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RESEARCH ARTICLE

LAPAROSCOPIC MANAGEMENT OF TUBAL ECTOPIC PREGNANCY: SINGLE-PORT VERSUS CONVENTIONAL MULTI-PORT LAPAROSCOPY.

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Abstract

Study objective: Evaluation of intraoperative (IO) and immediate postoperative (PO) outcome of single-port laparoscopy (SPL) compared to conventional multi-port laparoscopy (CMPL) for management of tubal ectopic pregnancy (TEP).

Design: Patients presented with acute abdominal manifestations during pregnancy were clinically evaluated and cases diagnosed with tubal ectopic pregnancy as confirmed by transvaginal ultrasonography (TVU) and higher β -hCG levels were enrolled in the study.

Patients: 52 patients had TEP diagnosed and fulfilling the inclusion criteria were randomly allocated into two equal groups according to laparoscopic procedure.

Interventions: SPL was conducted through a single 1.5-2 cm vertical umbilical incision and performed using standard laparoscopic instruments used for CMPL. Collected IO data included the need for conversion to laparotomy; operative time and need for blood transfusion. Collected PO data included pain scores and frequency of requests of PO analgesia, time of 1st ambulation and oral intake, and duration of PO hospital stay. Patients' satisfaction by cosmetic wound appearance was evaluated 3-months after surgery using a 5-points satisfaction score.

Measurements and main results: Total conversion to laparotomy was 3.8% in both groups. Pain scores were significantly lower till 4-hr PO in patients of SPL compared to patients of CMPL group. SPL patients could ambulate within shorter PO time and more patients could ambulate within 3-hr PO. Mean duration of hospital stay was shorter in SPL patients with a higher frequency of patients discharged within 24-hr PO. Frequency of patients satisfied by wound appearance was higher with SPL than CMPL.

Conclusion: SPL improves outcome of laparoscopic management of tubal ectopic pregnancy with significantly better short-term outcome and satisfactory cosmetic appearance compared to CMPL.

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Introduction:-

Ectopic pregnancy (EP) is the leading cause of maternal morbidity and mortality during the first trimester for women of childbearing age ⁽¹⁾. Improved detection and increased risk factors have led to a dramatic rise in the

incidence of EP in recent years ⁽²⁾. The presentation of extrauterine pregnancy is highly variable, ranging from an asymptomatic state, to pelvic pain that is worse on one side, to tubal rupture with hemorrhagic shock ⁽³⁾. Thus, early diagnosis is critical for the health of the patient as well as the success rate of future pregnancies ⁽²⁾. About 75% of tubal pregnancies can be detected by transvaginal ultrasonography ⁽³⁾, so sonography is considered as the mainstay for evaluating EP ⁽²⁾.

Different management strategies including expectant, medical, surgical management were recorded once diagnosis of TEP was confirmed on transvaginal ultrasonography (TVU) ⁽⁴⁾. Treatment of ectopic pregnancy with methotrexate is effective for saving tubal patency with a tubal patency rate of 75% in hysterosalpingography ⁽⁵⁾. Medical management should be abandoned in favor of surgical management if the patient presents with hemodynamic instability or other clinical parameters concerning for ruptured TEP, such as pain ⁽⁶⁾.

Laparoscopy provided a diagnostic method that is currently becoming consolidated for therapeutic use ⁽⁷⁾, and is becoming the gold standard in gynecological surgery ⁽⁸⁾. The laparoscopic approach in acute abdomen of gynecologic origin in comparative studies was found to be non-inferior to open surgery ⁽⁹⁾. A national survey study demonstrated that a total of 57% of TEP cases were managed laparoscopically, 31% medically, 5% by laparotomy and 6% conservatively and out of 44 surveyed centers, 29 have the facilities for training in both intermediate laparoscopic surgery and early pregnancy ultrasound ⁽¹⁰⁾.

With increasing surgical expertise and advanced diagnostic aids, patient satisfaction has become an important attribute of quality control and health care goal ⁽¹¹⁾. Multiple recent studies documented that one-day and outpatient laparoscopic surgery can be performed with high patient satisfaction ^(12, 13, 14). SPL surgery has been developed in order to improve minimally invasive surgery ⁽⁸⁾ and the present study tries to highlight the significant surgical outcome of SPL for management of tubal ectopic pregnancy.

