

Laparoscopy versus Conventional Laparotomy for the Management of Tubal Ectopic Pregnancy— A Randomized Controlled Trial

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Abstract

Objective: To assess the efficacy and surgical morbidity associated with laparoscopic management of tubal ectopic pregnancy (EP) compared to that of open laparotomy. **Study design:** A randomized, prospective clinical trial was conducted at a private clinic setting, over a period between February 2007 and December 2012. **Methods:** A total of 166 women were admitted for suspected EP. Out of them 149 patients who had confirmed tubal EPs were subjected to different management options (conservative/medical/surgical). The diagnosis was based on the patient's history, gynecological examination, ultrasound findings (transvaginal and or transabdominal), and serum [beta human chorionic gonadotrophin (β -hCG)] estimation. Based on inclusion criteria (only haemodynamically stable patients), a total of 85 patients were enrolled for the study. All the enrolled patients were managed surgically and randomly allocated to either laparoscopy group (n = 43) or laparotomy group (n = 42) by lottery method. Data regarding patient's demographics, clinical presentation, diagnostic modalities, and treatment outcomes of two surgical techniques (laparoscopy or laparotomy) were recorded for every patient in a pre-designed data capture form. Statistical analysis was done by using SPSS version-15. **Results:** No significant differences were found between the two study groups regarding age, parity, gestational age, size & location of the ectopic gestation, the mean pre-operative β -hCG level, history of previous surgeries, pelvic inflammatory disease, or endometriosis. Total operation time (entry to peritoneal cavity up to exit) needed in the laparoscopic group was less compared to that of laparotomy group (73.2 ± 26.8 min vs. 84.5 ± 34.3 min), which was not statistically significant ($p > 0.001$). The laparoscopic approach was associated with a reduction in intra-operative blood loss (subjective), need for post-operative analgesia (odds ratio 0.08, 95% CI, 0.04–0.43) and other post-operative morbidity (odds ratio 0.29, 95% CI, 0.18–0.55). The length of hospital stay following laparoscopic management was significantly less ($p < 0.001$) than that of laparotomy group (2.7 ± 0.6 vs. 3.2 ± 1.1 days). **Conclusion:** Laparoscopic management of EP offers major benefits in terms of less operating time, fewer analgesics, early recovery, and significantly shorter hospital stay within maximum safety and efficacy. **Key words:** Ectopic pregnancy (EP); Laparoscopy; Laparotomy; Beta human chorionic gonadotrophin (β -hCG).

INTRODUCTION

Ectopic pregnancy (EP) can be defined as the implantation of the fertilized ovum at any site other than normal endometrial cavity.¹ The incidence is gradually increasing from 0.5 to 2 per 100 pregnancies.² The incidence of EP is increasing worldwide and it reflects an increase in awareness and availability of effective early diagnostic facilities. Incidence varies from country to country and from situation to situation (spontaneous versus assisted pregnancies).² Despite increased awareness and improved methods of earlier detection, EP is responsible for a significant proportion of maternal mortalities (80% of all first trimester maternal deaths) and morbidity.³

In modern practice, the accurate diagnosis of EP can now be possible at an early stage by using sensitive pregnancy tests [urinary and/or serum beta human chorionic gonadotrophin (β -hCG)], and identification of an adenexal mass along with the absence of an intrauterine gestational sac, using high-resolution transvaginal ultrasound. A systematic approach to ultrasound, and in particular transvaginal ultrasound scanning, the early pregnancy will become the “new gold standard” and gradually replace the laparoscopy for diagnosis of all types of EP.⁴

The management of EP has also undergone a significant change in the past few years due to a number of important developments of medical sciences. With the availability of accurate and more sensitive human chorionic gonadotrophin (hCG) assays, advent of high-resolution transvaginal scan (TVS) in more clinically stable women with EPs are diagnosed earlier, even before surgery becomes necessary in many cases.⁵ Early diagnosis is, therefore, potentially life-saving, can reduce surgical intervention, and allows for implementation of nonsurgical conservative treatment options. Availability of laparoscopic surgery and trained laparoscopic surgeons, and a greater awareness of EPs led to more options for treating EP.⁵

Previously, salpingectomy by laparotomy was considered as gold standard for the treatment of EP, but nowadays the laparoscopy has virtually eliminated the need for laparotomy and become the recommended approach in most cases.⁴ Currently, laparotomy is the only preferred technique when the patient is hemodynamically unstable, and facilities for emergency laparoscopy and/or surgeons with laparoscopic skills are unavailable. Their use are also restricted for patients with cornual EPs, it also is a preferred method for and in patients in whom a laparoscopic approach is difficult (e.g.,

secondary to the presence of multiple dense adhesions, obesity, or massive hemoperitoneum).^{4,5}

Multiple studies have demonstrated that laparoscopic treatment of EP results in fewer postoperative adhesions than laparotomy. Furthermore, laparoscopy is associated with significantly less blood loss and a reduced need for analgesia. Finally, laparoscopy reduces cost, hospitalization time, and convalescence period.

