

The impact of the COVID-19 pandemic on the diagnosis and treatment of ectopic pregnancy: a retrospective comparison

COVID-19 pandemisinin ektopik gebelik tanı ve tedavi süreçlerine etkisi: Retrospektif bir karşılaştırma

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ABSTRACT

Aim: To investigate the impact of the COVID-19 pandemic on the diagnosis and treatment processes of ectopic pregnancies (EP) at a tertiary hospital in Turkey.

Materials and Methods: This retrospective study compared 221 cases of tubal EP diagnosed after March 15, 2020, with 217 cases diagnosed before this date. Patient demographics, clinical characteristics, and treatment modalities were analyzed. Statistical analyses, including independent t-tests, Chi-square tests, and multinomial logistic regression, were conducted to assess differences between the COVID and pre-COVID periods.

Results: The study found no significant differences in maternal age, gravidity, parity, or gestational weeks between the COVID and pre-COVID periods. However, there was a notable increase in patients presenting with abdominal pain (52.5% vs. 37.8%) and intraperitoneal hemorrhage (26.7% vs. 7.4%) during the COVID period. Despite the higher frequency of abdominal pain, vaginal bleeding was less common during the pandemic. Treatment approaches also shifted, with a significant increase in medical management (41.2% vs. 29.0%) and a slight decrease in surgical interventions during the COVID period. Multinomial logistic regression revealed that parity, gestational week, presence of Douglas fluid, and the period of diagnosis (COVID vs. pre-COVID) were significant predictors of treatment modality.

Conclusion: The COVID-19 pandemic influenced the clinical presentation and management of ectopic pregnancies in our hospital. While there were no significant differences in key demographic or laboratory parameters, the increased presence of abdominal fluid and a shift towards medical management during the pandemic period suggest changes in patient presentation and treatment preferences. This study underscores the importance of maintaining vigilant diagnostic and therapeutic approaches for EP, even during global health crises.

Keywords: Ectopic pregnancy, COVID-19 pandemic, diagnosis, treatment modalities, maternal health

ÖZ

Amaç: Bu çalışmanın amacı, COVID-19 pandemisinin Türkiye'deki bir üçüncü basamak hastanede ektopik gebeliklerin (EG) tanı ve tedavi süreçleri üzerindeki etkisini araştırmaktır.

Gereçler ve Yöntem: Bu retrospektif çalışmada, 15 Mart 2020'den sonra tanı konulan 221 tübal ektopik gebelik olgusu, bu tarihten önce tanı konulan 217 olgu ile karşılaştırıldı. Hasta demografik bilgileri, klinik özellikler ve tedavi yöntemleri analiz edildi. Gruplar arasındaki farkları değerlendirmek için bağımsız t-testi, Ki-kare testi ve multinominal lojistik regresyon analizleri yapıldı.

Bulgular: COVID dönemi ile COVID öncesi dönem arasında anne yaşı, gravida, parite veya gebelik haftası açısından anlamlı bir fark bulunmadı. Bununla birlikte, COVID döneminde karın ağrısı (COVID öncesi %37,8'e karşılık %52,5) ve intraperitoneal kanama (COVID öncesi %7,4'e karşılık %26,7) ile başvuran hasta sayısında artış gözlemlendi. Karın ağrısı daha sık görülmesine rağmen, pandemi sırasında vajinal kanama daha az yaygındı. Tedavi yaklaşımlarında da değişiklikler oldu; COVID döneminde medikal tedavi oranında (COVID öncesi %29,0'a karşılık %41,2) anlamlı bir artış ve cerrahi müdahalelerde hafif bir azalma görüldü. Multinominal lojistik regresyon analizine göre; parite, gebelik haftası, Douglas sıvısı varlığı ve tanı dönemi (COVID vs. COVID öncesi) tedavi modalitesinin önemli belirleyicileri olarak bulundu.

