

The feasibility and advantages of laparoscopic surgery for ectopic pregnancy at a secondary hospital in South Africa

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Background. Ectopic pregnancy (EP) is a gynaecological emergency with implications for maternal morbidity worldwide. Laparoscopic surgery is the preferred method of surgical management in most cases, as it has shown to improve patient outcomes and overall care and to be cost effective and efficient.

Objectives. To investigate the feasibility of laparoscopic surgery for EP management at a secondary hospital, based on incidence rates and comparing surgery-associated variables and outcomes with those in laparotomy.

Methods. A retrospective study design was used. All patients who were treated surgically for EP at the Worcester Provincial Hospital were included. The required sample size was 81. Data were collected from patient files and theatre reports. Cases were assigned to one of two cohorts based on the method of surgical management.

Results. A total of 84 cases were identified, of which 48 (57.1%) were managed laparoscopically and 36 (42.9%) with laparotomy. The average surgical time was 34.6 minutes and 44.9 minutes for a laparotomy and a laparoscopy, respectively. Patients who were treated laparoscopically required significantly less postoperative pain relief and had shorter hospital stays.

Conclusion. This study shows not only that laparoscopy treatment is a feasible option for EP in a secondary-hospital setting in South Africa, but also that the intervention is associated with significantly better patient outcomes than laparotomy. The demonstrated benefits make laparoscopy the preferred treatment modality for EP when surgical intervention is required.

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An ectopic pregnancy (EP) results from the implantation of a fertilised ovum outside the uterus.^[1] EP is one of the major causes of maternal morbidity and mortality worldwide.^[2] A 2017 report based on confidential enquiries into maternal deaths in South Africa (SA) shows that maternal deaths caused by EP have increased from 2.5% in 2011 to 3.4% in 2017.^[3]

Risk factors include a previous EP, during which treatment had been conservative, tubal pathology, previous genital infections, having multiple sexual partners, use of intrauterine devices, smoking, *in vitro* fertilisation and age.^[1] *Chlamydia* infection has been shown to be strongly associated with pelvic infections and thus increases the risk of EP.

EP should be a differential diagnosis in all women who present with vaginal bleeding or lower abdominal pain in the case of a positive pregnancy test.^[4] Early diagnosis makes conservative treatment possible and minimises morbidity and mortality.^[5] Tubal rupture can result in life-threatening haemorrhage and shock, which should be approached with urgent surgical management.^[4]

Treatment can be either surgical or non-surgical. Surgical treatment can involve either laparotomy or laparoscopy, whereas non-surgical treatment can be either expectant or medical.^[6] Treatment options depend on gestational age, evidence of rupture and requirements for future fertility.^[2]

Transvaginal ultrasound and serial beta-human chorionic gonadotropin measurements allow for early diagnosis, leading

increasingly to medical management with methotrexate and minimally invasive surgery.^[7]

The Royal College of Obstetrics and Gynaecology (RCOG) recommends a laparoscopic approach to surgical management, even in the case of a ruptured EP, if the operator is experienced.^[8] The benefits of laparoscopic surgery were described in a systematic review of randomised trials that compared laparoscopic salpingostomy with an open surgical approach. Laparoscopic salpingostomy was associated with a significantly shorter procedure time (73 minutes v. 88 minutes), less perioperative blood loss (79 mL v. 195 mL), shorter postoperative hospital stay (1 - 2 days v. 3 - 5 days) and shorter follow-up time (11 days v. 24 days) than open surgery.^[9]

A retrospective audit of surgically managed EPs over a 5-year period at the Cleveland Clinic, Ohio showed that 84.3% of patients were successfully managed with laparoscopic surgery, without any major intra- or postoperative complications. The study affirmed the benefits of a laparoscopic procedure and highlighted its safety and efficiency for overall patient care.^[10] The Cochrane review on EPs also notes that a laparoscopic approach is significantly less costly than open surgery.^[11]

A clinical audit over a 30-month period at a district hospital in the UK showed similarly encouraging findings, with 62% of all patients diagnosed with EP managed laparoscopically. The audit also showed that laparoscopic management was safe and could be performed effectively in a district-hospital setting, with notable advantages

including shorter hospital stays and reduced postoperative opiate requirement.^[12]

