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Original Research Article

Conservative management of unruptured ectopic pregnancy

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ABSTRACT

Background: Ectopic pregnancy accounts for 0.5-2% of all first-trimester pregnancies and is one of the important, yet often misdiagnosed, causes of maternal death. This study aimed to determine the success rate of conservative management of unruptured ectopic pregnancy in terms of pregnancy resolution.
Methods: A prospective study was conducted over a period of two years from 2020 to 2022 at the Department of Obstetrics and Gynaecology, LD Hospital of Government Medical College, Srinagar. A total of 200 patients diagnosed with unruptured ectopic pregnancy were managed with expectant or medical management, after counseling about the need of surgical options in the advent of failed treatment or rupture.
Results: The cumulative success rate of conservative management of unruptured ectopic pregnancies was 70% while 30% cases had to resort to surgical intervention.
Conclusions: A significant number of patients with an unruptured ectopic pregnancy can be successfully identified and treated by conservative management, thereby reducing the operative interference, morbidity and economic burden, and preserving future fertility.

Keywords: Beta HCG, Conservative management, Ectopic pregnancy, Surgical management, Unruptured

INTRODUCTION

Ectopic is derived from the Greek word 'Ekpos' meaning out of place. Normally the fertilization of ovum occurs in the fallopian tube, with the fertilized egg moving into the cavity of the uterus in 5-7 days for implantation. Implantation of the fertilized ovum on any tissue other than the endometrial membrane lining the uterine cavity results in an ectopic pregnancy (EP). Worldwide its incidence is 0.5-2% of all first-trimester pregnancies.[1] Ectopic pregnancy accounts for 3-10% of pregnancy-related deaths and the affected women have a 7-15% chance of recurrence.[2,3] After one previous ectopic pregnancy, the chance of another is increased fivefold.[4] With increasing frequency of sexually transmitted infections and medically assisted reproductive techniques, the incidence is 2-3 times higher than it was 2 decades ago. About 50% of ectopic pregnancies are associated with tubal disease and one-third with chlamydial infection.[5,6]

One-third of women with ectopic pregnancy have no clinical signs and 9% have no symptoms at all.[7] The diagnosis of an ectopic pregnancy is usually unexpected and emotionally traumatic. About 50 percent of ectopic pregnancies are misdiagnosed at the initial visit.[8] Diagnosis of ectopic pregnancy has been greatly improved by the advent of rapid serum beta-human chorionic gonadotropin (beta-HCG) tests and the widespread adoption of transvaginal pelvic ultrasonography (TVS).[9] A thick-walled cystic, non-homogenous structure in the adnexa is highly predictive of ectopic pregnancy.[10] Numerous conditions may have a presentation similar to an ectopic pregnancy but the common differential diagnosis are a ruptured corpus luteal cyst or ovarian follicle and a spontaneous abortion or threatened abortion.[11]

Ectopic pregnancy can be managed expectantly, medically or surgically. Expectant management is a conservative strategy consisting of observation and assessment of whether the ectopic pregnancy is continuing to resolve spontaneously and successfully without intervention.[12] Expectant management follows the natural history of disease and is free from the side effects associated with methotrexate. Intramuscular methotrexate is the most widely used and successful medical therapy for ectopic pregnancy. In an ectopic pregnancy, the drug prevents the proliferation of cytotrophoblast cells, reducing cell viability and β-hCG secretion and thus revokes progesterone support for the pregnancy. After assessing patient suitability for medical management, methotrexate can be given in a single or multi- dose regimen. Side effects of methotrexate treatment can be limited by the dose and length of treatment.[13] Surgical options include Salpingectomy or Salpingostomy, depending on the presence or absence of factors for subfertility. A laparoscopic approach is preferable to an open approach in a hemodynamically stable patient. In the presence of contralateral tubal disease, a salpingostomy should be considered if future fertility is desired. Persistent trophoblast is the main concern after a salpingostomy.[14]

Literature review

Fernandez et al (1998) conducted a study titled "Randomized trial of conservative laparoscopic treatment and methotrexate administration in ectopic pregnancy and subsequent fertility".[15] They concluded that methotrexate treatment was as safe and effective as laparoscopy and was associated with improved subsequent fertility.

