Original Research Article

A study illustrating the risk factors, clinical presentation and management of ectopic pregnancy in a secondary hospital in Bahrain

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ABSTRACT

Background: Assess the risk factors, clinical presentation and type of intervention indicated in ectopic pregnancies at American mission hospital in Bahrain.
Methods: This is a retrospective cohort study conducted from August 2021 to April 2022 at American mission hospital in Bahrain. All patients (n=205) who attended the hospital from January 2017 to June 2021 with a presentation suggestive of ectopic pregnancy were extracted from the electronic medical record database and reviewed. Data was recorded on Microsoft Excel version 16.61.1 and numerical data was extrapolated into graphs and tables via IBM SPSS Statistics version 28.0.0.0 (190). Data was subjected to descriptive and stratification analysis.
Results: The leading risk factor for ectopic pregnancy was previous pelvic surgery (40.4%). The most reported symptom was amenorrhea (65.9%). Risk of rupture was tripled when serum B-hCG level was elevated, rendering it the strongest predictor of rupture according to our data (95% CI=1.25, 7.19; p-value 0.0139). Majority of patients (56.4%) were treated with methotrexate with a success rate of 88.7% and 8.5% of cases were managed expectantly. Those who failed medical management or presented with rupture were treated surgically.
Conclusions: Our study found B-hCG levels to be the most sensitive predictor of rupture and need for surgical intervention. Therefore, management was largely, but not exclusively, based on B-hCG levels. Majority of cases were treated medically and patients undergoing expectant management experienced no complications.

Keywords: Amenorrhea, B-hCG, Ectopic pregnancy, Methotrexate, Risk factors

INTRODUCTION

An ectopic pregnancy (EP) is the implantation of a developing blastocyst outside the endometrial cavity of the uterus.[1] Currently, EPs account for 4%-10% of all pregnancy-related deaths. Fortunately, the mortality rate of EPs has decreased over recent years, suggesting that timely diagnosis and intervention have made a lifesaving impact.[1-3] While the exact etiology of EP is unknown, it is suggested that disruption to normal tubal anatomy secondary to pelvic infection or surgery impairs ciliary action and smooth muscle contractility causing improper implantation within the fallopian tubes.[4,5] A study by Tulandi et al reported the leading risk factors for EP to be pelvic surgery and a previous EP.[4] Other risk factors include late maternal age, smoking, history of miscarriage (≥1), history of polycystic ovary syndrome (PCOS), pelvic inflammatory disease (PID) and use of intrauterine copper device (IUCD).[3-7] There have been major advances in the diagnosis and management of EPs

during the last twenty years, however, there is still a significant portion of EPs that are missed at presentation.[5] This may be due to the variability of symptoms, ranging from asymptomatic to tubal rupture, hemorrhage and shock. Therefore, EP should be suspected in any patient of reproductive age presenting with vaginal bleeding preceded by amenorrhea for ≥4 weeks and/or abdominal pain.[8] Possible interventions include expectant management, pharmacologic treatment with methotrexate and surgery. International guidelines recommend that the type of intervention undertaken should be based on severity of clinical presentation, human chorionic gonadotropin level (B-hCG), transvaginal ultrasound suggestive of an extra-uterine pregnancy and fertility reducing factors, such as previous salpingectomy.[3,6,9] Treatment eligibility varies from patient to patient, but expectant management is recommended if the patient is clinically stable and pain-free with rapidly declining B-hCG levels below 1500 IU/l.[3,10] Methotrexate is preferred in women with B-hCG levels between 1500-5000 IU/l who are hemodynamically stable, have no fetal cardiac activity on ultrasound and are without underlying medical conditions such as renal failure.[3] Surgical management is imperative in the scenario of a ruptured EP and commonly consists of salpingectomy or salpingostomy; the preference of one over the other depends on the presence of a healthy contralateral tube. Generally, a laparoscopy approach is recommended due to shorter operating times, a decrease in intraoperative blood loss, shorter hospital stays and lower analgesia requirements.[5] In contrast, laparotomy is usually reserved for those with rupture and hemodynamic instability. During and after treatment, serial B-hCG levels are measured until undetectable to confirm interventional success. This study's objective is to illustrate the risk factors, clinical presentation, and common interventions for EP in a secondary hospital in Bahrain.