There have been a number of systematic reviews following the management of tubal EP by either salpingostomy or salpingectomy. The RCOG notes that there is no clear evidence that salpingotomy should be used in preference to salpingectomy if a healthy contralateral tube is present.^[8] However, in the case of contralateral tubal disease the RCOG advises that laparoscopic salpingotomy should be considered as primary treatment if future fertility is desired.^[13]

The complication rate of laparoscopic surgery is low. Up to 50% of complications occur at first insertion of the abdominal port, during which entry is blind. Complications can also arise from abdominal insufflation, tissue dissection and disrupted haemostasis. Conversion to an open procedure may be necessary to manage complications. Complications such as vascular injury and bowel perforation can lead to severe morbidity or mortality.^[14]

The primary objective of this study was to investigate the feasibility of laparoscopic surgery for EP in a secondary-hospital setting in SA. The study aimed to determine the proportion of laparoscopy compared with laparotomy from all surgically managed EPs. Secondary objectives involved the comparison of several variables in the two approaches to assess whether laparoscopy was a feasible method for surgical management in our setting.

Methods

A retrospective audit of 2 years' records (1 January 2015 - 31 December 2016) was performed at the Worcester Provincial Hospital (WPH), a secondary hospital in the Western Cape province, SA. Doctors of various experience levels work at this centre.

All patients who presented with suspected EP and received surgical management at WPH were included. Patients referred to WPH for management of complications following surgical treatment at another facility were excluded.

During data analysis, multivariate logistics regression was used to account for any confounding variables. If a patient's folder notes could not be found, but theatre reports and electronic records were available, the patient was eligible for inclusion in the study. As the information from the theatre notes met the criteria of our primary objective, these cases allowed for partial information to be used.

A sample size of at least 81 patients was required. This was based on an incident rate of 50 EP patients per year in the two previous years and an estimated underlying event rate of 60% - 80% for EP-associated laparoscopy.

All doctors at our unit received consultant-supervised training

in performing two- and three-port laparoscopic procedures. Once proficiently skilled in performing the procedure safely, the doctor was allowed to operate without supervision. This applied to doctors across all levels of experience, from interns to registrars.

Data were collected from the electronic database of all surgeries at WPH. EP procedures were identified using the search terms 'indication' and 'ectopic pregnancy' and the respective ICD-10 codes for laparoscopy and laparotomy. Identified cases were cross-referenced with the theatre record book, which holds a handwritten record of all surgeries performed. We then used patients' folder numbers and full names to obtain their files from records.

Participants were assigned to one of two groups based on the method of surgical management (laparoscopy or laparotomy). Data on a number of other variables were also captured and entered into a data sheet for each cohort. The totals were tallied and compared.

Data were analysed using biomedical statistics software (Stata 14). Parametric data were described using means and 95% confidence intervals, whereas medians, ranges and quartiles were used to describe non-parametric data. Chi-squared tests, odds ratios and standard deviations were used to compare frequencies. A significance level of $p < 0.05$ was used. Independent-sample *t*-tests were used to compare normally distributed variables, whereas Mann-Whitney *U* tests were used for comparison in non-parametric data sets. Logistic regression was used to account for possible confounding variables, such as loss of files, negative findings and incorrect information.

Ethical approval

Ethical approval was granted by both the Human Research Ethics Committee of the Faculty of Health Sciences, Stellenbosch University and the Provincial Research Ethics Committee (ref. no. S16/09/163). Confidentiality of patient information was maintained throughout the study.

Results

A total of 84 cases were identified, 42 each from 2015 and 2016. Theatre notes were available for all 84 patients, but only 71 full patient files were available. Data for age, post-surgery haemoglobin level and length of hospital stay were normally distributed, whereas data for gravidity, parity and estimated gestational age showed skewed distributions (Table 1). Means and associated standard deviations (SD) for age, post-surgery haemoglobin level and length of hospital stay were 28.5 (5.6) years, 9.9 (2) g/dL and 2.9 (0.9) days, respectively.

Records of previous EP and miscarriage were found for eight and nine patients, respectively. Comorbidities included pulmonary tuberculosis ($n=2$) and asthma ($n=1$) and 20% of the sample were HIV positive.

