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### **Original Research Article**

### Ectopic pregnancy: an observational study in a tertiary care centre of Southern Rajasthan, India

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### ABSTRACT

**Background:** One among the three chief obstetric causes of bleeding in first trimester, ectopic pregnancy is the first thing to rule out as a gestation is suspected. The present study observes and analyses sociodemographic distribution, risk factors, presentation, diagnosis and treatment modalities in a tertiary care centre.

**Methods:** An observational cross-sectional study, conducted among patients who were diagnosed and managed in department of obstetrics and gynaecology of a tertiary care centre. Data analyzed and explained as frequency, percentage, mean and standard deviation.

**Results:** Age group between 21 to 30 years (69.9%) and multigravida (68.5%) are high risk for ectopic pregnancy (EP). Menstrual history was regular in 86.3%. Risk factors identified were previous abortion (30%) and history of pelvic inflammatory disease (30%). In 80.9% pain in abdomen was presenting complaints followed by bleeding per vaginum (60%), amenorrhoea (60%) and nausea and vomiting (32.9%). Right salpingectomy was most common in 43.8%, followed by left salpingectomy in 28.8%, methotrexate in 15.1%, left salpingo-ophorectomy in 5.5%, right salpingo-opherectomy in 5.5% and removal of tubal abortion in 1.3% patients. Laparoscopy was chosen route in majority 64.4% patients.

**Conclusions:** Ectopic pregnancy - a gynecological catastrophe as well as a major challenge to the reproductive performance of women worldwide, should be considered a relevant public health issue. By providing adequate materials, manpower, well-equipped health facilities as well as a prompt and efficient referral system, good access roads and efficient transportation, will ensure early presentation in hospitals and prompt management of cases.

Keywords: Blood transfusion, Ectopic pregnancy, Laparoscopy, Management, Risk factors

#### **INTRODUCTION**

Ectopic meaning other than the normal location when occurring in pregnancy, can be devastating. One among the three chief obstetric causes of bleeding in first trimester, is the first thing to rule out as soon as a gestation is confirmed. Catastrophic spectrum of ectopic pregnancy has been encountered by every obstetrician in her career, no matter the duration. Incidence varies worldwide between 0.25% to 2%.<sup>1</sup> Ectopic pregnancy still accounts for 3.5-7.1% of maternal deaths in India.<sup>2</sup>

Cultural norms, irregular lifestyle, variable presentations are few pieces of the puzzle.

As assisted reproduction incidences have raised, number of ectopic pregnancies has increased proportionately. With the advancements in imaging techniques, mortality has reduced over time as well as medical management has also become possible.

The present study observes and analyses sociodemographic distribution, risk factors, presentation, diagnosis, treatment modalities in a tertiary care centre.

### **METHODS**

This observational cross-sectional study was conducted among patients in department of obstetrics and gynaecology of Geetanjali Medical College and Hospital, Udaipur who were diagnosed with ectopic pregnancy and managed at hospital.

From January 2018 to December 2018, total sample size was not calculated and 73 patients were enrolled conveniently in study during the study period after their written informed consent.

### Inclusion criteria

- All the patients of ectopic pregnancy admitted in GMCH
- A pregnancy is called ectopic pregnancy when a fertilized ovum is implanted and develops outside the normal endometrial cavity
- All patients of age >18 years
- Patient who have signed written consent.

#### Exclusion criteria

- Patients who are not diagnosed with ectopic pregnancy following surgical intervention
- Patients' clinical presentation not consistent with sonographic findings.

Semi structured questionnaire, physical examination, laboratory investigation and radiological examination.

Enrolment of study participants and method of data collection.

Data collected on the basis of detailed history and clinical evaluation was done on all diagnosed ectopic pregnancy patients.

