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Study of treatment modalities in ectopic pregnancy: Two years retrospective study at tertiary care centre India

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Abstract
Background: Ectopic pregnancy is the pregnancy that implanted outside the endometrial cavity and it is a medical emergency. Common complication that occurs is rupture of the fallopian tube and tubal abortion that leads to massive hemorrhage. Due to modern methods of diagnosis and treatment the patient can be treated before the symptoms and signs appear. Determination of β-HCG serum levels together with transvaginal ultrasound helped to improve diagnosis.
Material and Methods: We conducted a retrospective study on a 52 patients admitted to tertiary care in the department of OBGY, Smt. Kashibai Navale Medical College and General Hospital, Pune, India over a period of two years 2019 and 2020. Patient's records were retrieved from record section. We analyzed each patient, clinically hemodynamic stable or unstable. Hemodynamically stable patient had given medical treatment where unstable patient have received surgical treatment.
Results: A total number of 52 patients with ectopic pregnancy were identified and studied. The rate of ectopic pregnancy was 1:70 to 1:100 deliveries. Emergency laparotomy was performed in 35 (67.3%) women, 17 (32.7%) received methotrexate injection. All cases of laparotomy did not require any further procedure. Fifteen out of seventeen (88%) cases of medical treatment were successful while two (12%) proceeded to emergency laparotomy. The duration of hospital stay in laparotomy and medically treated was 6.5 and 5.9 days respectively considering few patients who took discharge against advice but followed in out patient department.
Conclusion: In the institutional setting ectopic pregnancy accounted for 1% to 1.4% of total deliveries. More than half of all women with ectopic pregnancy presented with acute abdomen and required emergency laparotomy. About 33% women could be managed with medical modalities with 88% success for methotrexate injection.

Keywords: ectopic pregnancy, methotrexate, laprotomy

Introduction
Ectopic pregnancy is when the implantation of the fertilized egg occurs than in the uterus, most commonly in the fallopian tubes. 95% of ectopic pregnancies are implanted in various segments of the fallopian tube: 70% ampullary, 12% isthmic, 11% fimbria, 2-3% interstitial, 2% cornice. The remaining 5% of non-tubular tasks are implanted in: ovary, peritoneal cavity, cervix, scarring following caesarean surgery.
Ectopic pregnancy is a medical emergency and the most common complication that occurs is rupture of the fallopian tube and tubal abortion.
Determination of β-HCG serum levels together with transvaginal ultrasound helped to improve the diagnosis. But there is a controversy regards β-HCG as a diagnostic method. During ectopic pregnancy, β-HCG is lower compared to in the intrauterine ones. In a normal pregnancy, the concentration of this hormone doubles every 48 hours to 72 hours from the 4th day to the 8th day of gestation.
The rise in β-HCG value suggests an extrauterine pregnancy. Serum progesterone is can be used for differential diagnosis with intrauterine pregnancy - Value less than 5ng of serum progesterone identifies the ectopic pregnancy.
In Ectopic pregnancy two treatment methods can be used which are medical and surgical. Drug treatment is with injection methotrexate intramuscular in a single dose, 50mg/m2/kg body surface area and more doses of 1mg/kg/body weight in days 0, 4 and 7 – Only if further injections required.

This is recommended only for stable hemodynamic patients and the surgical treatment for hemodynamically unstable patients. In surgery and in emergency situations, laparotomy is most preferred method by clinician.

If patient is diagnosed early, can save invasive procedures. This is important for reducing mortality and morbidity. The objective of the study was to evaluate and compare the results obtained in patients diagnosed with ectopic pregnancy treated with various treatment modalities like medical and surgical.

Non-surgical management has a role in the diagnosis and treatment of ectopic pregnancy but little data are available. In the tertiary care hospital where this study was conducted, facilities for modes of treatment of ectopic pregnancy were available i.e. laparotomy and medical treatment. Therefore this study was conducted using all the treatment modalities according to set protocols.

Material and Methods

The study was approved by the Institutional Ethics and Research Committee of Smt. Kashibai Navale Medical College and Hospital Pune, Maharashtra India. A retrospective cohort study carried over period of 2 years in the department of Obstetrics and gynecology SKNMCGH, Pune, India.

All 52 cases of ectopic pregnancy diagnosed with help of history, clinical examination and specific investigations but mainly ß-hCG were treated by medical or surgical method. Informed consent was taken. As a routine, details were recorded in patients file.

Patients presenting with haemodynamic shock, having ß-hCG levels >6000mIU/ml or those suspected to have ruptured tubal pregnancies were treated with immediate laparotomy.