METHODS

Study design and population

This is a retrospective cohort study conducted from August 2021 to April 2022 at American mission hospital (AMH), a private, non-profit secondary hospital located in Manama, Bahrain. All patients (n=205) who attended the hospital from January-2017 to June-2021 with a presentation suggestive of EP were extracted from the electronic medical record (EMR) database and reviewed. Those who were under 18 years of age, had EP ruled out, refused treatment, or were referred to another hospital were excluded from the study. Patients lost to follow-up were also excluded from the final analysis. Those with an EP diagnosis who meet the inclusion criteria (N=94) compose the entirety of this study.

Inclusion criteria

Inclusion criteria for current study were; age ≥18 years, one or more risk factors for EP than age ≥35 years,

previous EP, history of miscarriage (≥1), history of abdominal or pelvic surgery, history of PCOS, PID or infertility, use of IUCD, smoking, slow-rising or declining B-hCG levels, classic symptoms of EP: amenorrhea, abdominal pain and/or vaginal bleeding and ultrasound findings of empty uterus, adnexal mass and/or free fluid in pouch of Douglas.

Exclusion criteria

Exclusion criteria for current study were; age <18 years, suspected EP later ruled out, refused treatment and signed against medical advice (AMA) form, referred to another hospital for completion of treatment and lost to follow-up.

Data collection

Data was collected from a computerized clinical database that records all patient information across the five branches of AMH in Bahrain. Suspected EPs were reviewed and included in the study only if the diagnosis is confirmed and the inclusion criteria is met. Demographic characteristics such as age, nationality, parity, and gestational age were recorded. They were then stratified into different categories based on age over or under 35, gestational age over or under 6 weeks, clinical symptoms, risk factors as listed above, initial B-hCG levels, transvaginal ultrasound findings and management plan. Patients with more than one EP were included under one entry. B-hCG levels were monitored and recorded from admission until complete resolution regardless of treatment plan.

Data analysis

The data collected was de-identified, categorized and entered on Microsoft Excel version 16.61.1 before being analyzed on IBM SPSS Statistics version 28.0.0.0 (190). Numerical data was subjected to descriptive analysis to summarize the prevalence of risk factors and clinical presentations of EP in the Bahraini population. Stratification analysis was done to investigate whether different risk factors, presentations, and interventions (exposure) were causally implicated in the complications of EP, such as rupture or need for surgical intervention (outcome) while controlling for confounding variables.

RESULTS

Study population and demographics

From January-2017 to June-2021, there were 136 extra-uterine pregnancies diagnosed at AMH. Of those 136 EPs, 42 were excluded according to the exclusion criteria leaving a total of 94 (69.1%) participants. The mean maternal age at presentation was 30.94 (±4.22) years, and the majority (41.5%) were nulliparous (Table 1). There was a wide variety of nationalities with the majority being from India (43.6%), Bahrain (22.3%) or the

Philippines (14.9%). The most common risk factors were previous pelvic surgery (40.4%), history of miscarriage (26.6%) and age ≥35 years (24.5%) (Table 1).

Table 1: Characteristics of ectopic pregnancy patients (n=94).

Variable	N	%
Age (years)		
Mean	30.94	-
SD	4.22	-
20 to 30	47	50
31 to 40	46	48.9
>40	1	1.1
Parity		
0	39	41.5
1	32	34
2	20	21.3
3	2	2.1
4	1	1.1
Risk factors		
Age ≥ 35 years	23	24.5
History of miscarriage (≥ 1)	25	26.6
Prior ectopic pregnancy	13	13.8
Prior abdominal or pelvic surgery	38	40.4
History of PCOS	9	9.6
History of fibroids	2	2.1
History of infertility	5	5.3
History of PID	0	0
History of IUCD insertion	1	1.1
Smoking	2	2.1

N: number of subjects enrolled; n: total number of subjects; SD: Standard deviation; PCOS: polycystic ovary syndrome; PID: pelvic inflammatory disease; IUCD: intrauterine copper device.

Table 2: Clinical presentation of ectopic pregnancy (n=94).

Variable	N	%
Referred to AMH	5	5.3
Asymptomatic	16	17
Amenorrhea	62	65.9
Lower abdominal pain	51	54.3
Mild	4	4.3
Severe	11	11.7
Variable	36	38.3
Vaginal bleeding or spotting	58	61.7
Back pain	2	2.1
Nausea and/or vomiting	3	3.2
Bowel disturbance	1	1.1
Urinary disturbance	3	3.2
Loss of consciousness	1	1.1

Among the 38 women who underwent pelvic surgery, 22 (53.7%) had undergone C-sections and 5 (12.2%) had salpingectomies for prior EPs. Other risk factors such as PID, IUCD insertion and smoking were less common.

