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CLINICAL STUDY OF ISCHIAL SPINOUS FASCIA FIXATION, A NEW PELVIC RECONSTRUCTIVE SURGERY.

Hypothesis / aims of study

To provide an anatomical and biomechanical basis for the new attachment point for vaginal fornix suspension, and to evaluate the efficacy and safety of the new procedure by clinical application.

Study design, materials and methods

Anatomic dissection was performed on 10 Chinese female cadavers (3 fresh and 7 embalmed). The fascia 1 cm lateral to the ischial spine was firm and strong, with a thickness of 3 mm, ischial periosteum underneath, and no major vessels or nerves in the area. Next, 32 patients with stage III uterine prolapse underwent the ischial spinous fascia fixation procedure. Objective and subjective results were observed at follow-up evaluation with an average length of 18.3 months (range, 13~28 months). Complications were recorded both intraoperatively and at follow-up.

Results

No severe intra- or peri-operation complications were observed. The objective success rate was 100% at 6 weeks post surgery and 94% at one-year follow-up. There were significant improvements in Aa, Ba, Ap, Bp, and C (p<0.001), while two patients (6.2%) showed a recurrence. One patient each suffered from low back pain and right thigh pain, while three complained of the sensation of a foreign body in the vagina. Symptoms were resolved by physiotherapy or excision of the exposed suture. Interpretation of results

No severe intra- or peri-operation complications such as large vessel injury or organ injury were observed in our study. The objective index—POP-Q measurement were significant improved during 6 weeks after surgery. After 6 weeks, 2 patients showed symptomatic recurrence of stage II uterine prolapse. 1 patient complained of pain in lower back and right thigh, but without proof of recurrence, and was much relieved after physiotherapy. And another 3 patients suffered from a foreign body sensation in their vagina, for which suture exposure was one major cause, and was cured by taking out the exposed suture. Concluding message

The fascia 1 cm lateral to the ischial spine is a safe area to fix the vaginal fornix. Ischial spinous fascia fixation is a low-cost, safe, and efficacious option for the treatment of vaginal fornix prolapse, and is a simple operation.

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| 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 | Peking Union Medical College Hospital Ethics Committee |
| Was the Declaration of Helsinki followed? | Yes |
| Was informed consent obtained from the patients? | Yes |