INTRODUCTION

EP is a common clinical condition found in women at reproductive age, particularly in first trimester of pregnancy. Although EP can be implanted in different locations outside the uterine cavity, the most common location is reported as the fallopian tubes.

Nowadays, maternal mortality due to EP has significantly decreased; but EP still remains in 1-2% of pregnancies worldwide, affecting women's health and future fertility. Historically, diagnosis and treatment of this condition has been progressing significantly, from a life-threatening condition with no treatment before the 18th century, to an early diagnosed condition by non-invasive advanced technologies in the 21st century.

Management of EP include expectant, medical and surgical approaches. Health care professionals offer different management option, considering maternal mortality, fertility outcomes, side effects, contraindications, treatment costs, patient conditon, EPCh, patient's preferences, etc. Currently, controversy still exists about the optimal choice of treatment, according these multiple variables.

Definition of ectopic pregnancy

EP is an acute abdominal and gynaecological condition, found in women at reproductive age, which occurs when the developing blastocyst gets implanted outside the uterine cavity [1]. This condition can compromise women's health and future fertility [9].

Nowadays improvements in diagnostic methods allow a more accurate and early diagnosis of this condition, and a subsequent early management. This early management of EP offers treatment options according to the patient's characteristics,

considering not only the survival, but also the quality of life (QOL) during treatment and fertility outcomes [5, 21].

The best approach should be decided according to patient's medical status, however, many variables can influence it, variables such as success rates, complications, side effects, treatment costs, and subsequent fertility outcomes [12]. Also, taking into account the patient's preferences [23].

Preservation of the patient's fertility is the currently discussed issue in EP management, mainly after laparoscopic ST and MTX injection [7, 9].

Classification of ectopic pregnancy according anatomical locations

The majority of EP, 98%, occur in the fallopian tubes. Being the ampulla the most common tubal part of EP attachment. Other tubal EP attachment sites include: isthmus, infundibulum and fimbria [2, 8]. Extratubal pregnancies are those in which the blastocyst is implanted in the ovaries, endocervical canal, peritoneal surfaces or abdominal viscera, respectively named as ovarian, cervical and abdominal pregnancies. Uterine EP cases, which are proportionally lower than other types of EP, include attachment to caesarean scars, and entire or partial attachment to the myometrium [1].

Risk factors for ectopic pregnancy

It is well known that several RF influence in developing extra uterine implantations [21]. Potential RF include previous EP, history of tubal damage or tubal surgery, history of PID, usage of IUD, assisted reproduction technology techniques like IVF, and smoking habits [7]. The assessment of RF can help to identify high risk women, in which close monitoring would be very beneficial to provide an early diagnosis of EP [7].

Clinical picture of ectopic pregnancy

An embryo, to develop normally, needs to be implanted in the endometrium. When the embryois implanted elsewhere is unable to develop in normal conditions. In EP condition bleeding from the implanted location can occur, and, in some cases, even rupture [2]. Therefore, EP condition should be considered in any women at reproductive age, with or without abdominal pain, together with abnormal vaginal bleeding [7].

Traditionally, the most common clinical findings were: lower abdominal pain, vaginal bleedingand amenorrhea, symptoms forming the classical triad [2]. This triad, was firstly described by anItalian anatomist Giovanni Domenico-Santorini (1681-1737), but nowadays is only present in 50% of ectopic pregnancies, being a poor accurate diagnostic finding [21].

EP can present different clinical pictures, from asymptomatic conditions to complicated EP presenting shoulder pain, peritonitis, severe pain, severe hemorrhage or signs of shock. Other clinical symptoms include nausea, vomit, breast tenderness, symptoms that mimic intrauterine pregnancy(IUP), or any of the symptoms from the classical triad [2,13].

Clinical signs such as cervical motion tenderness, palpable adnexal mass and adnexal tenderness are examination findings that increase the likehood of EP.

Due to no single pathgnomic sign or symptom, history, RF and examination are important factors in EP, but insufficient to perform a diagnosis. The diagnosis is achieved by a combination of clinical presentation and complementary tests [21]. Also, clinical pictures can be useful to evaluate the presence of fallopian tube rupture [13].

