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A STUDY OF ASSOCIATION OF HEMOPERITONEUM AND TREATMENT OUTCOME IN ECTOPIC PREGNANCY.

Obstetrics & Gynaecology

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ABSTRACT

To study the effect of hemoperitoneum in the outcome of methotrexate (MTX) treatment of ectopic pregnancy (EP).

Materials and methods: This was an observational prospective study done in the department of OBGY in a tertiary medical college in India from January 2021 to June 2021. The percentage of women with hemoperitoneum at the beginning of MTX treatment was compared between two groups: those whose treatment was successful and those whose treatment failed.

Results: A total of 100 women with ectopic pregnancy were studied. MTX treatment was successful in 75 of 100 (75%) cases. The percentage of women with hemoperitoneum at the beginning of treatment was significantly higher in women in whom MTX treatment failed as compared to those in whom it was successful (15/25 (60%) vs 17/75 (22.6%); P = 0.001).

Conclusion: The presence of hemoperitoneum appears to be a risk factor for MTX treatment failure. It is important to inform women as fully as possible about the risk of such failure.

KEYWORDS

Ultrasonographic diagnosis, unruptured tubal pregnancy

INTRODUCTION:

The process of pregnancy starts with fertilisation of the egg after which it gets implanted into the inner lining of the uterus. The uterus is specially designed for implantation, nourishment of the fetus and its well being. In some cases, if the fertilised egg gets implanted anywhere else except the uterus, such pregnancy is called as ectopic pregnancy. Most common sites include fallopian tube called as tubal pregnancy, ovary or lower cervix, abdomen etc. as such parts are not desgined for pregnancy, the pregnancy is not viable there and the female presents with distress. There may be severe bleeding, abdominal pain, shoulder pain etc. the urine pregnancy test will be positive but the USG will show empty uterus. Such a condition is mostly caused by previous ectopics, history of use of IUCD, infections etc.

Among women with hemoperitoneum in this situation, only 50−62% have a tubal rupture(**1**-4) The presence of hemoperitoneum is not a contraindication for methotrexate (MTX) treatment of ectopic pregnancy (EP)(**5-7**) .

The presence of hemoperitoneum in women with an EP diagnosis is a risk factor for MTX treatment failure(**6**) and must therefore be further evaluated. The aim of this study was to determine if hemoperitoneum on ultrasound is a risk factor that suggests the likely failure of MTX treatment of EP and whether this ultrasound sign can be used diagnostically to predict treatment failure.

METHODOLOGY

This was an observational prospective study done in the department of OBGY in a tertiary medical college in India from January 2021 to June 2021. All women older than 18 years treated with MTX for EP were eligible and were invited to participate in the study. All women provided written informed consent before enrollment.

EP was diagnosed in women referred for pelvic pain, vaginal bleeding or both who met the following criteria: positive plasma human chorionic gonadotropin (hCG) (stable or rising plasma hCG level in separate measurements 48 hours apart) with an empty uterus on sonography and other sonographic signs in favor of EP such as an inhomogeneous adnexal mass, an empty gestational sac with a hyperechoic ring, or an extrauterine gestational sac containing a yolk sac or fetal pole with or without cardiac activity(**8**, **9**). Indications for MTX treatment were absence of embryonic cardiac activity detected by transvaginal ultrasonography, plasma hCG level < 5000 IU/L, EP < 4 cm as visualized by transvaginal ultrasonography and the ability to participate in follow-up. Contraindications for MTX treatment were hepatic or renal failure, thrombopenia, anemia or any suspicion of tubal rupture (hemodynamic instability, severe pain or large hemoperitoneum on ultrasonography).

Women received intramuscular MTX at a dose of 50 mg/m(**2**). The day of injection was considered day 1 of the protocol. Plasma hCG levels were measured on days 4 and 7. Follow-up was undertaken in outpatient clinics. If hCG levels decreased by ≥ 15% between days 4 and 7, weekly monitoring continued until they fell below 15 IU/L. If levels failed to decrease by 15% between days 4 and 7 or between weekly measurements, MTX injection was repeated. After the second injection, hCG levels were followed with a new day 1 reading. If levels failed to decrease appropriately after a total of three injections, treatment was considered to have failed and surgical treatment was recommended.

In our study, failure of treatment with MTX was defined as the need for surgical treatment for 'suspected tubal rupture', the absence of an appropriate hCG decline after three injections or the woman's refusal of a second or third MTX injection.

Measurement of the hemoperitoneum was reported as its anteroposterior size behind the uterus in a mid-sagittal plane including the uterus and the pouch of Douglas. All ultrasound examinations were performed by a senior consultant.