Detail history of the patient included: patient identity; complaints like history of amenorrhoea, acute pain abdomen, vaginal bleeding (if present - duration and nature), any attacks of syncope or vomiting, urinary or rectal symptoms, fever or other symptoms like backache or shoulder pain; detail menstrual and obstetric history including history of infertility or previous ectopic pregnancy, if present; history of previous surgery dilatation and curettage, tubal surgeries tuboplasty, appendicectomy or any other abdominal surgery; history of pelvic inflammatory disease or tuberculosis and treatment received for it; family history of tuberculosis; method of contraception - IUCD, oral contraceptive pill or permanent method

Clinical evaluation included general examination of patient - including presence of anaemia, shock, restlessness, cold and clammy extremities, pulse, respiration, blood pressure, temperature and cardiovascular and respiratory systems examinations; abdominal examination- for presence of mass, signs of free fluid in peritoneal cavity, guarding, rigidity, tenderness and presence of rare signs like Cullen's sign; vaginal examination for presence of bleeding, its nature, colour of the vaginal mucosa, position of the cervix, tenderness on movement of the cervix, size of the uterus, mobility and consistency, presence of mass and/or tenderness in any of the fornices; per-rectal examination whenever necessary for confirmation of findings.

On admission after a detailed examination, a sample of blood was drawn for blood grouping, Rh typing and cross-matching to arrange blood for transfusion. Investigations like Hb%, hematocrit, routine blood tests as advised by anaesthesiologists; total leukocyte count, differential count, ESR if necessary; urine pregnancy test and ultrasonography (USG) were carried out. In acute cases with the typical symptoms i.e. amenorrhoea, pain and bleeding which was confirmed by USG (wherever possible) followed by laparotomy/laparoscopy.

# Management of all diagnosed cases of ectopic pregnancy

Patients in shock were managed and taken for surgery. Basic investigations were done, along with viral markers. Blood transfusion was given intra-operative or postoperative as per the requirement of individual cases.

Prophylactic antibiotics were given to all patients at the time of induction of anaesthesia. Early ambulation (within 6 hours of surgery) was ensured as is the protocol in our institute. Patients were followed up in the postoperative period with special attention to the development of fever, abdominal pain, distension of the abdomen and wound sepsis. Patients were discharged with an advice to come for follow up after a week.

Surgery was performed under either spinal or general anaesthesia. Route chosen was either minimally invasive or open surgery. When patient was hemodynamically unstable or gross collection in peritoneal cavity was reported in ultrasonography, open surgical approach was chosen. Abdomen was opened with suitable incision. The site of ectopic gestation, status of the fallopian tube. contralateral tube, ovaries and uterus was noted. As majority of the patients had ruptured tubal gestation, a decision for removal of the tube i.e., salpingectomy was made. Drain was put whenever gross hemoperitoneum due to ruptured ectopic gestation was present, in turn preventing effective peritoneal fluid removal. The removed tissue (tube or gestational sac) was sent for histopathological examination. Pathological reports are however not studied in this study.

Methotrexate was given for medical treatment after urine pregnancy positive by serial hormonal assay (beta hCG) and imaging (ultrasonography). Criterion for medical management - no intrauterine g-sac or fluid collection on transvaginal sonography, beta hCG level less than 2000 mIU/ml, ectopic pregnancy less than 3.5 cm, no fetal cardiac activity. Gastrointestinal, hepatic, renal and hemopoeitc disease was excluded.<sup>3</sup>

Relevant investigations (hematocrit, liver function tests etc.) were done before initiation of medical management.

Doses of methotrexate given- single dose intramuscular injection (50 mg/m<sup>2</sup>). Every 3 days beta hCG levels was repeated until negative. A fall of 15 percent between day 4 and 7 should occur, otherwise a second dose was given. With multidose methotrexate, levels are measured at 48 hours intervals until they fall more than 15%. Once appropriately falling beta hCG levels are achieved in either regime, levels are then measured weekly until undetectable. Ultrasonographic assessment of reduction in the size of mass was done as and when required. Failure was judged if beta hCG levels plateaus or rises or tubal rupture occurs.

