International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 13, No. 7, July 2024 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_13.7.2024.118

ORIGINAL RESEARCH

To study clinical profile and outcome assessment in women with ruptured ectopic pregnancy

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Revised date: 10 May, 2024 Acceptance date: 22 June, 2024

ABSTRACT

Introduction: Ectopic pregnancy is the second leading cause for maternal mortality in underdeveloped nations and is diagnosed with a combination of clinical and laboratory parameters. **Objective:** To study the socio-demographic factors associated with ruptured ectopic pregnancy and to assess the factors associated with near miss event. **Methodology:** 64 patients were included in a retrospective, cross-sectional observational study conducted at Maharishi Markandeshwar medical college and hospital Solan, Himachal Pradesh after approval from ethical committee detailed history, examination findings, laboratory investigations, ultrasound findings, intraoperative and post operative findings were recorded as well as course and events during the hospital stay were recorded. **Results:** Women in reproductive age group in herearly pregnancy presenting with abdominal pain, bleeding per vaginum should be ruled out for ectopic pregnancy. On ultrasound location and size of gestational sac with cardiac activity and fluid in peritoneal cavity can be assessed. Previous surgery, abortions or ectopic pregnancy, history of PCOD/ endometriosis/ PID, use of infertility treatment or oral contraception pills are high risk factors for ectopic pregnancy**. Conclusion**: Ectopic pregnancies are most frequent 3 AM emergencies which if not managed well can lead to near miss mortality.

Keywords: Ectopic pregnancy, ultrasound, beta Hcg

INTRODUCTION

An ectopic gestation is defined as an abnormal implantation in a site other than intrauterine and poses a risk to the life of the mother. Despite the advancements in diagnostics that allow for earlier discovery and treatment, bleeding from an ectopic pregnancy remains the primary cause of pregnancy related maternal mortality in the first trimester, accounting for 4% of all pregnancy related deaths.[1]

Ectopic pregnancy is the second leading cause for maternal mortality in underdeveloped nations, after first trimester abortions. In Southeast Asia region, the incidence of ectopic pregnancy has increased and varies between 0.25% to 1.9%. Late diagnosis and late referral cause high risk of ruptured ectopic pregnancy in developing nations, if undiagnosed and untreated, ectopic pregnancy can cause maternal death.[2]

Early diagnosis and choosing the optimal treatment approach leads to patient survival and reduced side effects. Ectopic pregnancy is sub-divided into tubal, non-tubal (cervix, ovary, abdomen, previous caesarean scar, the rudimentary horn of a uni-cornuate uterus) and heterotopic pregnancy. Women with ectopic pregnancy can present as asymptomatic to severe abdominal pain and hemodynamic shock. The manifestations of rupture may be acute with severe abdominal pain, shock, and hemoperitoneum or subacute with abdominal pain, amenorrhea, and vaginal bleeding.[3]

According to the available data, abnormalty in the structure or function of fallopian tube, infections, surgeries, congenital abnormalities, tumors, previous ectopic pregnancy, sexually transmitted infection, pelvis adhesions, tubal infections, intrauterine devices (IUD), conception by assisted reproduction, tubal surgery history, tubal sterilization, cigarette smoking and exposure to diethylstilbesterol in uterus, damage to ciliary motility can lead to ectopic pregnancy A history of previous tubal surgery or ectopic pregnancy carries the highest risk.[1]

The diagnosis of Ectopic pregnancy is made with a combination of clinical and laboratory examination parameters. Ectopic pregnancy can be diagnosed with

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human chorionic gonadotropin (hCG) levels, ultrasounds to determine gestational sac location and size with presence of fetal cardiac activity and at times with uterine curettage.[4] There is a dearth of studies done to determine the incidence of ruptured ectopic pregnancy in Himachal Pradesh (HP). This study shall be undertaken to find the incidence of Recurrent ectopic pregnancy in district Solan to identify the risk factors associated with the acute life-threatening emergency in order to make recommendation for appropriate measures to reduce the incidence by early identification and interventions. To study the clinical profile and outcome assessment in women with ruptured ectopic pregnancy.