Olofsson et al (2001) in their study named "Clinical and Pregnancy outcome following an ectopic pregnancy, a prospective study comparing expectancy, surgery and systemic methotrexate treatment" found that the success rate in the Mtx group was 77% and 82% in those managed expectantly.[16]

As per the study of Kirk et al (2005) the overall success rate in the expectant management group and medical management group was 65.3% and 87.2% respectively.[17] Karen et al (2010) also reported that methotrexate treatment increased from 11.1% in 2002 to 35.1% in 2007 ($p<0.001$); while as the surgical management decreased over the study period from 90% to 65% ($p<0.001$).[18] Van et al (2013) suggest that the single-dose systemic MTX does not have a larger treatment effect compared with expectant management in women with an ectopic pregnancy and low and plateauing serum hCG concentrations.[19] Gopinath, et al (2018) revealed the expectant management as successful in 44.8% of patients.[20] Özge, et al (2020) observed 92.4% success rate of the multi-dose methotrexate treatment and Silvia Baggio et al (2021) found 70% success rate among the expectant management group and 82.6% among the medical management group.[21,22]

METHODS

In view of the paucity of comprehensive studies on the outcomes of expectant and medical management of ectopic pregnancy, examining the subject continues to be of interest in medical research, and the study at hand attempts to contribute to such a growing body of research. The present study was carried out to evaluate the outcomes of conservative management (expectant and medical) of unruptured ectopic pregnancy in terms of the patients showing pregnancy resolution, and the patients requiring surgical intervention. The study was conducted in the Department of Obstetrics and Gynecology, LD Hospital, Government Medical College, Srinagar, J&K.

Before initiating the study, ethical clearance was sought from the Institutional Ethical Committee of the Medical College concerned. Thorough history, clinical examination, and urinary pregnancy testing were done in all suspected patients of ectopic pregnancy, presenting or referred to the hospital under study over a period of 2 years from November 2020 to November 2022. Only those patients who fulfilled the inclusion and exclusion criteria were enrolled in the study. After admission and initial workup, consent was taken from patients for expectant/medical management with the understanding of the need for surgical options in the event of failed treatment or rupture. A total of 200 patients were studied, of which 107 patients were managed by expectant management and 93 by medical management.

Patients with baseline βhCG <1500 were managed expectantly by monitoring vitals and TVS follow-up; βhCG was repeated every 48hrs to check the falling trend of a failing ectopic gestation. Patients with baseline βhCG >1500 but <5000 who met criteria for medical management, were subjected to single or multiple doses of Methotrexate, a folic acid antagonist. Day 4 and Day 7 TVS and βhCG titers were assessed. A fall of 15% or more suggested successful treatment and the patients were followed with weekly serum βhCG assays until it became negative (<20mIL/mL). Patients initially managed by expectant management, on showing a rising trend or plateauing of serum βhCG, were shifted to medical management with Methotrexate. Patients were followed up weekly till the outcome of treatment i.e., either resolution of ectopic pregnancy depicted by a negative beta hCG titer (<20mIL/mL) or failure of conservative management depicted by landing up in surgical intervention.

Signs of treatment failure or tubal rupture including significantly worsening abdominal pain and hemodynamic instability regardless of the change in B-hCG levels, levels of B-hCG that do not decline by at least 15% after 1 week from pretreatment values, and increasing or plateauing B-hCG levels in the weeks following treatment were considered an indication to retreat to another regime of methotrexate or to resort surgical management. Medical

management was not considered successful until βhCG was no longer detectable in the serum.

RESULTS

The most common age group of patients with ectopic pregnancy in our study was found to be 25-29 years (44.5%); followed by the age group of 30-34 years (23.5%). The main risk factors for EP were a previous history LSCS (37.5%), prior history of abortions (22.5%), previous ectopic (11%), PID (6%), ovulation induction, ART (5.5%). No identifiable risk factors were seen in 18% patients.