Design

Prospective Comparative Study

Setting:

Tertiary referral hospital, KSA

Hypothesis

The current comparative study hypothesized that SPL provides early recovery and more satisfactory cosmetic abdominal appearance than CMPL for women presenting by TEP.

Aim of work

The aim of our study was to evaluate early recovery items including postoperative (PO) pain sensation, and need for PO analgesia, time till first ambulation and oral intake, and duration of PO hospital stay. Also, the study aimed to evaluate patients' satisfaction by cosmetic outcome at 3-month PO.

Patients & Methods:-

The current study was conducted from Jan 2015 till Feb 2018 to allow three-month follow-up for the last operated case. The study protocol was approved by the Hospital Local Ethical Committee. Women presented with acute abdominal manifestations during pregnancy were clinically evaluated. Considering the discriminatory zone of β -hCG was 1000 to 2000 mIU/ml ^(6, 15) with the use of transvaginal ultrasonography (TVU), women with tubal ectopic pregnancy as diagnosed by TVU in conjunction with β -hCG levels ≥ 1500 mIU/ml were enrolled in the study.

Collected preoperative data included age, body mass index (BMI) data, gravidity, parity, number of living children, history of IVF, and gestational age of ectopic pregnancy. Pain severity was assessed using 0-10-point numeric pain scale ⁽¹⁶⁾.

Clinical examination included abdominal examination for pain localization, presence of tenderness and rebound tenderness. Hemodynamic data including heart rate, and blood pressure measures were recorded.

Patients arriving to emergency room with severe compromised hemodynamic measures or in shock state, patients with large volume hemoperitoneum, and women with umbilical hernia were not enrolled in the study. Also, women

with history previous pelvic surgeries, previous ectopic pregnancy, or history of pelvic inflammatory disease, endometriosis, or cardiac disease were also excluded from the study. Patients fulfilling inclusion criteria were randomized, using sealed envelopes prepared by blinded assistant and chosen by patient herself, into two equal groups: Group CMPL included patients assigned for conventional multiple-port laparoscopy (CMPL) and Group SPL included patients assigned for single-port laparoscopy (SPL).

Venous blood samples were obtained for estimation of hemoglobin concentration and quantitative β -hCG level. Then, all patients underwent abdominal and transvaginal ultrasonography, if possible, assuring the diagnosis and defining the location of the gestational sac, if it is disturbed or not, presence of hemoperitoneum and its extent and assurance of absence of exclusion criteria.

Anesthetic technique

All patients were premedicated by midazolam 0.02 mg/kg; anesthesia was induced using propofol 2 mg/kg, fentanyl 1-2 μ g/kg, and rocuronium 0.6 mg/kg. Balanced anesthesia was continued with isoflurane, fentanyl and rocuronium adapted to the patient's physiological reaction to surgical stimuli. After intubation of the trachea, the lungs were ventilated with 100% O₂ using a semi-closed circle system.

Surgical procedure

For CMPL, intraperitoneal CO₂ insufflation was performed through Verres needle inserted into a small umbilical incision, an electronic variable-flow insufflator terminated when the intra-abdominal pressure reached 14-16 mmHg and then, one 10-mm trocar and two 5-mm trocars were placed. For SPL, a single 1.5-2 cm vertical umbilical incision was performed and a rectus fasciotomy was made and dilated to accommodate the wound retractor that was introduced through the umbilical incision for use as a fascial retractor. The single-port apparatus with the attached three cannulas was fixed to the outer ring of the wound retractor. Two cannulas were 5 mm in diameter, and the 3rd was either 10 or 12 mm in diameter according to the diameter of the instrument shafts. Then, the abdomen was insufflated with CO₂ to a maximum pressure of 14-16 mmHg according to requirement. Surgery was conducted by standard instruments used for conventional multi-port laparoscopy. Rigid 5-mm laparoscopic instruments and a rigid 30-degree, 5-mm laparoscope were inserted into the abdomen. All cases underwent salpingectomy; after abdominal exploration, tubal mass was identified, and tube was completely dissected and clamped at its junction to the uterus and Ligasure® was used to facilitate easier cutting of the fallopian tube. The affected tube with its ectopic pregnancy mass was completely excised (Fig. 1). In case of ruptured sac and presence of hemo-peritoneum, pelvic toilet was performed. Then, umbilical wound was closed. For patients of both groups, operative data included operative time, amount of intraoperative (IO) blood loss, frequency of need and amount of blood transfusion and need for conversion to laparotomy.

