a polypropylene mesh after vaginal hysterectomy or hysteropexy, showed significant improvement regardless of the technique. As expected, the Hysteropexy had less morbidity in terms of bleeding and surgical time and there were no differences between the groups related to the success rate of anatomic correction. So the hysterectomy is not necessary for the correction of uterine prolapse, because the preservation of the uterus did not increase the rate of POP recurrence[3], also observed in this study. The uterine preservation is a better technique because there is less morbidity due to less blood loss and minor surgical time. Both techniques had similar anatomic results and similar rates of mesh erosion

Concluding message

Classically the uterine prolapse is treated with vaginal hysterectomy. Due to the evolution of anatomical knowledge, diagnostic procedures and surgical techniques, one may ask: is hysterectomy essential for the correction of uterine prolapse, when the mesh was used to correction of apical prolapse?

This study showed that in treatment of uterine prolapse to the menopause women the Hysteropexy is a better option to correct uterine prolapse because there is less morbidity due to less blood loss and minor surgical time. Complications after the use of synthetic meshes need more prospective and randomized studies for evaluation of the safety and effectiveness in the correction of apical defects in the long term.

References

1. Lemos NL, Auge AP, Lunardelli JL, Carramão S da S, Faria AL, Aoki T (2008)Validation of the Pelvic Organ Prolapse Quantification Index (POP-Q-I): a novel interpretation of the POP-Q system for optimization of POP research. Int Urogynecol J 19(7):995-7
2. De Tayrac R, Picone O, Chauveaud-Lambling A, Fernandez H (2006) A 2-year anatomical and functional assessment of transvaginal rectocele repair using a polypropylene mesh. Int Urogynecol J 17(2):100-5
3. . Neuman M, Lavy Y (2007) Conservation of the prolapsed uterus is a valid option: medium term results of a prospective comparative study with the posterior intravaginal slingoplasty operation. Int Urogynecol J 18(8):889-93

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**196/96 CONEP/MS (HEALTH Ministery)** **437/06 Ethic Committee of Urogynecology and Vaginal Surgery of Central Hospital of the Santa Casa de Misericordia de São Paulo, and Urogynecology, Faculty of Medicine of ABC**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**437/06 Ethic Committee of Urogynecology and Vaginal Surgery of Central Hospital of the Santa Casa de Misericordia de São Paulo** **and Ethic commitee of Urogynecology, Faculty of Medicine of ABC**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**