Sonuç: COVID-19 pandemisi, hastanemizde ektopik gebeliklerin klinik prezentasyonu ve yönetimini etkilemiştir. Önemli demografik veya laboratuvar parametrelerinde anlamlı farklılıklar bulunmamakla birlikte, karın içi sıvı varlığında artış ve pandemi döneminde medikal tedaviye kayma, hasta başvurularında ve tedavi tercihlerinde değişiklikler olduğunu göstermektedir. Bu çalışma, küresel sağlık krizleri sırasında bile ektopik gebeliklerde dikkatli tanı ve tedavi yaklaşımlarının sürdürülmesinin önemini vurgulamaktadır.

Anahtar Kelimeler: Ektopik gebelik, COVID-19 pandemisi, tanı, tedavi yöntemleri, anne sağlığı

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INTRODUCTION

In an EP, implantation takes place outside of the uterus, most frequently in the fallopian tubes in roughly 95% of cases (1). While they may develop later, especially if the pregnancy is at an extrauterine location other than the fallopian tube, clinical signs of ectopic pregnancy normally present six to eight weeks following the last regular menstrual period. There are occasionally common pregnancy discomforts like nausea, frequent urination, and tender breasts. Since progesterone, estradiol, and human chorionic gonadotropin levels may be lower than during a typical pregnancy, early pregnancy symptoms may be less prevalent in ectopic pregnancy patients (2-4). In a retrospective research, 376 (18%) of 2026 pregnant women who had first-trimester vaginal bleeding and/or abdominal discomfort and went to the emergency room were found to have an ectopic pregnancy (5). The frequency of rupture was 18% in a population-based registry of ectopic pregnancies from France (6).

Early detection of tubal pregnancy, made possible by β -hCG, high-resolution ultrasonography, and more frequent use of laparoscopy, has significantly decreased maternal mortality and the need for major surgery. Furthermore, a conservative approach to medical therapy is possible when the problem is diagnosed before serious symptoms appear, particularly when methotrexate is used or when anticipated management is used. The advantages of medication therapy and avoiding surgery are numerous and obvious (7). Medical intervention is most effective in early pregnancy. The incidence of severe bleeding, difficulty in surgery, need for transfusion, and maternal death increases as EP continues (8).

The World Health Organization (WHO) proclaimed the COVID-19 sickness a pandemic affecting the Globe on March 11, 2020, and the Turkish Ministry of Health took swift action regarding health services.

In this study, we investigated the effects of COVID-19 disease on the diagnosis and treatment processes of ectopic pregnancies.

MATERIALS AND METHODS

Study Design

This study is a retrospective cohort analysis conducted at a tertiary hospital in Turkey. The objective was to compare the clinical presentation, diagnostic methods, and treatment modalities of ectopic pregnancy (EP) cases during the COVID-19 pandemic with those diagnosed in the pre-pandemic period. By focusing on tubal ectopic pregnancies, the study aimed to evaluate how healthcare constraints during the pandemic influenced clinical outcomes and decision-making processes.

Participants

The study included women diagnosed with tubal EP between January 1, 2018, and May 1, 2024. Cases after March 15, 2020, were categorized as the "COVID period," while cases before this date constituted the "pre-COVID period."

Inclusion criteria

- Patients with a confirmed diagnosis of ectopic pregnancy based on transvaginal or transabdominal ultrasonography and elevated β -hCG levels.
- Cases where detailed demographic, clinical, and laboratory data were available in the hospital records.

Exclusion criteria

- Cases with incomplete or missing records, including absent ultrasound or laboratory data.
- Non-tubal ectopic pregnancies, including interstitial or cervical ectopic pregnancies, due to differing diagnostic and management approaches.
- Cases where diagnosis remained uncertain or where treatment was initiated elsewhere and lacked detailed documentation.

Data Collection

All data were collected retrospectively from the hospital's electronic medical records and archived patient files. Information on demographic characteristics (e.g., maternal age, parity, gravidity), risk factors for ectopic pregnancy (e.g., history of cesarean section, prior ectopic pregnancy, intrauterine device use, or tubal surgery), and gestational age at presentation was extracted. Clinical presentations at hospital admission, including abdominal pain, vaginal bleeding, or both, were recorded. Laboratory findings, such as serum β -hCG levels and hemoglobin levels at admission and after 24 hours, were analyzed.