Case presentation



Fig. (1a):-Umbilical incision (arrowed)



Fig. (1b):-Single-port apparatus with three cannulas attached was fixed to the outer ring of the wound retractor

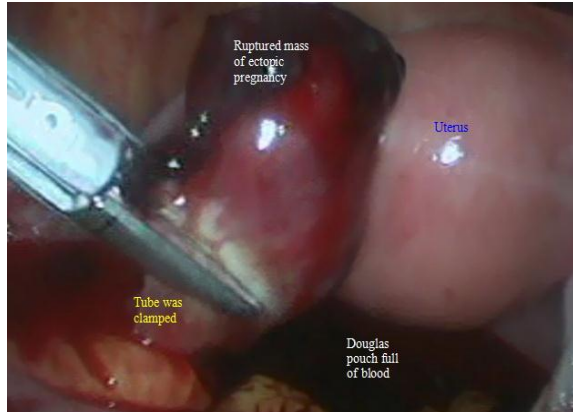


Fig. (1c):-Ruptured tubal pregnancy with flooding Douglas pouch with blood was detected.



Fig. (1d):-The affected tube with its ectopic pregnancy mass was completely excised



Fig. (1e):-Site of excised tube showed no stump bleeding and Douglas pouch was cleaned

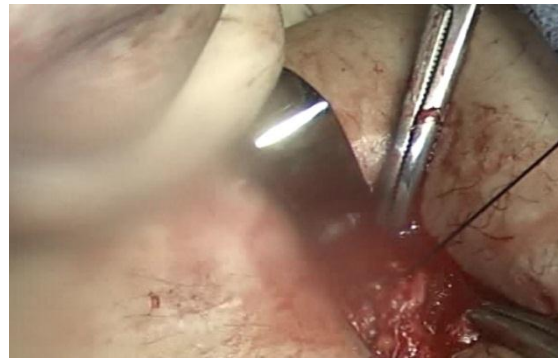


Fig. (1f):-Umbilical wound was closed

Postoperative care

Patients of both groups received their immediate PO care at post-anesthetic care unit (PACU) till full recovery and then transferred to ward. PO pain was evaluated using pain 0-10 numeric pain rating scale with 0 indicates no pain, 5 indicates moderate pain and 10 indicates worst possible pain. Pain scoring was determined at 1, 2, 4 and 8-hr PO and rescue analgesia in form of mepridine 50 mg intramuscular injection was given on pain score ≥ 4 . Patients were encouraged to move out-of-bed when there was no pain and to move gradually and supported till be tolerant to be self-dependent. Oral fluid was allowed after resumption of good intestinal mobility. Collected PO data included pain scores and frequency of requests of rescue analgesia, time for 1st ambulation and oral intake, the frequency and amount of PO blood transfusion and duration of PO hospital stay. Patients' satisfaction by cosmetic wound appearance was evaluated 3-months after surgery using 5-points satisfaction score; very dissatisfied, dissatisfied, good, satisfied and very satisfied.

Statistical analysis

Sample size was calculated using the standard nomogram proposed by **Kraemer & Thiemann** ⁽¹⁷⁾ depending on that previously documented by **Panelli et al.** ⁽⁶⁾ that the overall rate of EP is 1–2% in the general population, a sample size of >40 patients with documented TEP was found to be sufficient to detect a difference at the 5% significance level and give the trial >80% power ⁽¹⁸⁾. Sample size and power were re-calculated and assured using Power and Sample Size Calculation Software program provided by Department of Biostatistics, Vanderbilt University

Obtained data were presented as mean \pm SD, ranges, numbers and ratios. Results were analyzed using One-way ANOVA with post-hoc Tukey HSD Test and Chi-square test (X^2 test) with the alpha level set to 0.05. Statistical analysis was conducted using the SPSS (Version 15, 2006) for Windows statistical package.

Results:-

The study included 52 women had ectopic tubal pregnancy; preoperative data of women included in both groups showed non-significant difference (Table 1).