The clinical presentation in majority of the patients was amenorrhea (61%), abdominal pain (30.5%), bleeding PV (29%), vomiting (10%), syncope (7%), and altered bowel/bladder habits (6.5%). Of the total patients with EP, 20.5% were asymptomatic at presentation. Gestational age at presentation was <6 weeks in majority of the patients (64%), followed by 6-9 weeks (34.5%) and >9 weeks (1.5%). Pregnancy interval was reported to be 2 to 5 years in 65% patients, <2 years in 18.5% patients and >5 years in 16.5% patients. Majority of cases in our study were primigravidas (30%), 35% were para 1, 9% para 2 and 5% para 2 and above. History of previous 1 abortion was present in 12.5% patients, while 10.5% patients had previous 2 abortions and a history of >2 abortions was seen in 1% patients. About 18% patients had a history of previous ectopic pregnancy.

The baseline βhCG level at diagnosis was <1000 in majority of the patients (35.5%). While as 28% had βhCG levels of 1000-2000, 13% had βhCG of 3000-4000 and only 9.5% patients had βhCG levels of 4000-50000 at diagnosis. The gestational sac size was 1.5-2cm in 27.5% patients, 2-2.5cm in 25% patients, and 3.3-3cm in 16% patients. Gestational sac size of 2.5-3cm was reported in 15% patients, 1-1.5cm in 14% patients and <1cm in 2.5% patients.

Table 1: Management of patients.

Mode of management		Cases	Resolution	%	Laparoscopy/ laparotomy	%
Expectant management		107	73	68.2	25	23.4
Expectant switched to medical management		9	7	77.8	2	22.2
1 dose of methotrexate		6	5	83.3	1	16.7
2 doses of methotrexate		3	2	66.7	1	33.3
Medical Management	1 dose of methotrexate	48	29	60.4	19	39.6
	2 doses of methotrexate	39	27	69.2	12	30.8
	3 doses of methotrexate	6	4	66.7	2	33.3
Total		200	140	70	60	30

Note: Expectant Mx = 107 cases; Medical Mx = 93+9 cases

As demonstrated in Table 1, 107 out of 200 patients were managed expectantly and ectopic pregnancy was resolved in 73 (68.2%) cases and 25 (23.4%) cases ended up in laparoscopy/laparotomy (surgical management). The remaining 9 patients were switched to medical management; out of which 7 (77.8%) patients had resolution while 2 (22.2%) patients underwent surgical management. Among the 9 patients switched to medical management, 1 dose of methotrexate was used in 6 patients out of which 5 (83.3%) cases were resolved and 1 (16.7%) case underwent surgery and in 3 patients, 2 doses of methotrexate were used of which 2 (66.7%) patients resolved while 1 (33.3%) underwent surgery.

Initially, a total of 93 patients were managed medically, of whom 48 patients were administered with 1 dose of methotrexate while 2 doses of methotrexate were used in 39 patients and 3 doses of methotrexate were employed in 6 patients. Of the patients managed with 1 dose of methotrexate, 29 (60.4%) resolved and 19 (39.6%) underwent surgery. Among the patients managed with 2 doses of methotrexate, 27 (69.2%) resolved and 12 (30.8%) underwent surgery and of the patients managed with 3 doses of methotrexate, 4 (66.7%) patients showed resolution while 2 (33.3%) underwent laparoscopy/laparotomy. The single-dose regimen created fewer side effects but was slightly less effective as compared to multi-dose regimen. The overall outcome of medical management was resolution in 65.7% and surgery in 34.3% cases. Common side effects encountered by patients in our study after methotrexate were excessive flatulence, headache, nausea, vomiting, diarrhoea and stomatitis. The cumulative outcome of conservative management was resolution in 70% and surgical intervention in 30% cases.

The resolution of ectopic pregnancy was accepted when beta-hCG levels became negative on successive follow-ups. As demonstrated in Table 2, among patients with beta βhCG <1000, 53 patients resolved in 20 days while 18 patients with the same beta βhCG levels underwent surgery. Again 40 patients with 1000-2000 beta HCG levels resolved with conservative management in 31.5 days while 16 underwent surgery. A total of 18 patients with beta HCG levels of 2000-3000 had resolution in 33.5 days versus 8 patients who underwent surgery, while 18 patients with 3000-4000 beta HCG levels resolved in 34.5 days while 10 such patients underwent surgery. 11 patients

with 4000-5000 beta HCG levels resolved by conservative management in 35 days; 8 underwent surgery. Thus, the median time to resolution showed an increasing trend with rising levels of beta HCG.

