

NOTES VS LAPAROSCOPIC CHOLECYSTECTOMY. A PROSPECTIVE
RANDOMIZED TRIAL

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PURPOSE: The purpose of the study is to determine the feasibility of cholecystectomy made by a transvaginal approach with a NOTES procedure (natural orifice transluminal endoscopic surgery) and comparing it with a conventional laparoscopic cholecystectomy.

METHODS: Prospective randomized clinical series of 60 female patients with gallstones that underwent endoscopic surgery, 20 of them operated with conventional laparoscopic approach, 20 by transumbilical endoscopic approach and 20 of them by transvaginal endoscopic approach. Variables as surgical wound infection, urinary tract infection, evisceration, hernia, mortality and other complications will be analyzed.

Eligibility: Ages Eligible for Study: 18 Years to 65 Years; Genders Eligible for Study: Female; Accepts Healthy Volunteers: No; Inclusion Criteria: age over 18 and under 65 ; symptomatic cholelithiasis with an indication for performing laparoscopic surgery; absence of any gynecological condition that could complicate the procedure (pelvic inflammatory disease or endometriosis); perforated hymen; agreement on the patient's part not to use the vagina for two weeks after the surgery; signed specific informed consent upon providing specific information about the new surgical approach.

RESULTS: There were no significant differences in Surgical Complications.

Conversion to laparoscopic or open surgery. 1 case in transumbilical group, converted to laparoscopy by difficulty in handling the endoscope. No significant differences.

Enlargement of the entry port. In laparoscopic group 66.7% needed an enlargement, 45% in transumbilical group, while in transvaginal group expansion was not required in any case. Enlargement has not been associated with wound complications.

Postoperative pain. There were no differences in postoperative pain quantified by VAS scores. (Treatment: Dipyron 1 g ev x 6h).

Dyspareunia. The incidence of dyspareunia was nil (one year follow-up)

Hospital stay. There were no differences between groups. Hospital stay was 24 hours for 58 patients, two patients required two days. The protocol required one-day-stay.

Cost of the procedure. Cost was higher for groups that used the endoscope, because of the cost of the flexible endoscope. From case 30 onwards, the cost is the same for the procedures.

Surgical time. Significant differences between laparoscopy (47,04 minutes) and the other two techniques (transumbilical 59,80 and transvaginal 64,85). (Mann-Whitney test, $p < 0.001$).

CONCLUSIONS: Transumbilical approach with the flexible endoscope is as effective and safe as transvaginal one and it's is promising for the future (Flexible Single Incision Surgery). Transvaginal approach with flexible endoscope is not inferior in efficacy and safety to conventional laparoscopy.