*Clinical presentation and ultrasound findings*

23 (24.5%) patients had the classic triad of amenorrhea, vaginal bleeding, and lower abdominal pain while 16 (17%) were asymptomatic. The most common presenting symptoms were amenorrhea (65.9%), followed by vaginal bleeding (61.7%) (Table 2).

Table 3: Transvaginal or transabdominal ultrasound findings (n=94).

Variable	N	%
Location		
Fallopian tube	89	94.7
Left	47	52.8
Right	42	47.2
Unknown	5	5.3
Free fluid in POD	41	43.6
Other findings (N=13)		
Ovarian cysts	4	30.8
Fibroids	2	15.4
Other	7	53.8

POD: pouch of Douglas.

Other symptoms include nausea/vomiting, back pain, and urinary disturbances although those were relatively rare. The mean gestational age at diagnosis was 6.5 (±1.6) weeks. A urine pregnancy test was performed in all cases of suspected EP and was positive in 100% of the patients included in this study. A urine pregnancy test was followed by a quantitative B-hCG blood test and an ultrasound to assess the location of the pregnancy and the presence of free fluid. The location of extra-uterine pregnancy was the fallopian tubes in majority of cases (94.7%) with 52.8% being on the left and 47.2% being on the right (Table 3). 5 (5.3%) cases were classified as pregnancy of unknown location; 1 (20%) underwent diagnostic and therapeutic laparoscopy and the remainder were managed with methotrexate due to slow-rising B-hCG levels between 1500 and 5000 IU/l.
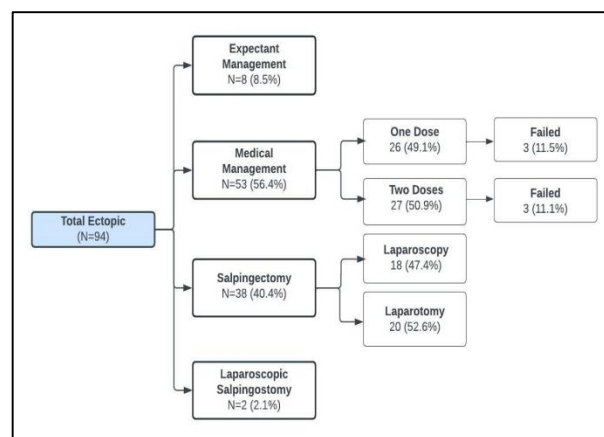
Figure 1: Management of ectopic pregnancy.

Table 4: Incidence of rupture based on risk factors (n=94).

Risk Factor	N	Rupture, N (%)	RR (CI)	P value
Age (years)				
≥35	23	7 (30.4)	1.66	0.2071
<35	71	13 (18.3)	(0.75, 3.66)	
Nationality§				
Middle Eastern	22	8 (36.4)	1.97	0.0775
Asian	65	12 (18.5)	(0.93, 4.18)	
Gestational age§ (weeks)				
≥6	62	13 (20.9)	1.01	0.9758
<6	29	6 (20.7)	(0.43, 2.39)	
B-hCG levels‡ (IU/l)				
≥1750	39	13 (33.3)	3	0.0139
<1750	54	6 (11.1)	(1.25, 7.19)	
History of abortion				
Yes	25	4 (16)	0.69	0.4651
No	69	16 (23.2)	(0.26 to 1.87)	
Prior ectopic				
Yes	13	2 (15.4)	0.69	0.5902
No	81	18 (22.2)	(0.18, 2.64)	
Prior surgery				
Yes	38	8 (21.1)	0.98	0.9652
No	56	12 (21.4)	(0.44, 2.17)	
Polycystic ovaries				
Yes	9	2 (22.2)	1.05	0.9416
No	85	18 (21.2)	(0.29, 3.81)	
Intrauterine copper device				
Yes	1	1 (100)	1.05	0.9416
No	93	19 (20.4)	(0.29, 3.81)	
IVF or infertility				
Yes	5	0	0.37	0.4623
No	89	20 (22.5)	(0.03, 5.34)	
Smoking				
Yes	2	1 (50)	2.42	0.2296
No	92	19 (20.7)	(0.57, 10.25)	

RR: relative risk; CI: 95% confidence interval, § 7 patients excluded due to unknown nationality, § 3 patients excluded due to unknown GA, ‡ 1 patient excluded due to unmeasured B-hCG

Although 41 (43.5%) patients had findings of free fluid in the pouch of Douglas on ultrasound, only 16 (39%) of them had ruptured. 13 (13.5%) patients had additional findings on ultrasound with the most common being ovarian cysts (30.8%) and fibroids (15.4%) (Table 3). Other findings seen include pelvic hematoma, chronic ectopic and non-active pregnancy.