Women who were minimally symptomatic with ß-hCG =5000mIU/ml, pregnancy diameter <5cm, non-viable pregnancy on TVS and no signs of rupture were treated with methotrexate injection.

A single intramuscular injection of methotrexate (1 mg/kg body weight) was given to eligible patients. A second dose was given in those cases in which more than 15% fall of ß-hCG level did not occur in 48 hours or size of the mass further increased. Methotrexate toxicity signs like gastritis, stomatitis, dermatitis, thrombocytopenia, pleuritis, leucopenia, raised hepatic enzymes, raised blood urea and creatinine levels were noted carefully.

Return of ß-hCG level to 10mIU/ml without any need for further intervention is considered as successful treatment with further follow up in OPD.

Outcome measures were proportion of those cases diagnosed as ectopic pregnancy out of total deliveries and success of eliminating ectopic pregnancies by indicated methods. Duration of hospital stay and the need for alternative methods of management were additional variables studied.

Results

Out of total 3500 deliveries at tertiary care centre, 52 cases of were ectopic pregnancies. The highest incidence in study was between ages of 26 and 32 year old. 28 years was mean age in this study. Of these, 22 primigravida, 27 multigravida and 3 grand multigravida were there. Out of these, 4(7.7%) patients were tubectomised by one or other methods and 7(13.4%) had pelvic surgeries. One patients had underwent caesarean section in her previous pregnancy. IUCD use history was given by total 7 patients (13.4%).

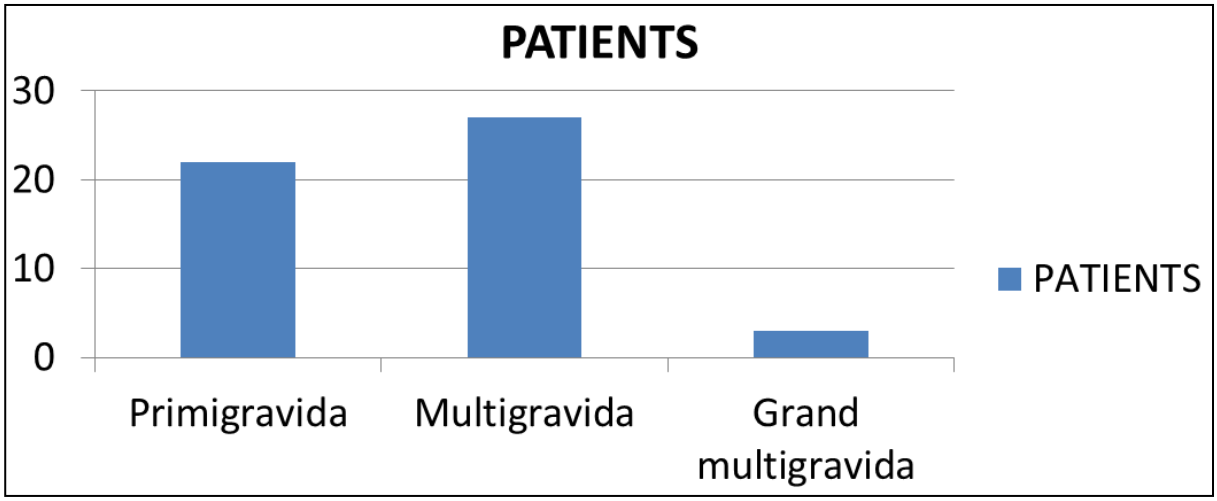

Fig 1: Incidence of patient as per age and gravidity

Emergency laparotomy was done in 35 (67.3%) patients who were unstable. Also two of medically planned patients had to shift for emergency laparotomy as they become unstable on day 2 and day 3 of methotrexate injection. In these patients, in 31 patients salpingectomy was done, 1 patient salpingostomy was done where 3 patients treated with milking product of conception. In none of patient resection and reanastomosis was attempted.

Thirty five (67.3%) patients underwent emergency laparotomy. Twenty six of them had haemoperitoneum and were haemodynamically unstable. Average blood loss of 1200ml was noted. Out of them, one pcv required by 8 patients, 15 patients required 2 pcv and 3 patients required 3 pcv.

Total seventeen (32.7%) patients given methotrexate injection. In that, Fifteen out of seventeen (88%) cases were successfully treated with medical method, But two (12%) proceeded to emergency laparotomy due to unstability on day 2 and day 3. Age of patient, gestational age, gravidity, parity, duration since last child birth, use of contraception and any pelvic surgery were comparable in all groups of patients (p>0.05).