Follow up on outpatient basis, but if any issue of patient compliance, patient condition or safety of the treatment was present- hospitalization was offered.

### Ethical consideration

Study was ethically approved by Institutional Research Review Committee and Institutional Ethical Committee. After ethical approval study was started and enrolled patients after their written informed consent. Confidentiality and privacy of the participants were maintained. All the data was kept in strict confidentiality with access to only the researcher and mentors

#### Statistical analysis

Data was entered in MS Excel 2010 spread sheet and analyzed with the help of Open Epi (freely available online), SPSS V.20 (freely available) and MS Excel (with licensed version).

- Qualitative data analyzed and explained as frequency and percentage
- Quantitative data analyzed and expressed as mean and SD
- Bar chart, pie chart and column diagram use for explained frequency and percentage.

### RESULTS

Figure 1 shows most common age group was 26 years to 30 years (38.4%) followed by 21 to 25 years (31.5%), more than 30 years (26%) and 4.1% (3) less than 20 years in our study.

Table 1 depicts nulliparous (31.5%) women had maximum incidence followed by second para (30.1%), primi para (27.4%) and third para (11%).

Ectopic pregnancy was found to be affecting more women with less than 5 years active married life (52.1%), followed by 5 years to 10 years (34.2%) and more than 10 years (13.7%).

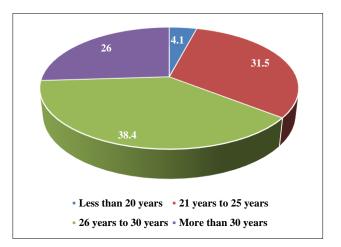


Figure 1: Distribution of ectopic pregnancy according age(n).

### Table 1: Parity wise distribution of patients, distribution according to married life.

Parity	No. of patients	%
Nulliparous	23	31.5
Primi para	20	27.4
Second para	22	30.1
Third para	8	11
Total	73	100
Married life		
Less than 5 years	38	52.1
5 years to 10 years	25	34.2
More than 10 years	10	13.7
Total	73	100

Mean±SD: 6.3±4 years, Minimum 0 years, Maximum 16 years.

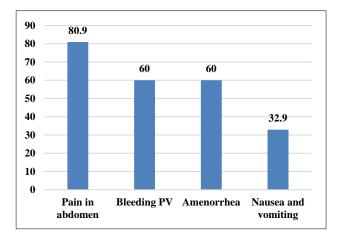
# Table 2: Previous menstrual history wise distribution,distribution of patients according to risk factors basedon past history.

Menstrual history	No. of patients	%
Regular	63	86.3
Irregular	10	13.7
Total	73	100
Past history		
Previous abortion	22	30.1
PID	22	30.1
H/o infertility	10	13.7
IUCD	8	11
Tubal ligation	6	8.3
H/o ectopic pregnancy	1	1.4
Total	73	100

Table 2 describes that 86.3% patients reported regular menses followed by irregular menses in 13.7% patients.

Most common risk factors identified were previous abortion (30%) and pelvic inflammatory disease (30%) based on past history. We also found history of infertility in 13.7% patients, use of IUCD in 11%, tubal ligation in 8.3% and prior history of ectopic pregnancy in 1.4% patients. Although pelvic inflammatory condition is considered most common etilology of EP with reason being cilliary dysmotility, although the theory is currently being challenged.

Figure 2 shows pain in abdomen (80.9%) was most common presenting symptom followed by bleeding per vaginum (60%), amenorrhoea (60%) and nausea and vomiting (32.9%). That follows the triad of EP amenorrhea, bleeding per vaginum, pain abdomen.



## Figure 2: Distribution according to clinical features at the time of admission (%).

Figure 3 shows most common general finding was abdominal tenderness in 45.2%, pallor in 38.4%, abdominal distension in 37%, tachycardia in 27.4%, guarding in 23.3% and raise temperature in 19.2% patients on general examination.