Management

Total 8 (8.5%) patients were managed expectantly as they were clinically stable, had a serum B-hCG level of ≤1,000 IU/L and were able to return for regular follow-up (Figure 1). Hemodynamically stable patients who did not fit the criteria for expectant management were managed medically using intramuscular methotrexate. Suitability for methotrexate was determined according to serum B-hCG <5000 IU/l, an unruptured ectopic pregnancy measuring <35 mm, medical fitness, and ability for

regular follow-up. 53 (56.4%) patients were treated using methotrexate, 26 (49.1%) of which had a single-dose and 27 (50.9%) had a multi-dose regimen (Figure 1). The dose of methotrexate was calculated according to the patient's surface area or body weight (50 mg/m^2 or 1 mg/kg) with a maximum dose of 100 mg. Following administration, patients were followed-up using B-hCG levels on day 1, day 4 and day 7. Subsequent methotrexate doses were given to patients whose B-hCG were unresponsive or increased; however no patients in our subset of cases received more than 2 doses. 3.8% of patients experienced new onset abdominal pain after methotrexate therapy and 9.4% had an increase in pain severity from initial presentation. 6 (11.3%) patients underwent a surgical salpingectomy due to failed medical management, with half having ruptured. A surgical salpingectomy was performed in 40.4% of cases that were deemed unfit for methotrexate therapy. Those include patients in significant pain, have a ruptured ectopic, a serum B-hCG level ≥5000 IU/l, an adnexal

mass ≥35 mm or visible fetal heartbeat on ultrasound. A laparoscopic approach was used in 47.4% of cases while laparotomy was used in emergent cases that required an open approach (52.6%). There were no complications during laparoscopy, but 2 (10%) patients who underwent laparotomy had intra-operative complications that resulted in an ipsilateral oophorectomy in one case and a

bilateral partial salpingectomy in the other. Salpingostomy was performed in a small number of patients (2.1%) who had a previous salpingectomy for EP and a high baseline B-hCG. The success rate of laparoscopic salpingostomy was 100% and no patients required further intervention.

Table 5: Incidence of surgical management based on risk factors (n=94).

Risk factor	N	Surgery, N (%)	RR (CI)	P value
Age (years)				
≥35	23	14 (60.9)	1.66	
<35	71	26 (36.6)	(1.06, 2.60)	0.0263
Nationality[δ]				
Middle Eastern	22	11 (50)	1.16	
Asian	65	28 (43.1)	(0.70, 1.92)	0.5612
Gestational age[§] **(weeks)**				
≥6	62	25 (40.3)	0.97	
<6	29	12 (41.4)	(0.58, 1.65)	0.9236
B-hCG Levels[‡] **(IU/l)**				
≥1750	39	27 (69.2)	3.12	
<1750	54	12 (22.2)	(1.81, 5.35)	<0.0001
History of abortion				
Yes	25	12 (48)	1.18	
No	69	28 (40.6)	(0.75, 1.95)	0.5086
Prior ectopic				
Yes	13	5 (38.5)	0.89	
No	81	35 (43.2)	(0.43, 1.85)	0.7551
Prior surgery				
Yes	38	15 (39.5)	0.88	
No	56	25 (44.6)	(0.54, 1.44)	0.6225
Polycystic ovaries				
Yes	9	4 (44.4)	1.05	
No	85	36 (42.4)	(0.49, 2.27)	0.9025
Intrauterine copper device				
Yes	1	1 (100)	2.38	
No	93	39 (41.9)	(1.88, 3.02)	<0.0001
IVF or infertility				
Yes	5	2 (40)	0.94	
No	89	38 (42.7)	(0.31, 2.82)	0.9075
Smoking				
Yes	2	2 (100)	2.42	
No	92	38 (41.3)	(1.89, 3.09)	<0.0001

RR: relative risk; CI: 95% confidence interval, [δ]7 patients excluded due to unknown nationality, [§] 3 patients excluded due to unknown GA, [‡] 1 patient excluded due to unmeasured B-hCG

