

# Clinical assessment of ectopic pregnancy in a tertiary care hospital: An observational study



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## ABSTRACT

**Background:** Ectopic Pregnancy is defined as pregnancy that occurs outside normal uterine cavity in an aberrant site. In developing countries like India, late presentations with tubal rupture and haemodynamic instability, causes maternal morbidity and mortality.

**Aims and Objectives:** To determine the incidence, risk factors, clinical features, associated with ectopic pregnancy in a tertiary care hospital and interventions for early diagnosis and conservative management. **Materials and Methods:** In this Time bound, Observational descriptive study with Longitudinal design conducted at Dept of G&O, R. G. Kar Medical College and Hospital, between March 2021 to August 2022. 138 participants, suspected to have ectopic pregnancy were enrolled for the study and detailed history taking and physical examination was done. Basic investigations including CBC, ABO & RH typing, UPT and USG were done. Post-op HPE reports were collected and final diagnosis was made.

**Results:** 63.8% of the study population belonged to 21 to 30 years of age. 63.7% patients presented with >5 wks. - 8 wks. of amenorrhoea. 18.1% of the study population were sterilized. The most common risk factor and clinical symptom was h/o Previous C-section (31.8%) and abdominal pain present in 131(94.9%), 44 (31.9%) participants had all the three classical symptoms with 100 % specificity. Forniceal fullness/tenderness was the most specific examination finding. The most common USG finding was Adnexal mass with empty Uterine cavity with Free fluid (49.2%). Most of the patients were managed with Partial Salpingectomy (30.4%). The final diagnosis of ectopic was made in 129 patients, which was confirmed by HPE reports in 124 patients. 5 patients underwent medical treatment.

**Conclusion:** Early diagnosis before rupture and referral are the key factor in reducing the maternal morbidity and mortality.

**Key words:** Ectopic pregnancy; Risk factors; Presenting complaints; Early diagnosis; Management modalities; Prevent morbidity and mortality

## INTRODUCTION

Ectopic pregnancy is defined as pregnancy that occurs outside normal uterine cavity due to implantation of fertilized ovum in an aberrant site like the Fallopian tube: Ampullary (79.6%); isthmic (12.3%); fimbria (6.2%), ovary (0.15%) and abdominal cavity (1.4%) or in an abnormal position within uterus cornual (1.9%), and cervical (0.15%).<sup>1</sup>

An accurate history taking and physical examination is considered to be the most important in diagnosing

ectopic pregnancies.<sup>2</sup> Classical triad of ectopic pregnancy (amenorrhoea, bleeding per vaginum [PV], abdominal pain) occurs only in 50% of the cases.<sup>3</sup>

It has been reported by Yadav et al., that ectopic pregnancies account for 7.1% of all pregnancy related deaths in rural India.<sup>4</sup> The main causes of these deaths are due to wrong diagnosis, delayed diagnosis, and late admissions with severe hypovolemic shock due to several factors such as delay in seeking healthcare, absence of investigations (such as beta-human chorionic gonadotropin [ $\beta$ -hCG], progesterone assays, and transvaginal sonography) and

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lack of suspicion in the diagnosis of ectopic pregnancy by inexperienced clinicians, early diagnosis is almost impossible in most developing countries. Main risk factor is the prior tubal damage due to any cause.<sup>5</sup> Chlamydial infection was found to be the risk factor for 30–50% of all ectopic gestation.

Ectopic pregnancy could be considered as a public health indicator in the developing world, because of its emergency presentation and life-threatening event providing an overall picture of a health system capacity to handle with the diagnosis and management of emergency situations. Education of the women regarding its signs and symptoms and motivation by them to visit a health-care facility on the appearance of these symptoms could decrease the morbidity and mortality associated with the same.

### Aims and objectives

- To estimate the incidence, risk factors, clinical manifestations and outcome following different management protocol.
- To estimate the morbidity and mortality with respect to different types of presentation and management.
- To understand the need for clinical assessment in order to diagnose early and provide urgent intervention and also to lean towards the possibility of conservative approach in order to preserve fertility.

## MATERIALS AND METHODS

This time bound, observational descriptive study with longitudinal design was done at R. G. Kar Medical College and Hospital, Kolkata, among the patients admitted in Department of Obstetrics and Gynecology from March 2021 to August 2022 after taking necessary ethical permission from hospital ethics committee.

The purpose of this study was to determine the incidence, risk factors, clinical features, diagnostic methods, treatments, morbidity, and mortality associated with ectopic pregnancy in a tertiary care hospital and analysis of various aspects of ectopic pregnancy with a view to suggest interventions to join the global trend of early diagnosis and conservative management.