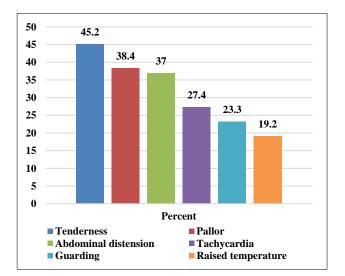




Table 3 shows 65.6% (48/73) patients had retroverted and normal size uterus, bulky uterus was found in 17.8% females only. 93% had complaints of forniceal, tenderness, fullness in fornices in 22/73 (30.1%).

### Table 3: Distribution according to findings of uterus,forniceal finding.

Uterus position and size	No. of patients	%
Bulky uterus	13	17.8
Anteverted and normal size	12	16.4
Retroverted and normal size	48	65.6
Total	73	100
Fornices		
Tenderness	68	93.2
Fullness	22	30.1
Mass	17	23.3

Figure 4 shows right sided ectopic (58.9%) was found to be more common than left side (41.1%).

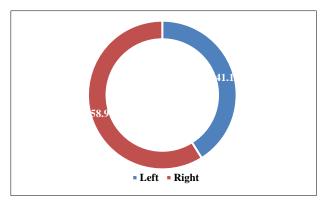


Figure 4: Tubal side involved wise distribution (%).

### Table 4: Distribution according to laboratory investigation, USG finding wise distribution.

Laboratory investigation	No. of patients	%	
UPT- Positive	73	100	
LFT-Normal	73	100	
Hb (mg/dl)	Mean	9.9	
	SD	2.1	
beta hCG	Mean	3886	
beta nCG	SD	3096.8	
USG finding	Number	%	
Unruptured	42	57.53	
Ruptured	28	38.35	
Adnexal Mass	3	4.1	
Total	73	100	
USG finding acc. To side involved	Left	Right	
Adnexal mass	1	2	
Unruptured	14	28	
Ruptured	14	14	
Total	30	43	

Urine test was found positive in 100% of cases. Liver function tests are also found normal in 100% cases. Among all patients mean beta hCG was found 3886 micrograms/L as seen in Table 4.

Our study reported unruptured EP in 57.53% (42/73), followed by ruptured EP in 38.35% (28/73) and adnexal mass in 4.1% (3/73) patients.

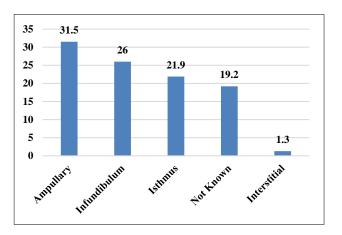


Figure 5: Site of ectopic pregnancy wise distribution (%).

Table 4 shows side wise distribution of USG finding. On left side, ruptured EP in 14 patients, unruptured in 14

patients and adnexal mass in 1 patient. While on right side, unruptured EP in 28 patients, ruptured in 14 patients and adnexal mass in 2 patients.

Figure 5 shows most common site of EP was ampullary in 31.5% patients, followed by infundibulum in 26% patients, isthmus in 21.9% patients, tubal site not known in 19.2% patients and interstitial in 1.3% patients confirmed while surgery or ultrasonography. Site could not be known in 14 tubal ectopics as no mention was made in imaging report as well as surgical record of patient, when the investigator was not the part of surgical team.

Table 5 shows age wise distribution of site of ectopic pregnancy.

Ampulla - 11 in 26 to 30 years followed by 7 in 21 to 25 years of age group and 5 in more than 30 years of age group.

Infundibulum- 8 in 26 to 30 years followed by 6 in more than 30 years and 5 in 21 to 25 years of age group.

Isthmus- 6 in 26 to 30 years followed by 5 in more than 30 years of age, 3 in 21 to 25 years and 2 in less than 20 years of age.