MATERIAL AND METHOD

Study design: Retrospective observational, cross-sectional study.

Study duration: 12 months

Selection of patients: All patients admitted in Department of Obstetrics and Gynaecology at MMMCH Solan with Ruptured ectopic pregnancy.

Sample population: All patients admitted In Department of Obstetrics and Gynaecology at MMU Solan with ectopic pregnancy.

Ethical considertaion: This study was conducted after obtaining due approval from Institutional Ethical Committee. The data of patients with incomplete records were not be included. The data of the patients were kept confidential, the study did not impart any financial burden on the hospital.

Inclusion criteria: All patients admitted with Ruptured ectopic pregnancy with complete records.

Exclusion criteria: All patients admitted with ectopic pregnancy with incomplete records.

Sample size: The study included a minimum of 59 patients calculated using the formula; Sample size = {Z1-α/2 2 p(1-p)}/d2 Where, Z1-α/2 2 is standard normal variate p is expected proportion in population based on previous studies d is absolute error or precision.

METHODOLOGY

The present study was conducted in Department of Obstetrics and Gynaecology at Maharishi Markandeshwar Medical college and hospital, Solan, Himachal Pradesh and included all patients presenting with acute abdomen with ruptured ectopic pregnancy. After approval from internal ethical committee (IEC) and Medical Superintendent (MS) for access to data from medical record department. Recording of descriptive data will include Age, Marital Status, Parity, previous history of ectopic pregnancy, Site of ectopic pregnancy, Gestational age, History of infertility, conception 5 following Ovulation Induction, history of pelvic inflammatory disease (PID) and use of contraceptives, onset & duration of abdominal pain, Data of examination findings including vital signs. Relevant laboratory investigations were recorded such as complete blood count (CBC) and β-HCG levels. The outcome of the ruptured ectopic pregnancy was analysed by -Volume of hemoperitoneum need for blood transfusion, admission to ICU, Prolonged stay, wound infections, post-op morbidity and mortality.

STATSTICAL ANALYSIS

Statistical analysis was conducted using IBM SPSS statistic version 22. The data was tabulated in Microsoft excel. Quantitative data was expressed as mean and standard deviation. Qualitative data was represented as numbers and percentages. Relevant graphs and charts were used for pictorial representation of the data. Relevant tests of statistical significance were employed where applicable.

RESULTS AND OBSERVATIONS

TABLE 1: distribution of baseline details of the study population

Baseline characteristics	Frequency (n=64)	Percentage (%)
Marital status		
Married	64	64%
Unmarried	0	0
Age		
<18 years	0	0%
18-24 years	24	37.5%
25-30 years	15	23.4%
31-35 years	15	23.4%
>35 years	10	15.6%
Education status		
Primary	1	1.5%
Upper primary	22	34.3%
Secondary	14	21.8%
Senior secondary	14	21.8%
Graduate	12	18.7%
Post graduate	1	1.5%
Socioeconomic status		

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Upper	0	0%
Upper middle	7	10.9%
Lower middle	17	26.5%
Upper lower	28	43.7%
Lower	12	18.75%
Parity		
Nullipara	30	46.8%
Primipara	20	31.2%
Multipara	14	21.8%
Referral status		
Non referred	54	84.3%
Referred	10	15.6%
Gestational age		
<6 weeks	13	20.3%
6week 1 day to 8 weeks	36	56.2%
8week 1 day to 10 weeks	14	21.8%
10 weeks 1 day to 12 weeks	1	1.5%
Symptoms		
Amennorhoea	64	100%
Abdominal pain	60	93.75%
Vaginal bleeding/spotting	54	84.3%
Shock	8	1.25%
Fainting attack	10	15.6%
Triad	52	81.2%
Signs		
Shock	8	12.5%
Pallor	28	43.75%
Abdominal tenderness	50	78.12%
Abdomen guarding/ rigidity	12	18.7%
Cervical motion tenderness	64	100%
Palpable adnexal mass	14	21.8%
Cervical ballooning	0	0%
Hypotension	28	43.7%
Tachycardia	46	76.6%
Duration of abdominal pain		
Less than 6 hours	4	6.2%
6 hours-24 hours	48	75%
1 day – 7 days	7	10.9%
1 week- 3 week	1	1.5%