A total of 138 participants who were suspected to have ectopic pregnancy were enrolled for the study after fulfilling the inclusion and exclusion criteria. (A sample size of 140 produces a two-sided 95% confidence interval; however, two candidates were lost to follow-up). The final diagnosis of ectopic pregnancy was made in 129 patients, which was confirmed by histopathological examination (HPE) reports in 124 patients. Five patients underwent medical treatment.

The formula used is  $n = \{(Z_{1-\alpha/2})^2 \times P \times Q\} / L^2$  where  $Z_{1-\alpha/2}$  = Standard normal deviation and as a value of 1.96, considering 95% confidence level.

$P=63.15$  (Expected proportion of cases obtained from a previous study done by Sudha, Thangaraj et al.,<sup>13</sup> [2016] on ectopic pregnancy at Thanjavur Medical College),  $Q=100-P$ ,  $L$ =Precision in absolute term ( $L=8$ ).

Our inclusion criteria were all consenting women who were diagnosed with ectopic pregnancy (acute and chronic; ruptured and unruptured, tubal abortion, cornual ectopic, cesarean scar ectopic, cervical ectopic, and ovarian pregnancy) and managed in Department of Obstetrics and Gynecology department of R. G. Kar Medical College and Hospital and our exclusion criteria were non-consenting patients with ectopic pregnancy.

A pro forma enlisting the demographics characteristics, such as the age of female, number of previous pregnancies, risk factor, clinical presentations, number of previous pelvic surgeries, history of pelvic inflammatory disease (PID), history of contraception, sterilization status duration of subfertility, number of blood and blood products transfused, duration of hospital stay, and duration of intensive care unit (ICU) stay was recorded.

Data collection was done by detailed history taking and relevant physical examination. A detailed history was taken from the patient (if the patient was in shock the history was taken retrospectively). After taking history, a physical examination was done especially for vital signs, abdominal examination, per vaginal examination, cervical excitation test, and culdocentesis when needed.

The basic investigations including hemoglobin, renal function test, blood grouping, and rhesus typing, urine pregnancy test (UPT), and ultrasound (USG) examination were done in all patients. Additional investigations such as serum  $\beta$ -hCG, Doppler study, computed tomography, and magnetic resonance imaging were ordered in case of doubtful diagnosis.

All data were collected in a structural data form and analyzed for descriptive statistics.

Postoperatively, HPE reports were collected from the pathology department and final diagnosis was made.

Data were summarized in tables and figures. For the calculation of sensitivity, specificity, and positive and negative predictive values for the diagnosis of ectopic pregnancy, 2-by-2 contingency tables were used. Ethical clearance was obtained from the RGKMCH ethical

committee. All details of the patients remained confidential. All patients were treated according to the hospital protocol.

For statistical analysis, data were entered into a Microsoft Excel spreadsheet and then analyzed by Statistical Package for the Social Sciences (SPSS) (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5.

## RESULTS

### Demography

The demographic profile of our subjects is given in Table 1. In 138 samples analyzed, 63.8% of the study population belongs to 21–30 years of age and 49 (35.55%) patients were more than 30 years of age (Table 1).

### Parity status

Among the study population, 74.5% were multigravida and 24.6% were primigravida.

### Period of amenorrhea

Last menstrual period was not known in 19 (13.8%) patients, 88 (63.7%) patients were presented with >5–8 weeks of amenorrhea, 29 (21.0%) patients were presented with >8–11 weeks of amenorrhea, and 2 (1.4%) patients had more than 11 weeks of amenorrhea.

### UPT

UPT was positive in 122 patients (88.5%). Negative in 6 patients (4.3%). Weakly positive in 10 patients (7.2%).

### Time since sterilization

Out of 138 participants, 25 (18.1%) were sterilized. The duration between the sterilization and the occurrence of ectopic pregnancy was 1–3 years in 7 (28%) patients, 4–10 years in 16 (64%) patients, and >10 years in 2 (8%) patients (Table 2).

### Risk factors

One or multiple risk factors were identified among 101 (73.2%) cases whilst no risk factors were identified in 37 (26.8%) cases. The most common risk factor was h/o Previous lower segment cesarean section (LSCS) (31.8%) followed by h/o Tubal sterilization and h/o previous abortions (managed medically or surgically (18.1%)) and PID (13.7%).