Table 1:-Preoperative data of patients included in both groups

Data			Group SPL (n=26)	Group CMPL (n=26)
Age (years)			24.3±3.6	24.7±3.5
BMI data	Weight (kg)		77.6±8.6	76.5±9.5
	Height (cm)		164.5±3.6	164.6±3
	BMI (kg/m ²)		28.6±3	28.2±3.5
Obstetric history	Gravidity	Primigravida	12 (46.2%)	10 (38.5%)
		Multigravida	14 (53.8%)	16 (61.5%)
	Parity	≤2	8 (28.6%)	9 (34.6%)
		>2	6 (25.2%)	7 (26.9%)
	Living offspring	≤2	10 (38.5%)	11 (42.3%)
		>2	4 (15.3%)	5 (19.2%)
	GA of current pregnancy		7.1±1.1	6.8±1
Presenting symptoms	Pain VAS score		5.8±0.8	6.1±1
	Vaginal bleeding	Amenorrhea	19 (73.1%)	20 (76.9%)
		Spotting	7 (26.9%)	6 (23.1%)
Hemodynamic parameters	Heart rate (beats/min)		87.2±4.5	89.3±4.8
	Systolic arterial pressure (mmHg)		107±4.7	107.3±5.5
Hemoglobin concentration (gm%)			8.4±1.3	7.8±0.9
Hemoperitoneum judged by TVU	Number of affected patients		12 (46.2%)	15 (57.7%)
	Amount (ml)		1113.8±342	1291±379

Data are presented as mean±SD & numbers; percentages are in parenthesis; VAS: Visual analogue score; TVU: Transvaginal ultrasonography; p>0.05 indicates non-significant difference; p<0.05 indicates significant difference

All patients passed uneventful intraoperative course, no patient in SPL required to conversion to conventional laparoscopy. Two cases required conversion to laparotomy; one case in SPL showed intraoperative hemodynamic instability secondary to raised intra-abdominal pressure and according to the advice of the anesthetist peritoneal desufflation was performed and laparotomy was conducted. During peritoneal exploration, a case was found to have massive hemoperitoneum that hampered proper visualization, so CMPL was cancelled and laparotomy was conducted for a total open conversion rate of 3.8%.

Operative time was non-significantly shorter with SPL than with CMPL. Twenty patients (38.5%) required blood transfusion; 9 cases required preoperative correction of anemia despite of the moderate amount hemoperitoneum and the other cases required blood transfusion for both correction of anemia secondary to presence of massive hemoperitoneum and to improve general condition to tolerate general anesthesia. However, no case required blood transfusion to compensate for intraoperative loss (Table 2).

Patients of SPL could ambulate within significantly (p=0.023) shorter PO time with significantly (p=0.028) higher frequency of patients ambulated within three hour PO compared to patients had CMPL. However, time till 1st PO oral intake was significantly shorter (p=0.049) in SPL patients compared to patients had CMPL (Table 2).

All patients did not request PO rescue analgesia for 2-hr PO; however pain scores were significantly lower till 4-hr PO; thereafter pain scores were non-significantly lower in patients of SPL compared to patients of CMPL group. Concerning the frequency of patients requested rescue analgesia, 11 patients requested PO analgesia at 4-hr PO, 9 patients at 8-hr PO and 18 patients at 12-hr PO, but no patient required twice injections with non-significantly higher frequency in CMPL patients than SPL patients (Table 2).

Postoperatively, all patients were admitted to emergency gynecological ward for a mean duration of stay of 21.4±9.7; range: 12-48 hr. Mean duration of hospital stay was significantly (p=0.035) shorter in SPL patients compared to CMPL patients. Thirty-nine patients (75%) were discharged on the same day of surgery with

significantly ($p=0.042$) higher frequency of patients discharged on the same day of surgery with SPL than with CMPL (Table 2).

At 3-m PO, the frequency of patients satisfied by wound appearance was significantly ($p=0.011$) higher among patients of SPL group compared to patients of CMPL group (Table 2).