Complications and associations

A total of 20 (21.3%) EPs ruptured, 85% of which had ruptured at the time of diagnosis and the remainder after methotrexate. All cases of rupture were appropriately managed with a surgical salpingectomy. Findings of hemoperitoneum on ultrasound were only present in 80% of cases. Among the 20 cases, 13 (65%) had a serum B-hCG level ≥1750 IU/l, 6 (30%) had a serum B-hCG level <1750 IU/l and 1 was unmeasured due to hemodynamic instability. Results showed that the single strongest

predictor of rupture is serum B-hCG levels. Patients with levels ≥1750 IU/l were 3 times more likely to rupture (95% CI=1.25, 7.19; p value 0.0139) when compared to those with a serum B-hCG level <1750 IU/l (Table 4). Other possible risk factors for rupture, such as age ≥35 years, advanced gestational age, prior ectopic or surgery, PCOS, and smoking were examined but were found to be insignificant. Variables with a strong correlation to surgical intervention include B-hCG level ≥1750 IU/l, age ≥35 years, use of IUCD and smoking. The risk of surgery was increased 3.12 times in those with a B-hCG level ≥1750 IU/l (95% CI=1.81, 5.35; p value <0.0001)

(Table 5). Patients ≥35 years of age were 1.66 times more likely to undergo surgery (95% CI=1.06, 2.60; p-value 0.0263). An IUCD increased the risk of surgery by 2.38 times when compared to other methods of contraception (95% CI=1.88, 3.02; p value <0.0001). Similarly, smokers were 2.42 times more likely to be managed surgically when compared to non-smokers (95% CI=1.89, 3.09; p value=<0.0001).

DISCUSSION

The participants in this study had various ethnic backgrounds with the majority being Asian (69.1%) followed by Middle Eastern (23.4%). This does not represent the general population in Bahrain as the Asian group only constitutes 45.5% of the population while Bahrainis and other Arabs account for 50.7%.[11] There was a slight increase in risk of rupture and need for surgical intervention among Middle Eastern women compared to Asian women (RR=1.97 and 1.16 respectively), but it was insignificant. Other studies, based in the Middle East and in the United States, showed the incidence rate of ectopic pregnancies to be 1%-2% in the general population and 2%-5% among those who used assisted reproductive technology.[12-14] A total of 205 files were reviewed for this study and 136 were confirmed as extra-uterine pregnancies. Among the 136, only 94 (69.1%) were included in this study and the remainder were either lost to follow-up (12.5%), referred to another hospital for financial reasons (8.82%) or refused treatment (3.67%). Those who refused treatment were informed about the risks before signing the AMA form. There were 8 patients (5.88%) who took methotrexate at another hospital and followed-up at our hospital; they were also excluded from our study. The number of patients lost to follow-up may impact the validity of the study and introduce selection bias. However, the losses remain under 20% and were non-selective in terms of exposure and outcome, hence, they do not pose a significant threat.[15]

Stratification was used during data analysis to control for confounding. Multivariable regression analysis is superior in that it can control for more variables simultaneously, however it was unfit for our data.[16] Although measures were taken to reduce confounding, our data may still be influenced by other variables. The lack of information on patient education, financial status, and access to healthcare may impact our data as it can influence patient perception, seeking of healthcare and agreement to management. A study by Stulberg et al found women with financial barriers to have higher rates of unintended pregnancies and overall pregnancy-associated hospitalizations due to late prenatal care.[17] In our study, the mean gestational age at diagnosis was 6.5 (±1.6) weeks. It was 7.1 weeks in a study by Tahmina et al.[18] There was no significant association found between gestational age ≥6 weeks and risk of rupture or surgery. While amenorrhea (65.9%), vaginal bleeding (61.7%) and lower abdominal pain (54.3%) were the most