Table 1. Summary of variable ranges across study sample

Parameter	Age (years)	Gravidity	Parity	Estimated gestational age (weeks)	Surgical time (min)	Blood loss (mL)	Hb level pre surgery (g/dL)	Hb level post surgery (g/dL)	Hospital stay (days)
Minimum	15	1	0	2	15	0	3.7	4.9	1
P25*	25	2	0	6	25	100	9.4	8.3	2
P50*	29	3	1	8	30	500	10.3	10.1	3
P75*	33	3	2	8	60	725	11.9	11	3
Maximum	42	8	7	18	120	2500	14.4	15.2	6
Cases included†	84	70*	70*	49*	84	84	71*	71*	71*

*P25 refers to the first quartile, P50 to the second quartile and P75 to the third quartile.

†Data from <84 case files used owing to missing information.

Hb = haemoglobin.

Laparoscopy was performed in 48 cases (57.1%) and laparotomy in 36 cases (42.9%). Three laparoscopy cases were converted to laparotomies owing to blood in the abdomen causing poor visualisation. In four of the laparoscopy cases, no evidence of an EP was found.

Day hours are considered to be from 08h00 to 16h00 on weekdays, during which a full staff complement is present. After-hours times are considered to be from 16h00 to 08h00 on weekdays and all hours of weekends and public holidays. After hours only one doctor is on call for each department and a full complement of theatre staff for one emergency theatre. Consultants are available off site. According to these definitions, 46 (54.8%) of the surgeries were performed during day hours ($p<0.0001$), of which 91.3% were laparoscopies and only 8.7% were laparotomies. Of the 38 procedures (45.2%) performed after hours, 15.8% were laparoscopies whereas 84.2% involved open surgery ($p<0.0001$).

When procedure type was categorised according to clinical skill level (Fig. 1; also see Table 2 for definitions), results showed that a consultant handled significantly more laparoscopic cases than clinicians from the other skill levels ($p<0.0001$). Laparotomy cases were performed mostly by grade 1 medical officers and community service medical officers (Fig. 1).

Records of ruptured EPs were found for 66 cases (78.6%) ($p=0.15$). Of these patients, 35 (53%) received laparoscopic management and 31 (47%) were treated by means of a laparotomy. In cases without rupture, 72.2% were managed laparoscopically; laparotomies were performed in the remainder of these cases.

Tables 3 and 4 show summary statistics for laparotomy ($N=36$) and laparoscopy ($N=48$),

respectively. No significant differences were found for age ($p=0.7$), gravidity ($p=0.6$) or parity ($p=0.7$) between the two treatment groups. Pre- and post-surgery haemoglobin levels also did not differ significantly between the two groups ($p=0.6$ and $p=0.4$, respectively).

Significant differences were found in surgical time, blood loss and length of hospital stay between the two treatment groups. Mean surgical time (in minutes) for laparotomies (34.6 (23.1); range: 15 - 120) was significantly less ($p=0.001$) than for laparoscopic procedures (44.9 (19.2); range: 20 - 115). Laparotomies were associated with significantly higher blood loss (712.5 (594.9) mL) than laparoscopies (386.5 (394.2) mL)

($p=0.001$). Hospital stay was significantly shorter ($p<0.0001$) in laparoscopy patients (2.5 days) than in laparotomy patients (3.6 days).

A comparison of analgesic use in the two treatment groups is shown in Fig. 2. Analgesics included opioids (morphine) and oral analgesics (paracetamol and non-steroidal anti-inflammatory agents). The average number of morphine doses (2.1) for the laparotomy group was significantly more ($p=0.04$) than for the laparoscopy group (1.3). A similar trend was seen for oral analgesic dose (10.5 for the laparotomy group v. 4.3 for the laparoscopy group; $p=0.004$).