Sonographic data, particularly the presence of Douglas fluid (abdominal free fluid) and signs of intraperitoneal hemorrhage, were thoroughly reviewed. Abdominal fluid was identified through transabdominal or transvaginal ultrasonography and categorized based on its volume and echogenicity. In cases where surgical intervention was performed, findings were corroborated intraoperatively to enhance diagnostic accuracy.

Clinical Assessment

Patients with hemodynamic instability, sonographic evidence of ruptured EP (e.g., substantial Douglas fluid or evidence of hemoperitoneum), or a β -hCG level exceeding 5000 IU/

mL were prioritized for immediate surgical intervention. Surgical procedures included salpingectomy or salpingostomy, depending on the patient's condition and surgeon's discretion. For patients who were hemodynamically stable and had β -hCG levels below 5000 IU/mL, medical management with methotrexate was considered based on established clinical protocols. Expectant management was employed for select cases with declining β -hCG levels and no clinical symptoms, following patient consent and close monitoring.

Impact of the Pandemic

During the COVID-19 pandemic, outpatient and emergency services faced significant constraints due to reduced staff availability and resource reallocation. The hospital implemented a shift-based system, reducing the number of healthcare personnel by approximately 30%. To minimize exposure to the virus, patient consultations were limited to one physician and one nurse per session. These measures resulted in a 40% reduction in monthly outpatient admissions, dropping from an average of 1,500 visits pre-pandemic to 900 during the pandemic. During the initial pandemic wave (March to June 2020), weekly outpatient admissions dropped further to approximately 200, reflecting widespread patient hesitancy to seek care. Partial normalization in healthcare utilization was observed in subsequent months as pandemic restrictions eased and public awareness improved.

Statistical Analysis

The data in this study was analysed using IBM SPSS Statistics version 26.0 software (IBM Corp., Armonk, NY, USA). The data's normality distribution was determined using Kolmogorov-Smirnov and histograms. The two groups were compared using an independent t-test, and the values are presented as the mean $\pm$ standard deviation (SD). The categorical data were compared using the Chi-square test, and the values were presented as percentages (%). In order to assess the parameters that influence the treatment modalities for ectopic pregnancy, multinomial logistic regression analysis was implemented. Treatment modalities (surgical, medical, waiting) were employed as dependent variables in this analysis. The independent variables were the presence of fluid in the Douglas cavity, β -hCG levels, age, parity, gestational week, and the distinction between the Covid and pre-Covid periods. The odds ratio (OR) and 95% confidence interval (CI) were used to quantify the impact of each independent variable on treatment modalities. We accepted a statistical significance level of $p < 0.05$.

Ethical Considerations

This study was conducted in compliance with the Declaration of Helsinki. Ethical approval was obtained from the Non-Interventional Clinical Research Ethics Committee of Necmettin Erbakan

University, Faculty of Medicine (Approval No: 2022/3874). Written informed consent was waived due to the retrospective nature of the study. Patient confidentiality was maintained throughout, with data anonymized before analysis.

RESULTS

The research group consisted of 221 different instances of EP that were managed by our division after 15 March 2020. The control comprised 217 EP cases admitted to our department before 15 March 2020.

The research group consisted of 221 different instances of EP that were managed by our division after 15 March 2020. The control comprised 217 EP cases admitted to our department before 15 March 2020.

There was no statistically significant difference between the two periods in terms of maternal age, gravidity, parity and gestational weeks. When the risk factors for ectopic pregnancy were analysed, the proportion of patients without risk factors was 162 (73.3%) in the Covid period and 136 (62.7%) in the pre-Covid period. The rate of patients with a history of previous ectopic pregnancy was found to be 2.7% in the Covid period and 7.4% in the pre-Covid period. In addition, the proportion of patients with a history of previous caesarean section was 20.4% in the Covid period and 29.0% in the pre-Covid period. The number of patients with a history of tubal reanastomosis surgery or intrauterine device use was very low in both periods (Table 1).