Salpingectomy was considered as the only treatment option in the past and within the last few decades, a more conservative surgical approach to unruptured EP using minimally invasive surgery has been advocated to preserve tubal function. The conservative approaches include linear salpingostomy and milking the pregnancy out of the distal ampulla. The more radical approach includes resecting the segment of the fallopian tube that contains the gestation, with or without reanastomosis.^{3,5}

Nowadays, laparoscopic salpingectomy is being gradually replaced with salpingostomy as a possible treatment option for tubal preservation. Salpingectomy is preferred over salpingostomy if the contralateral tube is healthy and only in patients with uncontrolled bleeding, extensive tubal damage, or recurrent EP in the same tube. It is also used when the patient wants a sterilization procedure to be performed.⁴ Therefore, nowadays in modern management, laparoscopy should be the operative tool of choice, whereas TVS the diagnostic tool of choice.

The present study was designed to compare the efficacy and surgical morbidity associated with laparoscopic management of tubal EP compared to that of open laparotomy.

MATERIALS AND METHODS

This study was a randomized, prospective clinical trial in the management of confirmed tubal EPs surgically treated in a private clinical setting, over a period between February 2007 and December 2012. This private setup hospital has accessibility to laparoscopic surgery and trained laparoscopic surgeons for 24 hours on call.

The definitive or probable diagnosis of EP was based on the patient's history, clinical presentation, gynecological examination, serum β -hCG levels, ultrasound findings (transvaginal and/or transabdominal), and/or laparoscopy.

The inclusion criteria for recruitment are: size of the EP < 5 cm, haemodynamically stable, accessibility for laparoscopic treatment, and trained laparoscopic surgeons.

The patients who are haemodynamically unstable and have other co-morbidities are excluded from the study.

The following demographic characteristics were recorded regarding the patient's age, height, weight, parity, gravidity, and gestational age of EP. Clinical presentation and TVS findings along with quantitative β -hCG level were also recorded for each patient. Body mass index (BMI) was calculated (in kilograms per square metre). Thorough history that predisposes to adhesion formation, including prior surgeries, EP, history of pelvic inflammatory disease, and endometriosis were also noted.

A total of 166 women were admitted for suspected EP. Out of them 149 patients who had confirmed tubal EPs were subjected to different management options (conservative/medical/surgical).

Based on inclusion criteria, a total of 85 patients were enrolled for the study. All the enrolled patients were managed surgically and randomly allocated to either laparoscopy group ($n = 43$) or laparotomy group ($n = 42$) by lottery method.

The amount of internal bleeding and unstable vital signs were the parameters used to determine whether to proceed or to shift to laparotomy in cases of laparoscopy group.

The following outcome information was collected from operative and anaesthesia records: estimated blood loss, operative time, operative complications, type of surgery performed, and length of hospital stay.

Operational Definition

Estimated blood loss: It is defined as the total amount of blood loss due to surgery and preexisting blood loss found during entry into the abdomen.

Operative time: It is defined as the time between the start and finish of the operation procedure.

Hospital stay: It is defined as the time calculated from the day of admission till the discharge date of the patient.

Data collection was done for all patients who were diagnosed to have EPs during the study period. Data regarding patient's demographics, clinical presentation, diagnostic modalities, and treatment outcome of two surgical techniques (laparoscopy or laparotomy) were recorded for every patient in a pre-designed data capture form. Statistical analysis was done by using SPSS version-15.

Results are presented as mean \pm standard deviation (SD). Continuous variables were tested for appropriation using the Student t or Mann-Whitney U test and numerical variables were tested using the chi-square or Fisher's exact test. A 2-tailed $p < 0.05$ was defined as statistically significant.

RESULTS

Eighty-five patients were identified as having pathologically documented tubal EPs that were treated surgically. Laparoscopy was performed in 43 patients and laparotomy in 42.