common presenting symptoms, they were only seen together in 24.5% of patients. Other studies found amenorrhea to be absent in 7%-52% of cases where patients may not be aware that they are pregnant.[19,20] Due to the variability in presentation, the diagnosis of ectopic pregnancy requires high clinical suspicion. The leading risk factors in this population were previous abdominal or pelvic surgery (40.4%), history of miscarriage (26.6%) and age ≥35 years (24.5%). Among the women who underwent previous pelvic surgery, 22 (57.9%) had C-sections, 7 (18.4%) had undergone dilation and curettage for various reasons, and 5 (13.2%) had salpingectomies for prior EPs. There are other important risk factors, such as endometriosis, that were not assessed in this study.[21] This is because we did not have patients in our cohort with endometriosis, despite the prevalence of endometriosis being higher among Middle Eastern and Asian women (12.9% and 15% respectively) compared to the Western populations (5%-10%).[22,23] This may be partially explained by the region's lack of reliable data on the symptomology and risk factors of endometriosis.[22] Those ≥35 years had a 66% greater chance of requiring surgical intervention (p value 0.0263), but they had no significant increase in risk of rupture. The only variable we found to be associated with an increased risk of rupture was a B-hCG level ≥1750 IU/l (RR=3; 95% CI=1.25, 7.19). Those with a high B-hCG level were also 3.12 times more likely to require surgery (p value <0.0001). Other studies also reported that B-hCG increment was a risk factor for rupture.[24,25]

Although placement of an IUCD (1.1%) and smoking (2.1%) were less common, they had a strong association with surgery (RR=2.38 and 2.42 respectively; p value <0.0001). Other risk factors such as PID (0%) were not seen in this study, and there were no other studies found on the overall prevalence in the Middle East. The presence of Chlamydia trachomatis and Neisseria gonorrhoeae was not ruled out in all cases due to the lingering stigma of STIs which may prevent those infected from accessing proper health care and performing cultures. One study examined the prevalence of Chlamydia trachomatis in the region and found it to be 3% which is significantly lower than that of the United States (4.2%).[26,27] In this study, the most common site of ectopic was found to be the fallopian tubes (94.7%). Other studies have also found the fallopian tube to be the most common site of EP overall (96%), with 70% of those located within the ampulla.[14,28] A small number of patients (8.5%) were managed expectantly in line with international guidelines as they were clinically stable and had a low initial serum B-hCG level.[3] Most patients (56.4%) were managed with methotrexate if they were deemed fit in accordance with international and hospital guidelines. Patients are considered fit if they have no contraindications and meet the following criteria: hemodynamic stability, no severe abdominal pain, agreement to follow-up until resolution and normal baseline liver function tests (LFTs) and renal function tests (RFTs).[29] Of those who were given methotrexate,

50.9% received a multi-dose regimen and the remainder received a single-dose regimen. Although medical management was successful in 88.7% of cases, 11.3% later required surgical intervention. Another study had similar findings where methotrexate was successful in 78%-96% of selected patients.[29] They also found that there was a significantly higher success rate with a multi-dose regimen than with a single-dose regimen (92.7% and 88.1% respectively) which was not found in our study. At presentation, 34% of patients required a salpingectomy, 52.6% of which were done by laparotomy and the remainder done laparoscopically. Laparotomies were performed more often than laparoscopies possibly due to a limited number of laparoscopy trained physicians within the hospital. Intra-operative complications were more common among those managed by laparotomy compared to laparoscopy (10% and 0% respectively). 17 patients (18.1%) had a ruptured EP at the time of presentation and 3 (3.19%) ruptured after medical management. All ruptures were treated with a surgical salpingectomy. Salpingostomy was performed in a small subset of patients (2.1%) who had other fertility reducing factors such as a prior salpingectomy and a high baseline B-hCG. The success rate of salpingostomies was 100% and no patients required any further intervention. A study by Mol et al examined the rate of spontaneous conception after surgical intervention and found pregnancy rate was 56.2% after salpingectomy and 60.7% after salpingostomy.[30] It also found the recurrence of EP to be higher with salpingostomy than with salpingectomy (8% and 5% respectively). Studies suggest that the overall rate of surgical intervention can be reduced with early diagnosis as it can allow for prompt management.[31] While we had a mortality rate of 0%, hemorrhage from ruptured EP remains the leading obstetric cause of maternal death in the first trimester.[32] Another study reported that death from ruptured EPs accounted for 2.7% of all pregnancy-related maternal deaths in the United States from 2011 to 2013.[33] 1 person (1.06%) in our study had a chronic ectopic, a result of repeated hemorrhages in the gestational sac with protracted local destruction.[19,34] The insidious onset of presentation and low or undetectable B-hCG levels differentiate it from ectopic pregnancy. Because the patient was hemodynamically stable with an unruptured tubal pregnancy <35 mm in size, she was managed medically in line with guidelines.[35]

CONCLUSION

Current study found B-hCG levels to be the most sensitive predictor of rupture and need for surgical intervention. Therefore, management was largely, but not exclusively, based on B-hCG levels. Majority of cases were treated medically and patients undergoing expectant management experienced no complications.

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