Table 2:-Operative and postoperative data of patients included in both groups

Group			SPL (n=26)	MPL (n=26)	P value
Data					
Operative time (min)			43.7±11.5	49.4±13	0.098
Need for blood transfusion	Frequency		9 (34.6%)	11 (42.3%)	0.569
	Number of units		0.9±0.8	1±0.9	0.844
PO time till 1 st ambulation (hr)	Frequency	<3-hr	14 (57.7%)	6 (23.1%)	0.023
		≥3-hr	12 (42.3%)	20 (76.9%)	
	Mean		2.7±1.4	3.6±1.3	0.028
PO time till 1 st oral intake (hr)	Frequency	≤6	13 (50%)	10 (38.5%)	0.134
		>6-9	12 (46.2%)	11 (42.3%)	
		>9	1 (3.8%)	5 (19.2%)	
	Mean		5.2±2.7	6.6±2.4	0.049
PO pain VAS score	1-hr PO		1.2±0.4	1.6±0.6	0.008
	2-hr PO		1.5±0.5	2.1±0.6	0.001
	4-hr PO		2.5±0.9	3.1±1.1	0.033
	8-hr PO		2.6±1.1	2.8±0.9	0.411
	12-hr PO		2.8±1.2	3.3±1.2	0.127
	Frequency of requested rescue analgesia	4-hr PO	4 (15.4%)	7 (26.9%)	0.576
		8-hr PO	3 (11.5%)	6 (23.1%)	
		12-hr PO	7 (26.9%)	11 (42.3%)	
Hospital stay (hr)	Frequency	Operative day	21 (80.8%)	18 (69.2%)	0.042
		2 nd PO day	5 (19.2%)	8 (30.8%)	
	Mean		18.5±7.3	24.2±11.1	0.035
Wound appearance satisfaction rates	Very satisfied		12 (46.2%)	5 (19.3%)	0.011
	Satisfied		7 (26.9%)	10 (38.5%)	
	Good		5 (19.2%)	7 (26.9%)	
	Dissatisfied		2 (7.7%)	3 (11.5%)	
	Very dissatisfied		0	1 (3.8%)	

Data are presented as mean±SD & numbers; percentages are in parenthesis; PO: Postoperative; $p>0.05$ indicates non-significant difference; $p<0.05$ indicates significant difference

Discussion:-

The obtained results support the previously documented work of **de Poncheville et al.**⁽¹⁹⁾ and **Kim et al.**⁽²⁰⁾ that transumbilical SPL using conventional laparoscopic instruments has operative outcomes comparable to CMPL for the surgical treatment of TEP and so may be offered as a feasible alternative to CMPL.

Two patients required conversion to laparotomy for a total conversion rate of 3.8%; such figure is superior to that reported previously^(21, 22). No case in SPL group required conversion to laparotomy for management of hemoperitoneum, while one case in CMPL required that; thus indicating effectiveness of SPL for management of TEP, irrespective of patients' conditions or intraoperative findings.

In line with these data, **Cohen et al.**⁽²³⁾ and **Cengiz et al.**⁽²⁴⁾ documented that laparoscopic surgery could replace open laparotomy for management of patients with TEP even those with elevated shock index, which is a unique determinant of acute hemorrhage. Moreover, **Kim et al.**⁽²⁵⁾ and **Yang et al.**⁽²⁶⁾ found that SPL surgery is a safe and feasible surgical approach for patients with TEP and was found to be more effective than conventional laparoscopic surgery for cases with massive hemoperitoneum.

Recently, in 2018, **Gasparri et al.**⁽²⁷⁾ reported no differences between CMPT and LESS with regards to length of operative time, length of hospitalization, mean hemoglobin drop, number of patients requiring transfusions and intra- and post-operative complications.

Furthermore, SPL provided significantly shorter duration till 1st ambulation and oral intake, lower PO pain scores with subsequent shorter duration of PO hospital stay. Moreover, SPL provided more acceptable cosmetic yield with significantly higher satisfaction rates by wound appearance compared to CMPL. These findings go in hand with previous studies evaluated these outcome items^(21, 28, 29, 30). Recently, in 2018, **Karasu & Akselim**⁽³¹⁾, in comparison of SPL to CMPT in ectopic pregnancies accompanied by severe hemoperitoneum, detected no intraoperative complications, nor significant differences in additional analgesic requirements, but postoperative pain scores were significantly lower in the SPL group till 12-hr PO.

The obtained results fulfilled the study hypothesis and allowed defining SPL as the preferred laparoscopic approach for management of TEP. In support of this assumption, multiple studies reported that SPL salpingectomy has comparable surgical outcomes to CMPL salpingectomy for the surgical treatment of TEP in terms of operative time^(32, 33), hospital stay and complication rates^(34, 35) regardless of the type of ectopic pregnancy and hemodynamic stability⁽²⁵⁾.

Conclusion:-

Single-port laparoscopy improves outcome of laparoscopic management of tubal ectopic pregnancy with significantly better short-term outcome and satisfactory cosmetic appearance compared to conventional multiple-port laparoscopy.

Conflict of interest:-

The authors have no conflicts of interest relevant to this article.

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