### Clinical symptoms

The most common clinical symptom among patients suspected of Ectopic pregnancy was abdominal pain present in 131 (94.9%) of participants followed by amenorrhea in 100 (72.5%) and Bleeding PV in 59 (42.8%), 44 (31.9%) participants had all the three symptoms. Some patients also presented with vasovagal symptoms

**Table 1: Age of the study participants (n=138)**

Age	No. of participants	Percentage
0–20	1	0.7
21–30	88	63.8
31–40	47	34.1
41–50	2	1.4

n=Number of the participants suspected to have ectopic pregnancy

**Table 2: Duration between sterilization and occurrence of ectopic pregnancy**

Years	No. of cases	Percentage
1–3	7	28
4–10	16	64
>10	2	8

10 (7.2%) and gastrointestinal symptoms 11 (8%). Out of the total 129 confirmed cases of ectopic pregnancy, the positive predictive value for patients with bleeding PV only, amenorrhea along with bleeding PV and classical triad was 100% (Table 3).

### Clinical signs

There were no abdominal signs in 46 (33.3%) patients. Abdominal distension was present in 57 (41.3%) patients. Abdominal tenderness/guarding was present in 78 (56.5%) patients. Abdominal distension with tenderness/guarding was presented in 43 (31.2%) patients.

On per vaginal examination, 38 (27.5%) patients had no positive findings. Others had one or more positive findings as mentioned below. Forniceal fullness was present in 39 (28.3%) patients. Forniceal tenderness was presented in 79 (57.2%) patients. Adnexal mass was present in 3 (2.8%) patients. Forniceal fullness and tenderness were present in 19 (13.8%) patients. Forniceal tenderness and adnexal mass were present in 2 (1.4%) patients. Cervical motion tenderness was done in 138 patients and found positive in 100 (72.5%) (Table 4).

### USG findings

Routine USG examination including both transabdominal and transvaginal scans were done in all patients on admission. The following findings were noted (Table 5). Empty uterine cavity with free fluid in the pouch of Douglas was the most specific finding with highest positive predictive value (Table 6).

### Management of patients with suspected ectopic pregnancy

Partial salpingectomy was performed in most of the patients 42 (30.4%) followed by total salpingectomy in 29 (21.01%) and unilateral Salpingo-oophorectomy in 20 (14.5%) of participants (Table 7).

**Table 3: Sensitivity, specificity, positive and negative predictive value of clinical symptoms in diagnosing ectopic pregnancy (n=138)**

Patients symptoms	Ectopic pregnancy		Sensitivity	Specificity	Positive predictive value	Negative predictive value
	Yes	No				
Amenorrhea						
Yes	95	5	73.6	44.4	95	10.5
No	34	4				
Abdominal pain						
Yes	124	7	96.1	22.2	94.7	28.6
No	5	2				
Bleeding PV						
Yes	59	0	45.7	100	100	11.4
No	70	9				
Amenorrhea+pain abdomen						
Yes	90	4	69.8	55.6	95.7	11.4
No	39	5				
Amenorrhea+bleeding PV						
Yes	47	0	36.4	100	100	9.9
No	82	9				
Abdominal pain+bleeding PV						
Yes	56	0	43.4	100	100	11
No	73	9				
Classical triad						
Yes	44	0	34.1	100	100	9.6
No	85	9				

n=Number of the participants suspected to have ectopic pregnancy, PV: Per vaginum

**Table 4: Sensitivity, specificity, positive and negative predictive value of clinical signs in diagnosing ectopic pregnancy (n=138)**

Patients symptoms	Ectopic pregnancy		Sensitivity	Specificity	Positive predictive value	Negative predictive value
	Yes	No				
Abdominal distension						
Yes	55	2	42.6	77.8	96.5	8.6
No	74	7				
Abdominal tenderness/guarding						
Yes	74	4	57.4	55.6	94.9	8.3
No	55	5				
Abdominal distension+tenderness/guarding						
Yes	42	1	32.6	88.8	97.7	8.4
No	87	8				
Forniceal fullness						
Yes	37	2	78.72	97.8	94.87	89.89
No	10	89				
Forniceal tenderness						
Yes	74	5	93.6	91.5	93.6	91.5
No	5	54				
Forniceal fullness+forniceal tenderness						
Yes	16	3	80	97.4	84.2	96.6
No	4	115				

n=Number of the participants suspected to have ectopic pregnancy

Out of 138 participants, 36 (26.1%) patients required no blood transfusion and 102 (73.9%) required more than one unit of blood transfusion. Forty-eight (34.8%) patients required ICU care 1–2 days. One patient required ventilator support. Most of the patients was discharged on 7<sup>th</sup> or 8<sup>th</sup> post-operative day.