Diagnosis of ectopic pregnancy

According literature, EP is a condition increasing in incidence in developed countries, but fortunately new diagnostic methods allow an early diagnosis [5], reducing the risk of tubal rupture and increasing medical management success [7]. Currently, EP diagnosis priorizes ectopic mass identification outside uterus, over the identification of IUP absence [21].

EP diagnosis is based on ultrasonography examination and β-hCG levels [7]. Findings like ectopic cardiac activity or ultrasound (US) detection of an embryo outside uterus are absolute criteria for diagnosis [2]. Findings in abdominal US suggesting EP, but being inconclusive, include: absenceof intrauterine sac, presence of ectopic mass and identification of fluid in the Douglas pouch. To confirm EP in inconclusive US findings, β-hCG in serum is assessed [7].

Due to abdominal US limitations, in early cases, transvaginal ultrasound (TVUS) is the most useful technique [7]. Interpretation of TVUS findings should be correlated to gestational age and β- hCG level, being a visible gestational sac at 5.5-6 weeks of gestation and above 1,500 mIU/mL hormone levels [7].

In unclear diagnoses, 48 hours serial serum β-hCG is measured, which allow us to distinguish between a failing pregnancy and active pregnancy.

However, a β-hCG level does not distinguish location of pregnancy (IUP or EP). After 48 hoursof the β-hCG levels being monitored, levels doubling or increasing around 66%, suggest a healthy IUP. Even in 15% of healthy intrauterine pregnancies levels do not rise by 66%. And, even in some cases, 13% of ectopic pregnancies, levels can rise around 66%.

Therefore, in early stages, diagnosis of EP is based on TVUS not showing IUP, with presenceor absence of ectopic mass, and monitored β-hCG levels above the

discriminatory zone (>1,500 mIU/mL β-hCG levels). Together with anamnesis, clinical pictures and RF assessments [7].

Choice of ectopic pregnancy treatment option

Management options for EP include expectant, medical treatment, conservative surgical treatment and radical surgical treatment [5].

To choose treatment modality many factors are considered, including patient age, tubal condition, serum β-hCG levels and the patient's future fertility desires [6]. Together with factors including success rates, complications, side effects, costs of treatments, surgeon experience, patient condition and fertility outcomes [12].

The choice of treatment, depends on the accurate triage of the patient. Patient categorizationhas been made by the evaluation of patient according Fernandez score (scoring system of 6 criteria including gestational age, β-hCG, progesterone level, abdominal pain, haemoperitoneum volume and haematosalpinx diameter) or according "level of activity", concept remaining subject of debate. Considering an active EP an extratubal pregnancy with hemodynamic failure, abundant hemoperitoneum, symptoms of rupture or high β-hCG hormone levels[3].

Expectant management

Expectant managements consist in monitoring serum β-hCG levels until spontaneous recovery occurs. β-hCG levels are assessed every second day initially, and then weekly, to detect a persistent trophoblast [3]. This treatment option is applied to clinically stable women, who presented uncomplicated EP with initial β-hCG measurements less than 1,500 mIU/mL [17].

Expectant treatment is considered safe in women that had been adequately counselled, compliant to treatment pathway with no barriers to healthcare access [21].

The METEX trial showed no differences between expectant management and MTX group in women with far fewer active EP (the criteria just mentioned above), therefore, METEX recommends expectant management as the first line for less active EP, and a MTX as second-line of treatment [3].

Medical treatment

MTX is an antimetabolite drug that acts on actively-proliferating cells, including trophoblastic cells [3]. It inhibits the enzyme dihydrofolate reductase (DHFR), enzyme that reduce folic acid to tetrahydrofolate. This inhibition of DHFR cause a depletion of cofactors required for deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) synthesis [7].