Amongst 64 women with ectopic pregnancy, all were married, 24(37.5%) belonged to the age group of 18-24 years and 30 (46.8) of them were nulliparous, 20 (31.2%) of them were primiparaous and 14(21.8%) of them were multiparous. Nearly 36(56.2%) were of gestational age between 6week 1 day to 8 weeks. 14(21.8) were of gestational age between 8week 1 day to 10 weeks. 28(43.75%) women were hypotensive and had pallor. 14(21.8%) of women had abdominal pain for 6- 24 hours.

TABLE 2: distribution according to blood investigations

Beta-HCG levels (mIU/ml)	Frequency (n=64)	Percentage (%)
<1500	8	12.5%
1500-3000	11	17.1%
3000-5000	16	25%
>5000	29	45.3%
Hemoglobin levels (gm/dl)		
<4	0	0%
4-6	13	20.3%
7-9	36	56.2%
10-11	9	14.0%
>11	6	9.3%

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29 women (45.3%) had beta Hcg levels > 5000 whereas 16 (25%) had between 3000-5000, 11 (17.1% had beta hch levels between 1500-3000. 36 (56.2% women had haemoglobin levels between 7-9 gm/dl. 13 (20.3%) had a further lower level of haemoglobin between 4-6 gm / dl whereas 9 women had haemoglobin between 10-11 gm/ dl.

TABLE 3: distribution according to ultrasound findings

Site of ectopic	Frequency (n=64)	Percentage
Tubal	59	92.1%
Ovarian	1	1.5%
Cervical	1	1.5%
Horn of uterus	1	1.5%
Caesarean scar	2	3.1%
Abdominal	0	0%
Heterotopic	0	0%
Gestational sac		
Ruptured	50	78.1%
Unruptured	14	21.8%
Size of gestational sac		
<3	13	20.3%
3-4	11	17.1%
≥5	40	62.5%
Free fluid		
Present	50	78.1%
Absent	14	21.8%

Out of 64, 59 (92.1%) women had tubal ectopic pregnancy whereas there were 1.5% case of each ovarian, cervical, horn of uterus types of ectopic pregnancy There were 2 (3.1%) previous caesarean scar ectopic. There were 50 (78.1%) ruptured gestational sac and 14 (21.8%) unruptured gestational sac. The size of gestational sac was >5 in 40 (62%) women and <3 in 13 (20.3%) and 3-4 in 11 (17.1%) women. There was presence of free fluid in 50 (78.1%) women.

TABLE 4: ectopic pregnancy distribution according to outcome, location & type of surgery

Outcomes	Frequency(n=58)	Percentage
Ruptured	40	68.9%
Unruptured	11	18.9%
Abortion	7	12.0%
Chronic	0	0%
Location		
Fimbrial	1	1.7%
Ampullary	44	75.8%
Isthmus	12	20.6%
Interstitial	1	1.7%
Type of surgery		
Salpingectomy with tubal sterilisation	15	25.8%
Salpingectomy	34	58.6%
Salpingotomy	0	0%
Salpingostomy	15	25.8%

Out of total 58 ectopic pregnancy, 40 (68.9%) were ruptured, 11 (18.9%) were unruptured and 7 (12%) were cases of abortion. 44 (75.8%) were located at ampulla of fallopian tube whereas 12 (20.6) were on isthmic site. Remaining 1.7% were found on fimbrial and interstitium of fallopian tube. A total of 34(58.6%) underwent salpingectomy whereas 15 (25.8%) had salpingectomy with tubal sterilisation and salpingostomy each.