Table 5: Age	wise	distribution	with	respect to	tubal	site involved.
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Site of optopie	Age				
Site of ectopic	Less than 20 years	21-25 years	26-30 years	More than 30 years	Total
Ampulla	0	7	11	5	23
Infundibulum	0	5	8	6	19
Interstitial	0	0	0	1	1
Isthmus	2	3	6	5	16
Tubal site Not known	1	8	3	2	14
Total	3	23	28	19	73

Interstitial - one case in more than 30 years of age group.

Among patients in whom sites were not identified, 8 were in 221-25 years of age, 3 in 26 to 30 years of age, 2 in more than 30 years of age and 1 in less than 20 years of age.

Table 6 shows right salpingectomy was most common procedure in 43.8%, followed by left salpingectomy in 28.8%, methotrexate in 15.1%, left salpingo-ophorectomy in 5.5%, right salpingo-opherectomy in 5.5% and removal of tubal abortion in 1.3% patients.

In patients where methotrexate was given patient were managed on OPD basis. Necessary investigations were done and patient received the methotrexate injection and came for next injection. beta hCG was done before starting the therapy. And further management was done as said above.

It was a co-incidence that during study period all patients chosen for medical therapy responded well to it. None of the patients required conversion to surgical treatment in this group.

A total of 24 patients were received in varying degrees of shock. In 2 patients 4 units blood transfusion (BT) was given. Both patients were operated in emergency hours via laparotomy route and were the only ones requiring intensive care unit services. Ours being a tertiary care centre and in tribal area of Rajasthan, 32.9% (24/73) patients received BT. 20 patients (13 opened by

laparotomy + 7 operated by laparoscopy) received 2 units of blood transfusion. Accessing the health services requires a considerable time in this tribal area that could explain the unstable hemodynamic condition that 32.9% patients arrived in.

## Table 6: Distribution according to mode of treatment, blood transfusion, condition at the time of discharge.

Mode of treatment	No. of patients	%
Rt Salpingectomy	32	43.8
Lt Salpingectomy	21	28.8
Methotrexate	11	15.1
Lt salpingo-opherectomy	4	5.5
Rt salpingo-opherectomy	4	5.5
Tubal abortion removal	1	1.3
Total	73	100
Blood transfusion		
Yes	24	32.9
Not needed	49	67.1
Total	73	100
Condition at discharge		
Normal	73	100%
Total	73	100%

As shown in Figure 6, laparoscopy was chosen route in 64.4% patients, laparotomy in 20.5% patients with no surgical intervention in 15.1% patients. 15.1% (11) patients were treated with medical management (methotrexate) alone.

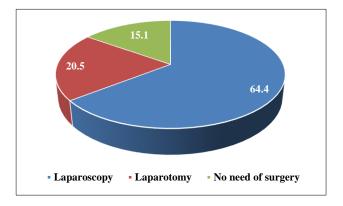


Figure 6: Mode of surgery wise distribution (%).

### DISCUSSION

Ectopic pregnancy is one of the life-threatening emergencies in pregnancy and a foremost cause of pregnancy death in the early days of pregnancy. In developing countries, ectopic pregnancy is still considered as cause for maternal morbidity and mortality. Because in these countries, majority of patients tend to present late with a ruptured form and hemodynamic compromise.<sup>4-6</sup> During study period, we enrolled 73 patients who were diagnosed with ectopic pregnancy by one of the way and admitted in obstetrics and gynecology department, Geetanjali Hopsital, Udaipur, Rajsthan after their written informed consent.

#### Incidence of ectopic pregnancy

Study conducted by Rajendra Wakankar and Kshama Kedar in Nagpur in the year 2015 reported the incidence of ectopic pregnancy to be 1.99%.<sup>7</sup> While study done by Shraddha Shetty K et al, reported the incidence of ectopic pregnancies was 5.6/1000 deliveries.<sup>8</sup> Murugesan A et al, found the incidence of ectopic pregnancy 1.77%.<sup>9</sup> In a study by Costa et al, in 2004 the annual incidence of ectopic pregnancy worldwide was found to be 0.1-0.17 in women of age group 15-44 years.<sup>10</sup> Thus, overall incidence of ectopic pregnancy reported by various studies varied worldwide.