Gestational age mean was 51.8±21.4 days for those women who were offered medical treatment. Adnexal mass size was measured using TVS and range was 2-5 cm (mean 3.35±1.2). 12 (70.5%) patients responded well to single dose of methotrexate while five (29.5%) required its 2nd dose. Regarding the side effects of methotrexate, stomatitis was there in one patient and

increase in abdominal pain was observed in other. But course of treatment was uneventful in the remaining patients. Cases of laparotomy did not require a secondary procedures meaning 100% success rate.

Comparison of laparotomy group with medical group was not found to be statistically significant (*p* value >0.05) as success rate was observed in both considering inclusion criteria of unstable or stable patient.

Mean duration of hospital stay in laparotomy and medical groups was 6.5 and 5.9 days respectively including those patients who took discharge against advice but later followed in OPD.

Table 1: Duration of hospital stay

Mode of Treatment Days	(Mean ± SD)
Methotrexate	5.9±3.2
Laparotomy	6.5±1.1

Discussion

Woman coming to clinic or casualty with symptoms such as amenorrhea, abdominal pain and vaginal bleeding should be suspected as ectopic pregnancy. The presentation may sometimes be dominated with the complaint or fainting, collapse, breathlessness, or dizziness. Uncommon symptoms observed are diarrhoea, urinary symptoms, pain in the shoulder, rectal pressure, and anaemia.

The incidence of ectopic pregnancy has increased in recent years. It remains as a very important contributor to maternal morbidity and mortality and is one in all the most typical causes of 1st trimester maternal deaths. It accounts for 3.5-7.1% of maternal mortality in India. In this study there was no mortality but two had serious morbidity requiring ICU care, which is comparable with a local study. Many maternal mortalities go unnoticed of illiteracy or lack of medical facilities and not reported to proper channel.

Treatment of ectopic pregnancies involves two approaches which are surgical and medical approach, depending on the condition of the patient at the time of diagnosis.

Drug commonly used is Methotrexate which is folic acid antagonist and it can be administrated single or in multiple doses, while the surgical treatment involve laparotomy.

Methotrexate in ectopic pregnancy prevents proliferation of cytotrophoblast cells by reducing cell viability and β-hCG synthesis but also progesterone, thus ectopic pregnancy fail to survive. It can also be applied also in corneal and cervical ectopic pregnancies, which has been reported successfully in the international literature.

The first case that it was treated with methotrexate occurred in 1987 in a study by Feichtinger and Kemeter.

In 1988, Leeton and Davison reported two cases that were diagnosed with uncomplicated and non-complicated extrauterine pregnancy, which were successfully healed by administering methotrexate.

Tanaka, *et al*. first described the successful resolution of ectopic pregnancy with systemic methotrexate in 1982. Forty-five percent of all ectopic pregnancies can be managed with methotrexate and it effectively treats ectopic pregnancy in 82-90% of selected cases.

The mean age was found to be 28 years and majority of them were multigravida. The commonest presenting symptom was abdominal pain (100%). These results are comparable with other studies.

In this study none of patient were treated conservatively. Emergency laparotomy was performed in 35 (67.3%) women, 17 (32.7%) received methotrexate injection.

The success rate of injection methotrexate in this study is comparable with other series (88% vs. 77-90%). A second injection of methotrexate was required in 5 (29.5%) patients in this study. In a large series of 120 patients treated with single intramuscular dose of methotrexate, Stovall and Ling needed to use a second dose in only 3.3% of cases, however in some series as many as 15-25% of patients required more than one dose. Patients with lower serum ß-hCG concentrations before treatment with methotrexate were significantly more likely to require only a single dose compared with those with higher levels (specially >3500mIU/ml).

Transvaginal ultrasound is the best diagnostic method for extrauterine pregnancies, in this study it was used in 87% of cases. Other diagnostic methods used were: serum β-hCG and progesterone levels in 74% of cases.

There are many statistics showing the benefits of medical therapy compared to surgery, where complications can be numerous. Among the most important are: hemorrhage, thrombi, infections, visceral damage or in tissues. Therefore, it is important that patients present themselves to the doctor in advance to prevent complications.

Conclusion

Incidence of ectopic pregnancy has increased over past few years and remains in high numbers. All the cases were diagnosed by a high index of clinical suspicion and USG findings. Serum β-hCG levels are important for further line of management and also important foe whether to give second dose of methotrexate or not. Tertiary care centre on an average has incidence rate of 1 to 1.4% in India mainly in those patient who are either multigravida, age around 28 years or having history of previous pelvic surgeries. Medical therapy with methotrexate is a safe and effective method for treating ectopic pregnancies. Over time, the mortality rate in patients with ectopic pregnancy has declined considerably due to modern and accessible preclinical investigations, diagnosis and treatment. Clinical trials have demonstrated a 95% to 100% rate of resolution in ectopic pregnancy through drug treatment compared in to this study with 88%.

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