The Mann–Whitney U-test was used to compare quantitative variables and chi-square or Fisher's exact tests were used for qualitative variables. A multivariable logistic regression analysis was performed and a P-value ≤ 0.05 was considered significant.

RESULTS:

A total of 100 women with ectopic pregnancy were included in the study. The success rate of MTX treatment was 75% (75/100) with one injection (55 women) or two injections (20 women). 25 women required surgical treatment after one injection (20 women) or two injections (five women).

Clinical and ultrasound characteristics are reported in Table **1**.

Table 1 showing analysis of ultrasonographic features of the ec topic pregnancy mass.

Characteristic	Group A Successful MTX treatment (n = 75)	Group B Failure of MTX treatment (n = 25)	P
Age (years)	31 ± 4.1	32.3 ± 4.0	0.93
Tobacco use	31 (43.4)	11 (42.8)	0.22
Previous ectopic pregnancy	8 (11.6)	2 (8.3)	0.96

Number of pregnancies	3.4 ± 2.5	3.3 ± 3	0.90
Parity	1.2 ± 1.2	1.1 ± 1.2	0.75
Body mass index (kg/m^2)	25.8 ± 5.5	26 ± 6.0	0.90
hCG D1 (IU/L)	1608 ± 2037	2600 ± 2078	0.005
Presence of hemoperitoneum*	17 (22.6)	15 (60)	0.001
Size of hemoperitoneum* (mm)	6.8 ± 12	16 ± 18	0.01
Size of ectopic pregnancy or inhomogeneous adnexal mass (mm)	16.43± 12.1	13.3 ± 12.1	0.20

The percentage of women with hemoperitoneum at the beginning of treatment was significantly higher in Group B (15/25, 60% vs 17/75, 22.6,%; P = 0.001). On multivariable analysis that took into account factors with a P-value ≤ 0.2 (EP size or inhomogeneous adnexal mass, size of hemoperitoneum, presence of hemoperitoneum, hCG day 1 level) the only factor significantly associated with MTX failure was the presence of hemoperitoneum (OR, 5.0; 95% CI, 1.73–15.15; P = 0.002).

Testing the value of hemoperitoneum in predicting the likelihood of requiring surgical treatment after MTX treatment revealed its sensitivity to be 0.68, its specificity to be 0.75 and its positive and negative predictive values to be 0.45 and 0.84, respectively.

DISCUSSION:

Hemoperitoneum is frequently present in ectopic pregnancies but is not systematically associated with tubal rupture. In our study, the presence of hemoperitoneum was the only independent factor significantly associated with MTX treatment failure. The presence of hemoperitoneum was more discriminatory than was size of the adnexal mass or initial hCG level. The presence of hemoperitoneum increased the likelihood of requiring surgical treatment after MTX, with an OR of (OR, 5.0; 95% CI, 1.73–15.15; P = 0.002).

Our study is an observational study and had no losses to follow-up. To our knowledge, only one study has assessed hemoperitoneum quantitatively in this context(**10**); Bignardi et al. reported a series of eight women with EP associated with hemoperitoneum in the pouch of Douglas(**10**). All were clinically stable with hCG levels < 5000 IU/L. The six women whose hCG levels decreased 48 hours later were managed expectantly (standard follow-up by clinical examination, sonography and hCG assays). The remaining two women, whose hCG levels had increased, were treated with MTX.

The presence of echogenic free fluid is strongly suggestive of hemoperitoneum(**11**, **12**, **13)**. In our study, hemoperitoneum was diagnosed as echogenic free peritoneal fluid. The ASRM (American Society for Reproductive Medicine) guidelines specify that hemoperitoneum is a risk factor for treatment failure(**6**). Although the presence of hemoperitoneum is a factor in MTX treatment failure, the success rate of MTX treatment nonetheless remains high and hemoperitoneum is not a systematic contraindication for MTX treatment. The presence of hemoperitoneum on ultrasound must be considered a factor in decision making.

After showing that hemoperitoneum is a risk factor for MTX treatment failure, we sought to assess whether its presence might be used to predict failure. We found that its sensitivity to be 0.68, its specificity to be 0.75 and its positive and negative predictive values to be 0.45 and 0.84, respectively. In practice, the presence of hemoperitoneum does not identify a sufficiently high proportion of women whose treatment will fail (63%). Similarly, its absence does not identify a sufficiently high proportion of women for whom MTX treatment will be effective (76%). The probability of failure when hemoperitoneum was present was 47% and the probability of success in its absence was 85%.

In summary, the presence of hemoperitoneum on initial ultrasound in women treated with MTX for EP was a more important risk factor for treatment failure than was ultrasound diameter of the EP or initial hCG level.

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