#### Follow-up

Out of 138 patients, the final diagnosis of ectopic pregnancy was made in 129 patients, which was confirmed

by HPE reports in 124 patients. Five patients underwent medical treatment. Hence, tissue was not available for HPE diagnosis. However, all five patients responded to medical management and were treated successfully. Corpus luteal cyst was diagnosed in three patients only after HPE reports. One patient had dermoid cyst, which was confirmed by HPE. Location of pregnancy was not identified in one patient. Heterotopic pregnancy was confirmed by HPE in one patient. One patient was



diagnosed to be having an ovarian cyst per operatively. Final diagnosis of ovarian cyst was made in two patients only after HPE report.

## DISCUSSION

In the present study, the incidence of ectopic pregnancy was 8.7 per 1000 deliveries. In a study conducted by Attri et al., the incidence was 9.1/1000 pregnancies.<sup>6</sup> The majority of the patients (63.8%) were in the age group of 21–30 years in our study. Similar results were found in Parmar et al., and Ara et al., studies.<sup>14</sup> This corresponds to the age of peak sexual activity and reproduction. There are studies stating that age related tubal changes increase the incidence of ectopic pregnancy.<sup>6</sup> In our study, multigravida (75.4%) were found to be more prone to have an ectopic pregnancy. This

result was similar to other studies conducted by Samantaray et al., and Chaudhary et al.<sup>15</sup>

The majority (54.3%) of the patients presented with 5–8 weeks of amenorrhea representing the time period required for the growing ectopic gestation to distend the tube and cause symptoms. These results are consistent with those from Attri et al., and Choubey et al.<sup>16</sup>

The most common risk factors among the study population were H/O previous LSCS, tubal surgeries, previous ectopic pregnancies, prior H/O abortions, H/O infertility, and PID. Similar risk factors were noted in various other studies.<sup>9</sup> The increasing trend in cesarean section was found to be associated with increased risk of ectopic pregnancy. 6 patients had H/O medical termination of pregnancy pills intake. The significance of this risk factor needs further studies. Seven patients gave history of ovulation induction. Advancement in infertility treatment was associated with significant risk of ectopic pregnancy. In our study, 25 (18.1%) cases were post sterilization ectopic pregnancies. Among the sterilization methods, concurrent and puerperal sterilizations were found to be associated with higher number of ectopic pregnancies. Ectopic pregnancies most commonly occur 4–10 years after the sterilization surgery.

The most common presenting symptom was abdominal pain which was found in 94.9% of patients, followed by amenorrhea in 72.5% of the patients. The classic triad was present only in 31.9% of cases. In Samantaray et al., study, 90.6% reported pain abdomen, 75.5% reported amenorrhea and the classical triad was present 41.5% cases.<sup>8</sup> In our study, the classic triad has 100% specificity and positive predictive value, but low sensitivity.

The most common examination findings were tachycardia (51.4%) and hypotension (12.3%). About 6.5% of the patients presented with shock. Tachycardia was not present in all cases of ruptured ectopic pregnancy. About 48.6% of patients were severely anemic with hemoglobin <5 g%.

**Table 5: Ultrasound features as found in the study subjects (n=138)**

Ultrasound findings	No of participants	Percentage (%)
Empty uterus, adnexal mass	15	10.9
Empty uterus, free fluid	34	24.6
Adnexal mass with empty uterine cavity with free fluid	68	49.2
Bicornuate uterus, free fluid	1	0.7
Bicornuate uterus, no Gsac	1	0.7
Bicornuate uterus with Gsac in both horns	1	0.7
Intrauterine Gsac with free fluid	2	1.4
Extrauterine Gsac with fetal pole and cardiac activity	7	5.1
Extrauterine Gsac with Fetal pole and without cardiac activity	1	0.7
Extrauterine Gsac without a fetal pole	3	2.2
Empty uterus with ovarian follicle	2	1.4
IUCD <i>in situ</i> , adnexal mass, and free fluid	1	0.7
Adnexal mass with localized fluid collection	2	1.4
Total	138	100

n=Number of the participants suspected to have ectopic pregnancy

**Table 6: Sensitivity, specificity, and positive and negative predictive value of ultrasound findings in diagnosing ectopic pregnancy (n=138)**