### Age group

In present study most common age group reported in 26 years to 30 years (38.4%) followed by 21 to 25 years (31.5%), more than 30 years (26%) and less than 20 years (4.1%). We reported mean age in 28.2±4.9 years with minimum 18 years and maximum 38 years. Study conducted by Rashmi et al, reported 70.2% cases belonged to the age group of 21-30 years.<sup>11</sup> Panchal D et al the maximum incidence was seen in the age group of 21-30 years which was 71.66%.<sup>11</sup> Study conducted by Dayal et al majority of cases belonged to age group of 25-29 years in 43.75%.<sup>13</sup> Study conducted by Prasanna et el majority of women (74%) in their study group belonged to the age group of 21-30 years.<sup>14</sup>

### **Clinical features**

In current study, most common presenting feature was Pain in abdomen (80.9%), followed by bleeding PV (60%), amenorrhoea (60%) and nausea and vomiting (32.9%). Kumari et al and Shetty et al reported pain in abdomen in 88.2% and amenorrhoea in 70.5% cases.<sup>8,15</sup> Kumari et al and Gaddagi and Chandrashekhar et al reported adnexal mass in 64.7% and 70.3% cases respectively.<sup>11,15</sup> Swami et al, reported pain in abdomen was present in all 34 cases, followed by amenorrhea which was present in 97.05% cases and bleeding P/V in 76.47% cases.<sup>16</sup> Chhate et al, reported abdominal pain and amenorrhea was present in 92.47% and 77.41% cases suggestive of most common presentation of patient with ectopic pregnancy.<sup>17</sup> Prasanna et al reported 96% of the patients had history of amenorrhea, 90% had history of pain abdomen and 68% had bleeding PV.14

### Parity

In current study, we reported nulliparous in 31.5% followed by second para (30.1%), primi para (27.4%) and third para (11%). Swami et al, reported incidence of ectopic pregnancy in Multigravida is 64.71% and that of primigravida is 35.29%.<sup>16</sup> The incidence in multigravida is high as they are more exposed to post abortal,

puerperal infections and STD's.<sup>16</sup> In study done by Prasanna et al majority of women with ectopic pregnancy were multigravidae (84%).<sup>14</sup> Current study reported 52% EP reported in less than 5 years of active married life (52.1%), followed by 5 years to 10 years (34.2%) and more than 10 years (13.7%). We reported average active married life 6.3±4 years. Present study reported regular menses in 86.3% patients and irregular menses in 13.7% patients. While Kharat et al reported primigravida in 17.5% whereas multiparas were 82.5%.<sup>18</sup>

### **Risk factors**

Present study reported history of previous abortion (30%) and pelvic inflammatory disease (30%) as most common risk factor based on past history. We also reported history of infertility in 13.7% patients, use of IUCD in 11%, tubal ligation in 8.3% and prior history of ectopic pregnancy in 1.4% patients. Similar findings reported in study conducted by Kumari et al reported pelvic inflammatory disease as strongest risk factor in 35.29% while similar result reported by Yakasai et al. 31.68% incidence.<sup>15,19</sup> Kumari et al and Singh et al reported history of tubal ligation in 23% of patients.<sup>15,20</sup> Kumari et al reported IUCD with EP in 11.76% of patients.<sup>15</sup>

### General examination

Our study reported tenderness in 45.2%, pallor in 38.4%, abdominal distension in 37%, tachycardia in 27.4%, guarding in 23.3% and raise temperature in 19.2%. our study reported retroverted and normal uterus in 65.6% was, bulky uterus in 17.8% and ante everted and normal in 16.4%. We found fornices tender in 93.2% patients, fullness in 30.1% patients and mass in 23.3% patients. Swami et el reported 82.35% presented with adnexal mass, 79.41% with cervical motion tenderness, 76.47% had bleeding p/v, 50% with pallor, 32.35% with abdominal lump and tenderness and 11.76% with fullness in pouch of douglas.<sup>16</sup>