TABLE 5: distribution of various clinical parameters

Clinical Parameters	Frequency(n=64)	Percentage
History of Abortion	24	37.5%
History of ectopic pregnancies	7	10.9%
Use of Contraception	34	53.1%
History of D & C	10	15.6%
History of infertility	40	62.5%

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History of endometriosis	6	9.3%
History of PCOD	22	34.3%
History of PID	14	21.8%

40 (62.5%) women had a history of infertility, 34 (53.1%) women used contraceptives, nearly 24(37.5%) women had a history of abortion and 22 (34%) had a history of PCOS. 14(21.8%) women also had a history of pelvic inflammatory disease.

TABLE 6: distribution according to method of contraception, duration and complications

Types	Frequency (n=34)	Percentage
Barrier method	5	14.7%
Spermicides	0	0%
Intrauterine devices	5	14.7%
Oral contraceptive pills	16	47.0%
Emergency pills	0	0%
Implants	4	11.7%
Surgical	4	11.7%
Duration		
<6 months	9	14%
6 months to 1 year	16	25%
>1 year	9	14%
Complication		
Irregular cycles	1	2.9%
Heavy menstural bleeding	1	2.9%
Oligomenorhoea	1	2.9%
Intermenstrual spotting	1	2.9%
Misplaced iuds	2	5.8%
Latex allergy	0	0%
Dysmenorhoea	6	17.6%

Oral contraceptive pills were the most frequent 16 (47%) method of contraception used followed by barrier method and intrauterine device (14.7%) each followed by implants and surgical method (14%) each. 16 women (25%) used contraceptive for 6 months to 1 year. And 9 (14%) used contraceptive for < 6 months. 6 (17.6%) had dysmenorrhoea as an associated complication of contraceptive use, whereas 2.9% women faced irregular cycles, heavy menstrual bleeding, oligomenorrhoea, intermenstrual spotting each.

TABLE 7: distribution according to infertility treatment

Infertility treatment	Frequency (n=40)	Percentage
Ovulation induction	30	75%
IUI	17	42.5%
IVF	10	25%

30 (75%) women took ovulation induction drugs, whereas 17 (42.5%) had an intrauterine insemination. 10(25%) had an IVF.

TABLE 8: distribution of various intraoperative findings

Type of Anaesthesia	Frequency (n=64)	Percentage
Spinal anaesthesia	62	96.8%
General anaesthesia	2	3.12%
Hemoperitoneum		
Absent	14	21.8%
Less than 500ml	42	65.6%
500ml- 1L	8	12.5%
More than 1L	0	0%
Site of ectopic		
Tubal	58	90.6%
Ovarian	2	3.12%
Cervical	1	1.56%
Horn of uterus	1	1.56%
Caesarean scar	2	3.12%
Abdominal	0	0%

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Heterotopic	0	0%
Intra operative blood transfusion		
Yes	13	20.3%
No	51	79.6%

In 42(65.6%) women there was presence of haemoperitoneum of less than 5900 ml. Whereas 8 (12.5%) women had hemoperitoneum between 500ml and 1 L. 58 (90.6%) women had a tubal ectopic pregnancy, 2 (3.12%) had an ovarian and caesarean scar ectopic each, whereas 1 (1.5%) had a cervical and horn of uterus ectopic each. In 13(20.3%) intraoperative blood transfusion was required.

TABLE 9: distribution of various post operative events

ICU Admission	Frequency (n=64)	Percentage
Yes	19	29.6%
No	45	70.3%
Mean duration of ICU stay	22 hours	
Blood transfusion		
Yes	36	56.2%
No	28	43.75%
Prolonged stay		
Yes	7	10.9%
No	57	89.0%
Wound Infection		
Yes	4	6.2%
No	60	93.7%
Other complications		
Yes	2	3.12%
No	62	96.8%
Near miss events	17	

Out of 64 women 19 (29.6%) had an ICU admission and their mean ICU stay was 22 hours.
36 (56.2%) women were given blood transfusion post operatively, 28 (43.7%) were not given any sort of blood transfusion. 4 (6.2%) had a wound infection at incision site. There were nearly 17 near miss events seen.