Table 2: Time to resolution.

Baseline beta (βhCG)	Cases resolved (n=140)	Median time to resolution (days)	Surgery (n=60)
<1000	53	20.0	18
1000-2000	40	31.5	16
2000-3000	18	33.5	8
3000-4000	18	34.5	10
4000-5000	11	35.0	8

Correlation of BHCG with outcome

The rising values of initial βhCG showed a positive correlation with the odds of failure of conservative management. Among patients with βhCG levels of <500, 12 out of 15 patients (80%) had successful resolution with expectant management while 3 (20%) failed, with an overall odds ratio of 1.0 and 0.25 odds of failure (Table 3). Of 36 patients with beta-hCG of 1000-1500, over 23 (64%) were successfully managed while 9 (25%) patients landed up in surgery. Hence, the odds of failure of expectant management showed an increasing trend with increasing beta-hCG.

Among patients with beta hCG levels of <1000, 4 out of 5 (80%) were managed successfully while 1 (20%) failed medical management, with an overall odds ratio of 1.0 and 0.25 odds of failure (Table 4). 11 (57.9%) of patients with beta-hCG of 4000-5000 were successfully managed while 8 (4 2%) patients landed up in surgery. Hence, the odds of failure of medical management showed an increasing trend with rising initial beta-hCG titers.

Table 3: Correlation of βhCG with outcome of expectant management.

Range of βhcg	Cases	Resolution (%)	Failure (%)	Odds of failure	Odds Ratio	Cases switched to medical Mx (%)
<500	15	12 (80.0)	3 (20.0)	0.25	1	0
500-1000	56	38 (67.9)	13 (23.2)	0.34	1.37	5 (8.9)
1000-1500	36	23 (63.9)	9 (25.0)	0.39	1.57	4 (11.1)
Total	107	73 (68.2)	25 (23.4)			9 (8.4)

Chi-square for linear trend = 0.16, p value = 0.68

Table 4: Correlation of βhCG with outcome of medical management.

Range of βhcg	Cases	Resolution (%)	Failure (%)	Odds of failure	Odds ratio
<1000	5	4 (80)	1 (20.0)	0.25	1.0
1000-2000	24	17 (70.8)	7 (29.2)	0.41	1.65
2000-3000	26	17 (65.4)	9 (34.6)	0.53	2.12
3000-4000	28	18 (64.3)	10 (35.7)	0.56	2.22
4000-5000	19	11 (57.9)	8 (42.1)	0.73	2.91
Total	102	67 (65.7)	35 (34.3)		

Chi-square for linear trend = 0.97, p value = 0.32

Table 5: Correlation of gestational sac size with outcome of expectant Mx.

Sac Size	Cases	Resolution (%)	Failure (%)	Odds of failure	Odds ratio	Switched to medical Mx (%)
<1cm	5	4 (80.0)	1 (20.0)	0.25	1.0	0
1-1.5cm	28	20 (71.4)	6 (21.4)	0.30	1.2	2 (7.2)
1.5-2cm	55	37 (67.4)	13 (23.6)	0.35	1.41	5 (9.0)
2cm- 2.5cm	19	12 (63.1)	5 (26.4)	0.42	1.67	2 (10.5)
Total	107	73	25			9

Chi-square for linear trend = 0.16, p value = 0.68

Correlation of gestational sac size with outcome

Data contained in Table 5 reveals that of the women with gestational sac size of <1cm, 80% had successful resolution with expectant management, while treatment failed in 20% patients; with an overall odds ratio of 1 and 0.25 odds of failure. Over 63% patients with sac size of 2-2.5 cm were successfully managed expectantly while failure occurred in case of 26.4% patients, with odds of failure 0.42 and 1.67 odds ratio. Hence, the odds of failure of conservative management show an increasing trend with increasing gestational sac size.