Significant differences in clinical characteristics were observed between the COVID and pre-COVID periods ($p=0.001$). Abdominal pain was seen in 52.5% (116/221) patients in the Covid period and 37.8% (82/217) patients in the pre-Covid period. Vaginal bleeding was detected in 23.1% (51/221) patients in the Covid period and 40.1% (87/217) patients in the pre-COVID period. Both abdominal pain and vaginal bleeding were present in 2.7% (6/221) patients in the Covid period and 0.5% (1/217) in the pre-COVID period. Menstrual delay was not seen in the covid period, but was seen in one patient in the pre-covid period. In terms of laboratory findings, there was no statistically significant difference between β -hCG level, haemoglobin level at admission, haemoglobin level after 24 hours and endometrial thickness. However, intraperitoneal haemorrhage was observed in 26.7% (59/221) patients in Covid period and 7.4% (16/217) patients in pre-COVID period ($p=0.001$). Fetal heartbeat positivity was observed at a low rate in both periods (4.1% & 3.2%, $p=0.637$). There was no statistically significant difference in terms of ectopic pregnancy localisation ($p=0.805$).

Table 1. Comparison of Ectopic Pregnancies between Covid and Pre-Covid Periods in terms of Sociodemographic Characteristics

Variables		Ectopic pregnancies in the Covid period (n =221)	Ectopic pregnancies in the pre-Covid period (n=217)	p-value
Maternal age (years)		32.06 ± 6.58	33.09 ± 6.10	0.091
Gravidity		2 (0- 8)	1 (0- 13)	0.058
Parity		1 (0 - 7)	0 (0 - 6)	0.205
Gestational week		6.06 ± 1.48	6.03 ± 1.45	0.850
Ectopic pregnancy risk factors	None	162 (73.3%) ^a	136 (62.7%) ^b	0.001
	History of ectopic pregnancy	6 (2.7%) ^a	16 (7.4%) ^b	
	History of C/S	45 (20.4%) ^a	63 (29.0%) ^b	
	Tubal reanastomosis surgery	0 (0.0%) ^a	2 (0.9%) ^a	
	Intrauterine device	5 (2.3%) ^a	0 (0.0%) ^b	
	Others	3 (1.4%) ^a	0 (0.0%) ^a	

Table 2. Comparison of Clinical Characteristics and Outcomes in Ectopic Pregnancies Between Covid and Pre-Covid Periods

Variables		Ectopic pregnancies in the Covid period (n =221)	Ectopic pregnancies in the pre-Covid period (n=217)	p-value
Clinical characteristics	None	48 (21.7%) ^a	46 (21.2%) ^a	0.001
	Abdominal pain	116 (52.5%) ^a	82 (37.8%) ^b	
	Vaginal bleeding	51 (23.1%) ^a	87 (40.1%) ^b	
	Abdominal pain & Vaginal bleeding	6 (2.7 %) ^a	1 (0.5%) ^a	
	Menstrual delay	0 (0.0 %) ^a	1 (0.5%) ^a	
β-hCG level (mIU/mL)		3426.0 ± 1153.0	5080.9 ± 1452.9	0.085
Hgb level on admission (gr/dL)		12.49 ± 1.46	12.36 ± 1.25	0.334
Hgb level after 24 hours (gr/dL)		11.39 ± 1.48	11.20 ± 1.29	0.199
Endometrial thickness (mm)		9.80 ± 4.40	10.47 ± 4.45	0.115
Intraperitoneal haemorrhage		59 (26.7%)	16 (7.4%)	0.001
Fetal Heartbeat positivity		9 (4.1%)	7 (3.2%)	0.637
Blood tranfusion rate		17 (7.7%)	18 (8.3%)	0.816
Localization of ectopic pregnancy	Location unknown	108 (48.9%)	113 (52.6%)	0.805
	Right tuba uterina	63 (28.5%)	55 (25.6%)	
	Left tuba uterina	44 (19.9%)	43 (10.0%)	
	Scar pregnancy	6 (2.7%)	4 (1.9%)	
Treatment modalities	Expectant management	63 (28.5%) ^a	77 (35.5%) ^a	0.028
	Medical treatment	91 (41.2%) ^a	63 (29.0%) ^b	
	Surgical treatment	67 (30.3%) ^a	77 (35.5%) ^a	