As any chemotherapy agent acts on rapidly-dividing cells, damaging DNA and causing the inability to divide, causing cell death. Meaning that methotrexate not only affects the blastocyst implanted in the tubes; it also affects rapidly dividing cells of the body, which are in the gastrointestinal tract, hair, skin, nails, bone marrow, ovarian and endometrial cells [3].

MTX is most often administered as a single-dose intramuscular injection, according to the single-dose protocol: a single dose (50mg/m2 or 1mg/kg) is administered on day 0, if β-hCG levels do not drop 15% between day 4 and day 7, a second dose can be administered on day 7 [3].

According to literature, predictors of successful treatment include: Initial β-hCG < 1,000mIU/mL, absence of gestational sac and no ectopic fetal cardiac activity [17]. However, hormonallevel cut-offs ranges from 1,000 to 5000 mIU/mL [22].

A recent study about predictive factors of MTX treatment, a comparison of 400 cases, concluded that pre-treatment β-hCG level is an important factor predicting

MTX treatment success, being effective at hormone less than 1,000 mIU/mL, in patients with Fernandez score less than 13 [22]. After treatment initiation, showing small increase or a decrease of β-hCG measurements are also predictors of successful treatment [17].

Therefore characteristics such as adnexal fetal cardiac activity, presence of free peritoneal blood, the size of gestational mass being > 4cm, high initial β-hCG levels >5000 mIU/mL, rapidly increasing β-hCG concentrations (>50%/48h), and β-hCG levels rising continuously during MTX treatment, are predictors of MTX treatment failure [7].

Before any MTX treatment, contraindications are evaluated, including conditions like hepatic dysfunction, renal dysfunction, active peptic ulcer disease, severe anemia, active pulmonary disease, and hemodynamically unstable or immunodeficient patient (Table 1) [7].

Confirmation of no viable IUP must be clear, because in case of viable pregnancy misdiagnosed, MTXe can induce embryopathy, a serious and avoidable complication [21]. The adverse effects of the treatment are most frequently haematological, digestive, hepatic, pulmonary or buccal [22].

According to toxicology literature, this chemotherapeutic agent is fully excreted from the body within a period of 4-6 months after administration [4].

The National Institute for Health and Care Excellence (NICE) recommends MTX treatment as the first-line treatment, for patients able to return for follow-ups, in which US confirmed no IUP, with no significant pain, no ruptured EP, no fetal heartbeat, presenting β-hCG serum levels between 1,500 mIU/mL and ectopic mass smaller than 35 mm [17].

MTX can be administered as post-operative treatment, showing a decrease in failure rate, beingbeneficial in risk of persistent EP [3].

Post-operative MTX is injected during the first 24 hours after surgery, and it is mainly used in early stage EP, meaning those measuring less than 2 cm, presenting high initial β-hCG levels or in cases of incomplete resection [7].

Table 1. Contraindications to Methotrexate

(Practice Committee. Medical treatment of ectopic pregnancy. Fertil Steril 2013)

Absolute contraindications	**Relative contraindications**
• Intrauterine pregnancy • Evidence of immunodeficiency • Moderate to severe anemia, leukopenia, orthrombocytopenia • Sensitivity to MTX • Active pulmonary disease • Active peptic ulcer disease • Clinically important hepatic dysfunction • Clinically important renal dysfunction • Breastfeeding • Ruptured ectopic pregnancy • Hemodynamically unstable patient	• Embryonic cardiac activity detectedby transvaginal ultrasonography • High initial β-Hcg concentration (>5,000mIU/mL) • Ectopic pregnancy >4 cm in size as imaged by transvaginal ultrasonography • Refusal to accept blood transfusion • Inability to participate in follow-up

Surgical treatment

Tubal EP patients can be treated surgically, either by ST, in which the affected fallopian tube is preserved, or salpingectomy, removal of fallopian tube together with EP [3, 10].

Laparotomy with salpingectomy was the standard procedure until 1978, when laparoscopic ST was first reported [3]. Comparing laparoscopy and laparotomy approaches, laparoscopy allows a faster recovery for the patient and less painful postoperative, providing diagnostic methods and treatment methods, at the same time. In clinical practice the choice depends on the patient and surgeon, factors connected to the EP and preferences [11, 14].