### Diagnostic tests

Study conducted by Kumari et al did UPT in all patients and ultrasound was done in 15 (88.23%) patients for the diagnosis.<sup>15</sup> UPT was positive in 14 (82.35%) patients.<sup>14</sup> While in our study UPT was done and found positive in 100% of cases. Study conducted by Shraddha Shetty K et.al reported UPT positivity in 87.1%.<sup>8</sup> We reported average hemoglobin and beta hCG 9.9±2.1 mg/dl and 3886±3098.6 respectively.

Present study reported unruptured EP found in 57.53%, followed by ruptured EP in 38.35% and adnexal mass in 4.1% patients. Swami et al reported out of 33 tubal pregnancy tubal rupture was seen in 27 cases (79.41%), tubal abortion in 4 cases (11.76%) and unruptured tubal pregnancy in (05.88%) cases. Contrary to our study, tubal rupture is the most common fate of tubal pregnancy in their study.<sup>16</sup>

### Site of pregnancy

In current study, we found most common site of ectopic pregnancy was ampullary in 31.5% patients, followed by infundibulum in 26% patients, isthmus in 21.9% patients, site not known in 19.2% patients and interstitial in 1.3% patients. This shows that ampullary region is the most common location for tubal ectopic gestation. Chate et al, reported commonest site for ectopic pregnancy is ampulla in present study accounting for 51.61% cases followed by fimbria in 19.35% cases. Isthmus was next most common site in 10.76% cases. Ovary and corneal involvement was seen in 9.67% and 8.61%.<sup>18</sup> Unfortunately, during the study period, we did not encounter any other site ectopics, only tubal ones. Present study reported involvement of right side in 58.9% patients followed by involvement of left side in 41.1% patients. Kharat et al, reported right sided tubal pregnancy was present in 53.1% cases and left tubal involvement in 46.9% cases.<sup>18</sup>

### Management

In our treatment, most common mode of treatment was right salpingectomy in 43.8%, followed by left salpingectomy in 28.8%, methotrexate in 15.1%, left salpingo-ophorectomy in 5.5%, right salpingoopherectomy in 5.5% and removal of tubal abortion in 1.3% patients. Swami et el reported 30 cases (88.24%) underwent unilateral salphingectomy. 2 (5.88%) cases were treated with methotrexate 1 mg/kg of body weight and in 2 (5.88%) cases milking was performed with postoperative methotrexate therapy.<sup>16</sup> Study conducted by Chate et al unilateral salpingectomy was done in 75.26% cases followed by unilateral salpingooopherectomy in 21.51% cases. Laparoscopic salpingectomy was done in 2.15% cases. Salpingostomy was done in 1.08% cases.<sup>17</sup> Present study reported most common mode of surgery being laparoscopy in 64.4% patients, followed by laparotomy in 20.5% patients and no surgical intervention in 15.1% patients. In our study, blood transfusion needed in 32.9% patients and blood transfusion was not required in 67.1% patients. 58.88% of patients recovered with 2 units of blood transfusion. 2 cases required 4 units of blood transfusion.

Limitations of this study was small sample size. Hospital based study, difficult to generalize the findings, distance travelled was not evaluated. This could have helped policy makers.

### CONCLUSION

In nutshell, this paper concluded that Ectopic pregnancy a cataclysm as well as a hindrance to reproductive performance, should be considered a public health issue. Overall, our results demonstrate with strong effect that with timely and efficient care, prognosis is favourable even in severe shock conditions. Therefore, it's suggested that by providing adequate materials, equipments and man-power at referring health care facilities combined with good access roads and efficient transportation; at time presentation and swift management of patients can be ensured.

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