When the Covid-19 period was compared with the pre-Covid-19 period, although there was no statistically significant difference in terms of expectation management and surgical treatment, differences in rates were observed (expectation management: 28.5% vs. 35.5%; surgical treatment: 30.3% vs. 35.5%). On the other hand, medical treatment was administered at a significantly higher rate during the Covid-19 period compared to the pre-Covid-19 period (41.2% vs. 29.0%) (Table 2).

The results of multinomial logistic regression analysis for the parameters affecting the treatment methods in ectopic pregnancy are as follows (Table 3).

Parity, gestational week, Douglas fluid presence, and the Covid period were all significant predictors in the comparison between surgical and expectant management. Parity was associated with an increased likelihood of selecting surgery over expectant management (OR: 1.147, 95% CI: 1.035–1.270, p=0.009). In the same vein, the probability of surgical intervention was significantly elevated by a later gestational week (OR: 1.212, 95% CI: 1.060–1.387, p=0.005). The presence of Douglas fluid significantly predicted a preference for surgery (OR: 4.202, 95% CI: 4.187–4.217, p=0.001). Furthermore, the odds of surgery were lower during the Covid-19 phase than during the pre-Covid-19 phase (OR: 0.783, 95% CI: 0.777–0.789, p=0.001).

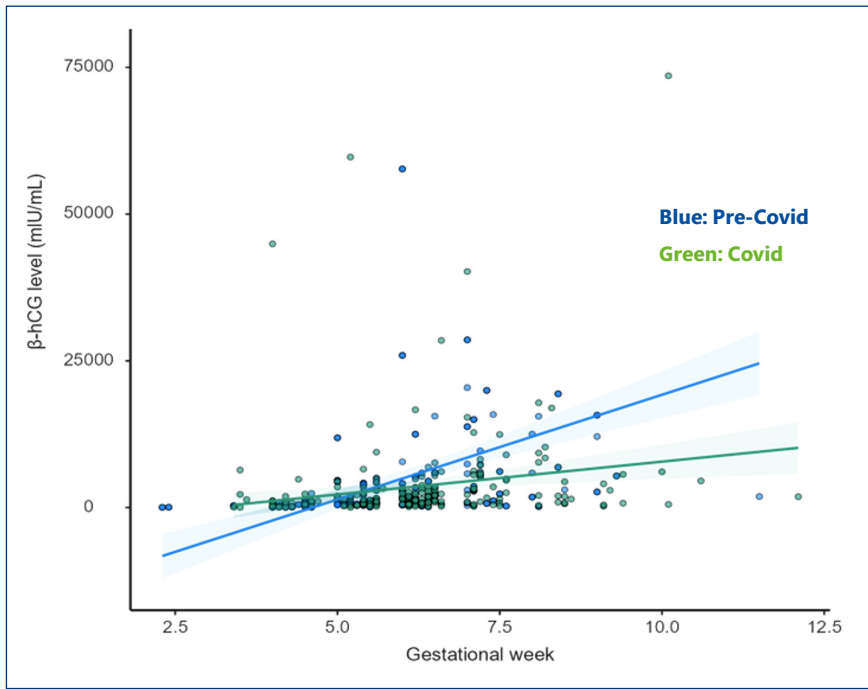


Figure 1. Relationship of β -hCG Levels with Gestational Week in Pre-Covid and Covid Periods