The study results (Table 6) reveal that all the patients with gestational sac size of <1-1.5cm managed medically showed successful resolution. Over 72% of the cases with sac size of 2-2.5cm were medically resolved and only 27.3% cases resulted in failure. The study further reported that there were 32 patients with sac size of 3-3.5 cm of which 56.3% were successfully managed medically while failure occurred in 43.7% patients with odds ratio of 3.11 and 0.78 odds of failure. Thus, the odds of failure of conservative management show an increasing trend with increasing gestational sac size.

Table 6: Correlation of gestational sac size with outcome of medical Mx.

Sac size	Cases	Resolution (%)	Failure (%)	Odds of failure	Odds ratio
1-1.5cm	2	2 (100.0)	0 (0.0)	0.0	0
1.5-2cm	5	4 (80.0)	1 (20.0)	0.25	1
2-2.5cm	33	24 (72.7)	9 (27.3)	0.38	1.5
2.5-3cm	30	19 (63.3)	11 (36.7)	0.58	2.32
3-3.5cm	32	18 (56.3)	14 (43.7)	0.78	3.11
Total	102	67 (65.7)	35 (34.3)		

Chi-square for linear trend = 2.09, p value = 0.14

DISCUSSION

In the present study, a total of 200 patients were studied of which 107 patients were managed by expectant management and 93 by medical management with methotrexate. Of the 107 patients managed expectantly, ectopic pregnancy was resolved in 73 (68.2%) and 25 (23.4%) ended up in laparoscopy/laparotomy (surgical management). These results are comparable to the study done by Elson et al (2004) in which 107/179 tubal ectopics were managed expectantly.[23] Again 75 out of 107 (70%) women resolved while the remaining underwent surgery. Our results are in line with those of Trio et al who also selected 63% of women with ectopics for expectant management achieving a 75% cure rate.[24]

Initially, 93 patients were managed medically including 48 patients in whom 1 dose of methotrexate was used, and 2 doses of methotrexate were used in 39 patients and 3 doses of methotrexate were employed in 6 patients. Of the patients managed with 1 dose of methotrexate, 29 (60.4%) resolved and 19 (39.6%) underwent surgery. These findings are similar to those of Chandana et al (2020) where 10 out of 16 patients (62.5%) had successful management with one dose of MTX.[25] Among patients managed with 2 doses of MTX, 27 (69.2%) resolved and 12 (30.8%) underwent surgery. Barnhart et al in their study on the use of a 2-dose regimen of methotrexate established that 73 out of 101 patients (72.2%) had successful management.[26] The overall outcome of medical management was resolution in 65.7% while 34.3% landed up in surgery. Similar outcomes were found by Zhang et al (2020) in their study of 238 ectopic pregnancies treated with MTX. The overall success rate of MTX therapy for ectopic pregnancy was 69.74% (166/238).[27]

Our study had an overall success of 70% (140 cases out of 200) with conservative management of EP, with 30% (60 cases) landing up in failure/surgical intervention. Van Mello et al (2013) conducted a randomized comparison between expectant and medical management of ectopic pregnancy.[19] The treatment success rate of MTX versus expectant management in this study was 31/41 (76%) and 19/32 (59%), respectively.

Our findings are in agreement with several other reported studies, which identified resolution with conservative management between 23-31 days. Baseline hCG levels were also positively associated with the risk of requiring rescue surgery, particularly when baseline hCG levels were >3000IU/L. A lot of previous studies have shown that higher initial hCG levels correspond to increased rates of surgical intervention.[28-30]

CONCLUSION

The conservative management of ectopic pregnancies plays a vital role in preserving future fertility, particularly in young women. Advances in high-resolution transvaginal ultrasound (TVS) and serum β-hCG level monitoring have significantly improved our ability to detect and manage these cases effectively. Notably, our data indicate that the initial serum β-hCG level is a robust predictor of treatment outcome, with success rates decreasing as β-hCG levels exceed 5000 mIU/mL. The study demonstrates that by adopting a conservative approach, we can minimize surgical intervention, reduce morbidity, and alleviate the economic burden associated with ectopic pregnancies. Moreover, accurate documentation and counseling enable women to make informed decisions about their management, ultimately optimizing their reproductive outcomes.

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