The number of blood transfusions was

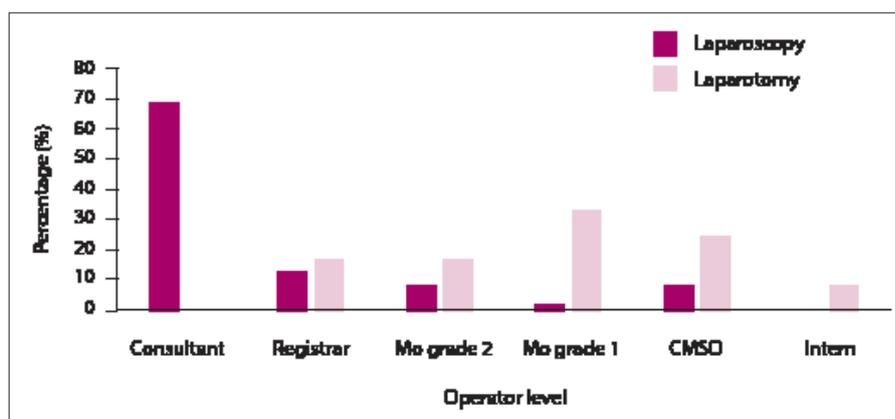


Fig. 1. Frequency of procedure type grouped according to operator level ($p<0.0001$). MO = medical officer; CSMO = community service medical officer.

Table 2. Key to operator levels

Level	Description
Consultant	Specialist
Registrar	Specialist in training
Medical officer grade 2	Practising for >5 years
Medical officer grade 1	Practising for <5 years
Community service medical officer	Completed internship; registered doctor
Intern	Completed medical school; now serving in supervised internship position

Table 3. Summary statistics of laparotomy cases ($N=36$)

Parameter	Age (years)	Gravidity	Parity	Estimated gestational age (weeks)	Surgical time (min)	Hb level pre surgery (g/dL)	Hb level post surgery (g/dL)	Blood loss (mL)	Hospital stay (days)
Minimum	19	1	0	2	15	7.3	4.9	100	3
P25*	23	2	1	4	20	9.7	8.6	350	3
P50*	29.5	2	1	6	30	10.3	10	500	3
P75*	33	3	2	8	37.5	11.5	10.7	1000	4
Maximum	36	4	3	13	120	14	15.2	2500	6
Mean (SD)	28.3 (5.6)	2.5 (1)	1.3 (1)	6.2 (2.7)	34.6 (23.1)	10.5 (1.6)	9.7 (1.9)	712.5 (594.9)	3.6 (0.8)
Cases included	36	31 [†]	31 [†]	13 [†]	36	31 [†]	31 [†]	36	31 [†]

*P25 refers to the first quartile, P50 to the second quartile and P75 to the third quartile.

[†]Data from <36 case files used owing to missing information.

Hb = haemoglobin; SD = standard deviation.

Table 4. Summary statistics of laparoscopy cases (N=48)

Parameter	Age (years)	Gravidity	Parity	Estimated gestational age (weeks)	Surgical time (min)	Hb level pre surgery (g/dL)	Hb level post surgery (g/dL)	Blood loss (mL)	Hospital stay (days)
Minimum	15	1	0	3	20	3.7	6.5	0	1
P25*	23	2	0	6	30	9.1	8.2	100	2
P50*	29	3	1	8	42.5	10.9	10.4	250	2
P75*	33	4	2	8	60	12.6	11.65	500	3
Maximum	42	8	7	18	115	14.1	14.1	2000	5
Mean (SD)	28.7 (5.7)	2.8 (1.5)	1.4 (1.5)	8.2 (3.2)	44.9 (19.2)	10.5 (2.6)	10 (2)	386.5 (394.2)	2.5 (0.7)
Cases included	48	39 [†]	39 [†]	29 [†]	48	40 [†]	40 [†]	48 [†]	40*

*P25 refers to the first quartile, P50 to the second quartile and P75 to the third quartile.

[†]Data from <48 case files used owing to missing information.

Hb = haemoglobin; SD = standard deviation.