Table 3. Results of Multinomial Logistic Regression Analysis of Parameters Affecting Treatment Modalities in Ectopic Pregnancy

Surgery-Expectant		Predictors	β	SE	p-value	Odds Ratio	(95 % CI)
		Parity	0.137	0.052	0.009	1.147	(1.035 - 1.270)
		Age	-0.002	0.013	0.902	0.998	(0.973 - 1.024)
		β -hCG Level (mIU/mL)	1.140	1.340	0.392	1.022	(0.996 - 1.036)
		Gestational Week	0.193	0.069	0.005	1.212	(1.060 - 1.387)
		Douglas Fluid	1.435	0.002	0.001	4.202	(4.187 - 4.217)
		Covid Period - Pre-Covid Period	-0.244	0.004	0.001	0.783	(0.777 - 0.789)
Medical-Expectant		Predictors	β	SE	p-value	Odds Ratio	(95 % CI)
		Parity	0.016	0.052	0.757	1.016	(0.918 - 1.126)
		Age	0.029	0.012	0.020	1.029	(1.005 - 1.054)
		β -hCG Level (mIU/mL)	1.460	4.190	0.226	1.013	(0.994 - 1.028)
		Gestational Week	0.096	0.070	0.170	1.100	(0.960 - 1.261)
		Douglas Fluid	0.410	0.001	0.001	1.507	(1.503 - 1.511)
		Covid Period - Pre-Covid Period	0.443	0.006	0.001	1.558	(1.539 - 1.576)
Medical- Surgery		Predictors	β	SE	p-value	Odds Ratio	(95 % CI)
		Parity	-0.121	0.055	0.027	0.886	(0.796 - 0.987)
		Age	0.030	0.013	0.015	1.031	(1.006 - 1.056)
		β -hCG Level (mIU/mL)	-1.570	4.180	0.001	0.983	(0.966 - 0.998)
		Gestational Week	-0.097	0.068	0.156	0.907	(0.794 - 1.038)
		Douglas Fluid	-1.025	0.001	0.001	0.359	(0.358 - 0.360)
		Covid Period - Pre-Covid Period	0.687	0.006	0.001	1.988	(1.966 - 2.011)

Age, the presence of Douglas fluid, and the Covid period were significant predictors of medical versus expectant management. A higher likelihood of medical management was associated with older age (OR: 1.029, 95% CI: 1.005–1.054, $p=0.020$). The presence of Douglas fluid was also a significant factor, increasing the likelihood of medical management (OR: 1.507, 95% CI: 1.503–1.511, $p=0.001$). Additionally, the odds of medical management were significantly elevated when contrasted with the pre-Covid period (OR: 1.558, 95% CI: 1.539–1.576, $p=0.001$).

Parity, age, β -hCG levels, Douglas fluid presence, and the Covid period were all significant predictors in the comparison between medical and surgical management. A preference for medical management over surgery was associated with lower parity (OR: 0.886, 95% CI: 0.796–0.987, $p=0.027$). Medical management was once again significantly predicted by older age (OR: 1.031, 95% CI: 1.006–1.056, $p=0.015$). Medical management was preferred over surgery when β -hCG levels were lower (OR: 0.983, 95% CI: 0.966–0.998, $p=0.001$). The presence of Douglas fluid was significantly associated with a lower likelihood of selecting medical management over surgery (OR: 0.359, 95% CI: 0.358–0.360, $p=0.001$). Furthermore, the odds of medical management surpassing surgery were substantially elevated during the Covid-19 pandemic (OR: 1.988, 95% CI: 1.966–2.011, $p=0.001$).

DISCUSSION

This study aimed to evaluate the impact of the COVID-19 pandemic on the diagnosis and treatment of ectopic pregnancies (EP) in our clinic. Our findings reveal several noteworthy trends when comparing the pandemic period to the pre-pandemic period.