Patients symptoms	Ectopic pregnancy		Sensitivity	Specificity	Positive predictive value	Negative predictive value
	Yes	No				
Adnexal mass with empty uterine cavity						
Yes	13	2	10.7	77.8	86.7	5.7
No	116	7				
Empty uterine cavity along with free fluid						
Yes	33	1	25.6	88.9	97.1	7.6
No	96	8				
Adnexal mass with empty uterine cavity with free fluid						
Yes	64	4	52.7	55.6	94.1	7.1
No	65	5				

n=Number of the participants suspected to have ectopic pregnancy

**Table 7: Surgical and medical management of people with suspected ectopic pregnancy (n=138)**

Management	No. of patients	Percentage
Partial salpingectomy	42	30.4
Total Salpingectomy	29	21.01
U/L Salpingo-oophorectomy	20	14.5
B/L Salpingo-oophorectomy	1	0.7
SO +Salpingectomy	16	11.6
B/L total salpingectomy	16	11.6
Rt. Cornual resection	2	1.4
Removal of Rt. ectopic horn	1	0.7
Hysterectomy	1	0.7
Rt. Total salpingectomy+ovarian cystectomy	1	0.7
Left total salpingectomy+manual vacuum aspiration	1	0.7
Left ovariectomy+D and C	1	0.7
B/L ovarian cystectomy	1	0.7
Negative laparotomy+D and C	1	0.7
Medical management, MTX-multidose	5	3.6
Total	138	100

n=Number of the participants suspected to have ectopic pregnancy

On per abdominal examination, abdominal tenderness (56.5%) was the most common finding. On per vaginal examination, forniceal tenderness (57.2%) was the most common finding. Cervical excitation test was positive in 72.5%. Culdocentesis was done only in 39 patients. Among them 38 were positive. In PV, the presence of adnexal mass has highest specificity and positive predictive value (100%).

UPT and USG examination were done in all patients. Serum  $\beta$ -hCG was sent only in hemodynamically stable patients with unruptured ectopic pregnancy to decide for medical management and in doubtful cases. UPT has highest (98.4%) sensitivity, but the specificity was low. In USG examination, an empty uterus, adnexal mass, and free fluid were strongly suggestive of ectopic pregnancy, especially in the presence of positive UPT.

Medical management criteria were applicable to 11 patients. Among them, only 5 patients had medical management. The remaining were multiparous women who wanted definitive surgery rather than medical management. Multi dose of methotrexate regimen was used in all five patients and were treated successfully.

In the surgically managed group, all 133 patients underwent laparotomy. Total/partial salpingectomy and salpingo-oophorectomy were the common surgeries performed. In developing countries, open method by laparotomy still remains the most commonly used management for ectopic pregnancy. However, the trend is changing toward laparoscopic surgery and conservative management. In

Kumari et al., study, the surgical management was by open method in all cases.<sup>10</sup> During laparotomy, 109 (79%) cases were found to be ruptured including one chronic rupture. In developing countries, still majority of cases present late with rupture. This was evidenced by many studies.<sup>11</sup>

Ampulla was the most common site of ectopic pregnancy found in 43.5% of the patients. This result was similar to other studies.<sup>12</sup> During laparotomy, 124 patients were found to be having ectopic pregnancy. One patient was found to be having a rare variety of pregnancy known as heterotopic pregnancy. One patient had negative laparotomy. One patient was found to be having dermoid cyst. One patient had ovarian cyst. Remaining five patients were diagnosed as ectopic pregnancy per operatively, then diagnosis was changed to gynecological lesions (three corpus luteal cyst and two simple ovarian cyst) after HPE report.

#### Limitations of the study

- Patients who didn't give consent to be a part of this study.
- Patients who were lost to follow up and didn't come back to the hospital with their histopathology reports and wanted to seek further treatment outside.

#### CONCLUSION

- Ectopic pregnancy is unique for its diversity of clinical presentations and atypical presentations. Strong suspicion is required for its early diagnosis
- UPT and USG should be advised to all reproductive age group patients presenting with abdominal pain, and bleeding PV with or without amenorrhea
- Sterilization could not rule out the possibility of an ectopic pregnancy
- Hence, we should advise the patient to come for check-up if she miss the periods as early as possible
- To join the global trend of conservative management for ectopic pregnancy, early diagnosis before rupture is important
- USG is the simple and gold standard diagnostic method for ectopic pregnancy in low resource settings and routine 1<sup>st</sup> trimester USG should be done to all pregnant woman
- UPT kits and sonographic equipments should be made available in all primary health centers and emergency gynecological units
- Early diagnosis and referral are the key factor in reducing the maternal morbidity and mortality
- Because of the high incidence of tubal rupture in our set up, community education is required to inform the women to attend the health facilities as early as possible once they have symptoms.

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