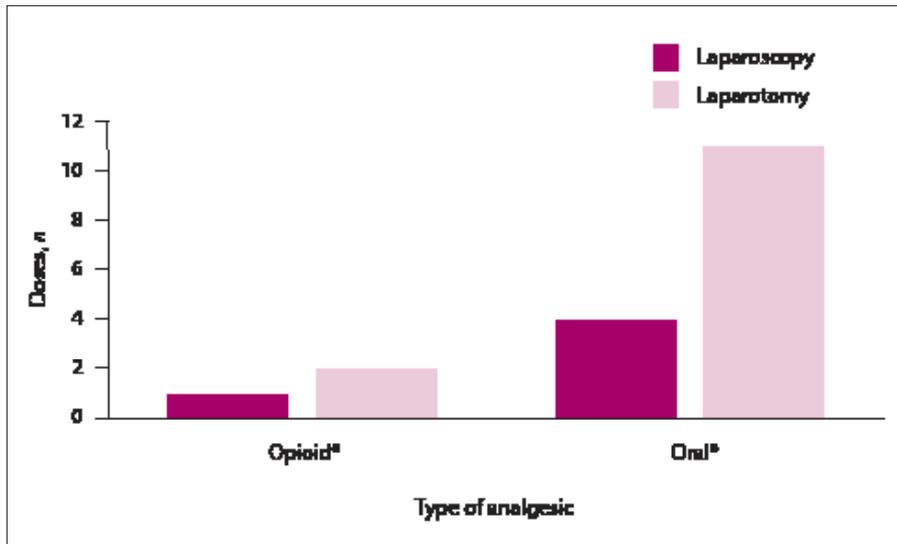


Fig. 2. Analgesic use per surgical group.

not significantly different between the two surgical groups ($p=0.8$). Only one patient in the laparotomy group required two units of fresh frozen plasma ($p=0.3$).

In total, four complications occurred: three in laparotomy patients (one case of sepsis and two cases of postoperative haemorrhage) and one in a laparoscopy patient (urinary retention).

Discussion

We identified 84 cases from the 2 years' records (42 cases per year), which exceeded the minimum requirement of 81 for adequate statistical power. Electronic theatre reports were found for all 84 cases, but complete patient files with complementary handwritten notes were available for only 71 cases, possibly owing to human error (e.g. incorrect identification or filing of records). Despite some consequent bias in the summary data, adequate data were available in the theatre records to allow us to fulfil our primary study objective (i.e. determining the rate of laparoscopy v. laparotomy for EP).

Results showed a laparoscopy rate of 57.1% compared with 42.9% for laparotomy, which is in keeping with international literature.

We also found that laparoscopic surgeries were preferentially performed during daytime hours. This may have been due to factors such as a consultant, with high-level surgical skill, being on duty during the day or a patient being stable enough to delay surgery until daytime hours. Junior doctors on duty after hours may not have had the experience and skill to perform laparoscopic procedures safely and may have felt more confident performing open surgery when a consultant was not available on site.

Consultants preferentially opted for laparoscopic management compared with junior doctors; as safe laparoscopy requires advanced training and surgical skill, this is not an unexpected finding. However, from the results in Fig. 1, it is evident that junior doctors are indeed being taught these skills and that they are performing laparoscopic management of EPs, albeit still in limited cases.

The majority of cases were found to be ruptured (79%), as defined by blood being visible in the abdomen at surgical entry and required urgent treatment. However, in four unruptured cases, where the patients would have been stable enough to qualify for less invasive laparoscopic management, laparotomy proceeded instead owing to a junior doctor being on call, unable to offer laparoscopic surgery. Our study further suggests that the presence of blood in the pouch of Douglas in a haemodynamically stable patient is not a contraindication to laparoscopic surgery for ectopic pregnancy.^[8]

Patients who were treated laparoscopically required significantly less analgesia, showed less blood loss and spent fewer days in hospital than those who received open surgery. Although laparoscopic surgery took, on average, approximately 13 minutes longer than a laparotomy and was found to be a statistically significant difference, the difference is deemed small and does not outweigh the cost benefits of laparoscopy, both for the patient and for the hospital. The complication rate was low in the laparoscopy group, with only one patient presenting with urinary retention postoperatively.

Conclusion

This study suggests that with the right training programme and equipment in place, laparoscopy treatment rates comparable to that seen in high-income countries are possible. In addition, laparoscopy appears to be a feasible treatment option for EP in our setting and is associated with significantly better outcomes for the patient with regard to pain management and hospital stay. The benefit of laparoscopy makes this the treatment modality of choice when surgical intervention for EP is required. Shorter hospital stays and less analgesic use also reduce costs for the hospital. We recommend

that laparoscopic training and equipment be made available in all hospitals in SA to provide EP patients with optimal surgical treatment.

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