One of the most significant observations was the increase in intraperitoneal hemorrhage detected in EP patients during the COVID-19 period. Specifically, 26.7% of patients presented with intraperitoneal hemorrhage during the pandemic, compared to only 7.4% before the pandemic ($p=0.001$). This finding suggests a possible delay in the presentation of patients during the pandemic, leading to more advanced stages of EP at the time of diagnosis. This delay could be attributed to patients' fear of contracting the virus in healthcare settings, leading to postponement of hospital visits despite experiencing symptoms.

Interestingly, despite the increased rate of intraperitoneal hemorrhage, there was no significant difference in gestational age at the time of presentation between the two periods. This finding contradicts the hypothesis that delays in seeking care would result in more advanced gestational ages at presentation. However,

it aligns with the study conducted in Israel, which also reported increased fluid in the Douglas space without a corresponding increase in gestational age at presentation (9).

Moreover, our study observed a higher rate of abdominal pain as a presenting symptom during the COVID-19 period (52.5% vs. 37.8%, $p=0.001$), while the incidence of vaginal bleeding was significantly lower (23.1% vs. 40.1%, $p=0.001$). The shift in clinical presentation could be due to variations in the stage at which EP was diagnosed, potentially driven by delayed healthcare access during the pandemic. The lower incidence of vaginal bleeding might indicate that patients were presenting at a later stage of the disease, when the bleeding had subsided, or that abdominal pain had become the predominant concern prompting medical attention.

Regarding treatment modalities, our study found that medical management with methotrexate was utilized more frequently during the COVID-19 period compared to the pre-pandemic period (41.2% vs. 29.0%, $p=0.028$). This could be explained by a shift towards more conservative management strategies during the pandemic to minimize surgical risks and reduce hospital stays. However, surgical treatment rates were slightly lower during the pandemic (30.3% vs. 35.5%, $p=0.028$), which may reflect a cautious approach to avoid potential COVID-19 exposure in surgical settings.

The results of our multinomial logistic regression analysis revealed that the presence of fluid in the Douglas cavity and the COVID-19 period were significant predictors of the treatment modality. Specifically, the odds of opting for surgery were lower during the pandemic, whereas medical management was more likely. These findings suggest that the pandemic influenced clinical decision-making, likely prioritizing less invasive treatments to reduce the burden on healthcare resources and limit patient exposure to the virus.

Our study's findings align with the results of studies conducted in Israel and USA, which reported similar trends in the clinical presentation and management of EP during the pandemic (9–11). However, unlike studies that reported an increase in tubal rupture cases due to delayed access to healthcare, our study did not find a significant increase in tubal rupture rates during the pandemic. This may indicate that despite delays in presentation, the management strategies employed were effective in preventing severe outcomes.

The strength of our study lies in its large sample size and the comprehensive analysis of a significant clinical issue during an unprecedented global health crisis. However, the retrospective nature of the study is a limitation, as it relies on existing records and may be subject to biases inherent in such analyses. Additionally, the

study is limited to a single center, which may limit the generalizability of the findings to other settings.

The limitation of our study is that it was conducted retrospectively. However, the difficulty of conducting a prospective study during a process such as the COVID-19 pandemic, which has deeply shaken the whole world and adversely affected health systems in many countries, is very clear.

CONCLUSION

In conclusion, our study indicates that the COVID-19 pandemic had a substantial impact on the presentation and management of ectopic pregnancies. The increased incidence of intraperitoneal hemorrhage and the shift towards medical management highlight the need for ongoing vigilance and adaptation of clinical practices during global health crises. Despite the challenges posed by the pandemic, our findings suggest that the adjustments made in patient management were effective in maintaining patient safety and outcomes.

Conflict of Interest

The authors declared that they have no conflict of interest.

Author Contributions

S.Ö.: Conceptualization, data interpretation, manuscript writing and supervision.

F.A.: Statistical analysis and interpretation of data.

E.E.D, R.B.D., S.S.: Data collection and review of clinical records.

A.A.: Supervision and critical revision as mentor.

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Data Availability Statement

Upon a reasonable request, the corresponding author will provide access to the data supporting the conclusions of this research.

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