The general characteristics of the patients and conditions that predispose to adhesion formation, such as previous surgeries, EP, endometriosis, and pelvic inflammatory diseases are shown in Tables 1 and 2. No statistical differences were found in the patient's age, BMI, gestational age, β -hCG level or history of previous surgeries, pelvic inflammatory disease, or endometriosis between the two groups. Table 3 shows the mean of estimated blood loss, operative time, and hospital stay between the two groups. Total operation time required in the laparoscopic group was less compared to that of laparotomy group (73.2 ± 26.8 min vs. 84.5 ± 34.3 min), which was not statistically significant ($p > 0.001$). The laparoscopic approach was associated with a reduction in intra-operative blood loss (subjective), need for post-operative analgesia (odds ratio 0.08; 95% CI, 0.04–0.43) and other post-operative morbidity (odds ratio 0.29; 95% CI,

Table 1: Patient's characteristics for both laparoscopy and laparotomy groups

Parameter	Laparoscopy (n = 43)	Laparotomy (n = 42)
BMI*	22.2 \pm 4.5	21.9 \pm 3.0
Age (y)	28.3 \pm 6.3	30.0 \pm 7.9
Parity	0.87 \pm 1.0	1.45 \pm 1.26
Gestational age (WK)	6.0 \pm 1.3	6.5 \pm 0.9
β -hCG	3082 \pm 5023	5175 \pm 6223

*BMI: Body mass index; β -hCG: beta human chorionic gonadotrophin.

Table 2: Predisposing factors of the two groups

Characteristics n (%)	Laparoscopy (n = 43)	Laparotomy (n = 42)
Previous surgery	25 (58.13)	26 (61.90)
Previous EP	9 (20.93)	16 (38.09)
Previous PID	6 (13.95)	0
History of endometriosis	3 (6.97)	0

EP = ectopic pregnancy; PID = pelvic inflammatory disease; $p > 0.05$.

Table 3: Estimated blood loss and hospital stay of the two groups

Parameter	Laparoscopy (n = 43)	Laparotomy (n = 42)
Estimated blood loss (ml)	318.4 ± 514.7	934.5 ± 11.6.8
Operative time (min)	73.2 ± 26.8	84.5 ± 34.3
Hospital stay (day)	2.7 ± 0.6	3.2 ± 1.1

p < 0.05.

0.18–0.55). The length of hospital stay following laparoscopic management was significantly less (p < 0.001) than that of laparotomy group (2.7 ± 0.6 vs. 3.2 ± 1.1 days).

DISCUSSION

Ectopic pregnancy remains a common gynaecologic condition that causes significant maternal morbidity and mortality. The incidence of EP has increased from 0.5% 30 years ago to a current incidence of 1% to 2%.⁶ The risk of EP is increased by several factors: previous EP, tubal damage from surgery, a history of infertility, treatment using in vitro fertilization, and increased age.⁷ In our study, the laparotomy group had a significantly greater number of patients with a history of previous EP.

Because laparoscopy has been shown to be superior to laparotomy, it has become the gold standard for the treatment of EP.³ However, in women who are hemodynamically unstable, the role of laparoscopy remains controversial. But as surgeons gain increased expertise in laparoscopic surgery, even in the presence of a large hemoperitoneum, operative laparoscopy is still achievable.⁸ In our study, 42 patients (49.41%) underwent laparotomy and 43 patients (50.58%) underwent laparoscopic approach.

Obesity has an impact on whether laparoscopic surgery can be performed. Obesity, defined as BMI > 30, is considered by some to be a relative contraindication to operative laparoscopy. Also, laparoscopic surgery in the obese population can be challenging.⁹ Increased abdominal wall thickness makes it difficult to achieve pneumoperitoneum and to visualize the inferior epigastric vessels. Moreover, increased omental and retroperitoneal fat limit maneuverability of the instruments.¹⁰ However, a recent report reveals that laparoscopic management of tubal EP does not appear to significantly increase surgical morbidity in obese patients.¹¹ In our study, BMI was not significantly different between the two groups.

The mean operative time was shorter in the laparoscopic group. This may contradict the results of many studies documenting the unpredictability of time needed for laparoscopic surgery, especially for EP.¹² Blood loss was less and hospital stay was shorter in the laparoscopy group. Previous randomized studies also have shown that laparoscopy results in less blood loss, a shorter hospital stay, and lower cost compared with laparotomy.^{13,14}

CONCLUSION

Laparoscopic management of EP offers major benefits in terms of less operating time, fewer analgesics, early recovery, and significantly shorter hospital stay with maximum safety and efficacy.

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