Literature review showed preference of ST over salpingectomy, in patients presenting a healthycontralateral tube [17], and salpingectomy was the preferred treatment option for patients with severe tubal damage or uncontrolled bleeding from tubes [3].

Salpingectomy should be applied to woman with a history of previous EP, history of previous PID, contralateral tubal damage or previous abdominal surgeries [3].

Emergency surgery is indicated in hemodynamically unstable patients or ongoing tubal rupture. In hemodynamically stable patients, surgery intervention should only be performed in patients with a clearly visible mass or ectopic sac in US. In patients presenting contraindications, failed MTX therapy,or heterotopic pregnancy with a viable IUP, surgical treatment should also be considered [3].

Costs of surgery are higher over medical costs, because methotrexate is able to be administered in an office-setting, without need for hospitalization. However in cases presenting predictors of MTX failure, surgery is preffered [11].

The subsequent fertility after ectopic pregnancy treatment

Fertility is defined as the spontaneous occurrence of IUP [5]. The effect of subsequent fertilityis an important fact to consider when choosing the treatment option for ectopic pregnancy, therefore one of the main goals of EP management is the preservation of future fertility, mainly at developed countries [3].

Even management option has an important role in subsequent fertility preservation, other aspects are involved, such as patient's age, size of ectopic pregnancy, level of serum β-hCG and contralateral patency [6, 12, 15].

MTX causes toxic effects to ovaries, however, this negative effect to fertility is limited to 180 days, after which the effect is reversed [4].

The effect of salpingectomy, removal of the tube, impairs fertility, which is only is preservedby the resting fallopian tube. ST can cause tubal blockage, due to inflammatory factors released and scarring tissue formed. In some cases, tube adhesions and hydrosalpinx are presented after the procedure. Tubal blockage leads to future oocytes not being able to leave fallopian tubes, therefore fertility is impaired [6].

A similar study called ESEP study [10], a controlled trial comparing ST and salpingectomy surgeries in EP, in which women with contralateral tube diseases were excluded, concluded that salpingectomy should be preferred over ST, according the higher recurrent EP results after ST. Being important to mention patients' strong preference towards salpingectomy, they preferred a complete tubal removal rather than a possibility of EP recurrence [10]. Opposite conclusions reported byDEMETER study, showing higher recurrences of EP after salpingectomy. However both recurrent findings were considered non-significant due to small samples.

REVIEW OF LITERATURE

Patel and Desai (2019) determine the clinical presentation, and treatment associated with ectopic pregnancy. Methods: This is a prospective study which was carried out at Obstetrics and Gynaecology department, GMERS SOLA civil hospital from August 2017 to October 2018. Total 416 patients were admitted during study period out of them 50 patients diagnosed with ectopic pregnancy were enrolled in the study and information was collected and analysed. Results: 80% patients were between the age group of 21-30 years. 56% patients were nulliparous. Amenorrhea (92%) with lower abdominal pain (94%) is the most common presenting symptom. 26% of patients show typical triad of amenorrhea, abdominal pain and bleeding per vagina. UPT and USG were most commonly performed investigations. 96% cases showed UPT positive. 100% USG showed adnexal pathology. Serum beta-hCG was done in 37 patients as an aid for diagnosis and to decide the line of management. Conservative medical management with Injection MTX was done in 4 patients of which 1 patients required laparotomy later on. Surgical management was done in 90% of patients. Laparoscopic management was done in 54% of cases. Conclusions: Early diagnosis and timely intervention in the form of conservative or surgical treatment will help in reducing the morbidity and mortality associated with ectopic pregnancy.