DISCUSSION

This is a retrospective observational study and aims to find the clinical profile and outcome assessment in women with ruptured ectopic pregnancy. Amongst 64 women with ectopic pregnancy all were married and mainly were of 18-24 age group and belonged to upper lower-class strata (34.3%), whereas in a study by Namika et al.[2], 97.2% were married whereas 2.8% (2cases) were single. 45.8% (33 cases) were between 26–30-year-old, two cases were under age of 20 years, around 25% were nullipara, 38% were primipara and 36% were multipara. Nearly half of them were nullipara and had a gestational age of 6week 1 day to 8 weeks (56.2%).

All of the patients presented with amenorrhoea and more than 90% with complaints of vaginal bleeding/ spotting. almost all patients presented with cervical motion tenderness and nearly 80% with abdominal tenderness and tachycardia whereas in a study by Answara et al.[4], the classical triad of ectopic pregnancy is found in 28-29%, whereas in a study by Namika et al., amenorrhoea was seen in 91.6% and the classic triad in about 58% cases.

In about 45% patient's beta hcg levels were more than 5000.Goksedef et al. concluded that > 5000IU/ml is a significant risk for rupture[5]

Out of total ectopic, 92% were tubal ectopic and 78% amongst those were ruptured. there was presence of free fluid in 78% cases.69% of tubal ectopic were ruptured and were present at ampulla of fallopian tube, and salpingectomy was the main stream of intervention for them whereas in a study by Behera et al right-side tubal pregnancy is more common than left side. Most common was ampulla of fallopian tube, 16%were found in isthmus and 6% had cornual pregnancy[6]

63% of patients presented with history of infertility as the main clinical parameter according to a study by job-spira et al, neither past history of any pelvic infection nor operations for infertility treatment was associated with elevated rupture risk[7]. Ovulation induction was done in 75% of total patients in the past whereas 47% of them also gave the history of oral contraceptive drug intake, dysmenorrhoea was the leading complication (17.6%).

While managing the patient 96.8% of them were given spinal anaesthesia. there was presence of less than 500ml hemoperitoneum in 65.6% patients. There was no need of intraoperative blood transfusion in 79.6% patients, whereas 56.2% of patients were transfused blood in postoperative period whereas in a study by orazulike et al, nearly 50% of ruptured ectopic were admitted with shock and 85% of cases were found to be with hemoperitoneum of more than 500ml of blood[8] and 29.6% had an ICU admission

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with 10.9% of them having a prolonged stay and 6.2% acquiring a wound infection.

In this study we interpreted that women between age of 18-24 years , especially nullipara have higher incidence of ectopic pregnancy. Ectopic pregnancy is usually diagnosed between 6 to 8 weeks period of gestation. In current study, all patients presented with amenorrhoea followed by acute abdominal pain which was less than 24 hours in onset or vaginal bleeding. only 80 percent patients approximately had classical triad of ectopic pregnancy. The most common site of ectopic was found to be ampulla of fallopian tube with beta hcg levels more than 3000 in 70 percentage of cases. Because this study was conducted at a tertiary care centre most of the patients presented with ruptured gestational sac with mean sac diameter of 5mm or more with free fluid in cavity. History of infertility treatment, previous ectopic pregnancies or abortions, contraceptive use or recurrent PID are risk factors for ectopic pregnancies

CONCLUSION

In conclusion, this study shows that incidence of ectopic pregnancy can be reduced by preventing associated risk factors. All women belonging to reproductive age group should be educated regarding ectopic pregnancy. It is a major cause of maternal morbidity and mortality in developing nations. Health care workers should always have suspicion of ectopic pregnancy in high-risk women unless ruled out. Early screening and diagnosis will decrease incidence of ruptured ectopic, thus improving maternal outcome.

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