Attri P et al (2020) This prospective study was conducted in the department of Obstetrics and Gynecology, Dr. Rajendra Prasad Government Medical College Kangra at Tanda, Himachal Pradesh after all ethical permissions, to study the incidence, management and outcome of ectopic pregnancy. 98 women, who were diagnosed as having ectopic gestation, were enrolled for the study after their informed consent. **Results:** In the present study, the incidence of ectopic pregnancy was 9.1 per thousand deliveries. 58.16% of the patients presented at the gestational age of 6-8 weeks. History

of abdominal and pelvic surgery (30.61%) and infertility (22.45%) were the most common associated risk factors. The typical triad of amenorrhea, pain abdomen and bleeding was observed in 40% of cases. 7.95% of the patients were severely anemic and 5 patients presented with shock. Adnexal tenderness was the most common sign elicited clinically (84.69%), whereas, complex adnexal mass was confirmed in 96.93% of the patients on sonography. 84.69%, 16.32% and 1.02% of the total patients were managed with surgical, medical and expectant treatment respectively. The most common procedure performed was unilateral salpingectomy in 75.56% of the patients. 76.53% of the cases required blood transfusion for resuscitation in their operative and postoperative period and 8 patients needed ICU admission. There was no maternal mortality in the current study. **Conclusion:** Rising incidence rates of ectopic pregnancy should alert gynecologist in general, efforts should be made for early diagnosis of ectopic pregnancy and timely referral to reduce maternal morbidity and mortality.

Verma ML et al (2022) We aimed to analyze the profile of patients of ectopic pregnancies and their outcome. **Materials and Methods:** The sample for this retrospective cross‐sectional study was derived from the database from January 2017 to December 2020. Data from outdoor patient registers, case record files, discharge summaries and hospital admission/discharge registers were screened. Parameters age, parity, risk factors, clinical presentation, per‐operative findings, and maternal outcome in terms of morbidity and mortality were assessed. **Results:** Totally 27,525 deliveries occurred during the study period of 3 years, of which 640 were ectopic pregnancies, i.e., 2.3%. Out of 640, 415 (64.8%) were acute ruptured ectopic pregnancies, 62 (9.6%) were chronic ruptured pregnancies, and 163 (25.4%) patients were unruptured ectopic pregnancies. The mean age was 28.67 years (range: 29.5–27.8). The most common site of rupture was ampullary (54%, 225/415). 14.8% (95/640) of cases were in hemorrhagic

shock out of total ectopic patients, and in ruptured group, they comprised 22.8% (95/415). Success for medical management with single‐dose methotrexate in our study was 90.2% (147/163). **Conclusion:** Pelvic inflammatory disease and history of induced abortion were found to be the most important etiological factor in ectopic pregnancies. Comprehensive clinical examination is 100% sensitive in diagnosis of EP. In ultrasound, the presence of adnexal mass is the most common finding which is additive to clinical findings and not substitute. Although multiple management options are available, best outcome is attained if management of EP is done at earliest without any delay.

Suliman et al (2023) It was a prospective descriptive, cross-sectional hospital-based study conducted at Bashair Teaching Hospital during the period January 2021–June 2021. An interview questionnaire was used, and eighty-two (82) women were included after informed consent. Demographic and clinical data concerning personal history, symptoms of presentation, risk, site, and type of management were recorded. Results: Ectopic pregnancy incidence was 2% and most risk factors were infection 29.3%, surgery 15.9%, miscarriage 13.4%, infertility 12.2%, tubal surgery 4.9%, previous ectopic pregnancy 4.9%, intrauterine contraceptive device (IUCD) 3.6%, and tubal ligation 2.4%. Women presented with bleeding and abdominal pain at 47.5%, bleeding at 18.3%, abdominal pain at 9.7%, and shock at 8.5%. The sites are ampullary (57.3%), fi mbria (9.7%), interstitial (8.5%), isthmus (8.5%), ovarian (7.3%), cervical (4.8%), and abdominal (3.6%). Surgical management was 93.9%, medical and surgical management was 3.6% and medical management was 2.4%. A blood transfusion was received at 37.8%. Conclusion: The study concluded that women of reproductive age are at risk of ectopic pregnancy, so healthcare providers and doctors should have a high

index of suspicion, prompt diagnosis, and intervention for ectopic pregnancy. Assessment of women at risk factors and modifications will reduce incidence.

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