e-ISSN: 2987-0836 DOI: https://doi.org/10.59585/ijhs

Publish: Association of Indonesian Teachers and Lecturers
International Journal of Health Sciences (IJHS)
Journal Homepage: https://jurnal.agdosi.com/index.php/IJHS/index
Volume 4 | Number 1 | March 2026 |

Diagnostic and Clinical Characteristics of Ectopic Pregnancy: A Retrospective Audit in a UK Early Pregnancy Unit

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ABSTRACT

Background: Ectopic pregnancy remains a leading cause of maternal morbidity and mortality in the first trimester. Early and accurate diagnosis through ultrasound examination is crucial for optimal patient outcomes.

Objective: To analyze the demographic characteristics, clinical presentation, ultrasound findings, and diagnostic patterns of ectopic pregnancies managed in an Early Pregnancy Unit (EPU) over a one-year period.

Methods: A retrospective clinical audit was conducted on 140 consecutive cases of ectopic pregnancy diagnosed and managed at the Princess Royal University Hospital EPU during 2020. Data were extracted from ultrasound reports and clinical records, including patient demographics, gestational age at presentation, ultrasound findings, ectopic location, and mass characteristics. Statistical analysis was performed using SPSS version 28.0, with descriptive statistics, chi-square tests, and correlation analysis where appropriate.

Results: The mean maternal age was 31.9 ± 5.3 years (range 21-44 years), with the highest incidence in the 30-34 years age group 44 (31.9%). Mean gestational age at presentation was 6.4 ± 2.0 weeks. Fallopian tube involvement accounted for 91 (89.2%) of cases, with 49 (48.0%) in the right tube and 42 (41.2%) in the left tube. Ovarian ectopic pregnancies comprised 8 (7.8%) of cases. The mean ectopic mass size was 22.6 ± 11.8 mm (range 3-80 mm). Ultrasound visualization of ectopic gestational structures varied, with gestational sacs visible in 34 cases, yolk sacs in 12 cases, and embryonic structures in 9 cases.

Conclusion: This audit demonstrates the typical demographic and clinical patterns of ectopic pregnancy in a UK EPU setting. The findings support the importance of early ultrasound assessment and highlight the predominance of tubal ectopic pregnancies. These data contribute to quality improvement initiatives and provide benchmarks for EPU services.

Categories: Obstetrics/Gynecology, Quality Improvement

Keywords: Clinical Audit, Early Pregnancy Unit, Ectopic Pregnancy, Maternal Health, Ultrasound

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e-ISSN: 2987-0836 DOI: https://doi.org/10.59585/ijhs

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1. Introduction

Ectopic pregnancy, defined as implantation of a fertilized ovum outside the uterine cavity, occurs in approximately 1-2% of all pregnancies and remains a significant cause of maternal morbidity and mortality in the first trimester [1,2]. The condition represents a medical emergency that requires prompt diagnosis and appropriate management to prevent life-threatening complications such as tubal rupture and hemorrhage [3].

The establishment of Early Pregnancy Units (EPUs) has revolutionized the management of early pregnancy complications, providing specialized care for women presenting with bleeding, pain, or other concerns in the first trimester [4]. These units utilize high-resolution transvaginal ultrasound as the primary diagnostic tool, enabling accurate and timely diagnosis of ectopic pregnancies [5].

The incidence of ectopic pregnancy has increased over the past decades, attributed to various factors including increased prevalence of pelvic inflammatory disease, assisted reproductive technologies, and improved diagnostic capabilities [6,7]. Understanding the demographic characteristics, clinical presentation patterns, and ultrasound findings of ectopic pregnancies is crucial for optimizing diagnostic protocols and improving patient outcomes [8].

Risk factors for ectopic pregnancy include previous ectopic pregnancy, tubal surgery, pelvic inflammatory disease, intrauterine device use, smoking, and assisted reproductive techniques [9,10]. The classic triad of amenorrhea, abdominal pain, and vaginal bleeding is present in only a minority of cases, emphasizing the importance of maintaining high clinical suspicion and utilizing appropriate diagnostic tools [11].

Ultrasound examination, particularly transvaginal scanning, has become the gold standard for diagnosing ectopic pregnancy, with sensitivity and specificity exceeding 90% when performed by experienced operators [12]. The identification of an empty uterus in the presence of positive serum β-hCG levels, combined with the visualization of an adnexal mass or free fluid in the pelvis, supports the diagnosis of ectopic pregnancy [13].

Clinical audit serves as an essential quality improvement tool in healthcare, enabling systematic review of clinical practices against established standards and facilitating evidence-based improvements in patient care [14]. Regular audit of ectopic pregnancy cases allows EPUs to monitor diagnostic accuracy, treatment outcomes, and adherence to clinical guidelines [15].

This study aims to provide a comprehensive analysis of ectopic pregnancies diagnosed and managed in our EPU, examining demographic patterns, clinical characteristics, ultrasound findings, and diagnostic accuracy. The findings will contribute to quality assurance initiatives and provide valuable benchmarking data for similar units.

2. Materials And Methods

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a. Study Design and Setting

This retrospective clinical audit was conducted at the Early Pregnancy Unit of Princess Royal University Hospital, King's College Hospital NHS Foundation Trust, covering the period from January 1, 2020, to December 31, 2020. The EPU operates as a dedicated service for women with early pregnancy complications, staffed by experienced sonographers and gynecologists.

b. Study Population

The study included all consecutive cases of ectopic pregnancy diagnosed and managed in the EPU during the study period. Cases were identified through the unit's ultrasound database and clinical records. Inclusion criteria were: (1) confirmed diagnosis of ectopic pregnancy on ultrasound examination, (2) complete clinical and ultrasound data available, and (3) gestational age ≤20 weeks at presentation. Exclusion criteria included incomplete records and cases managed primarily in other departments.

c. Data Collection

Data were extracted from electronic patient records, ultrasound reports, and clinical databases using a standardized data collection form. Variables collected included:

Demographic characteristics: Maternal age, parity, medical history. Clinical presentation: Gestational age at presentation, symptoms, examination findings. Ultrasound findings: Ectopic location, mass size and characteristics, presence of gestational structures (gestational sac, yolk sac, embryo), fetal heart activity. Laboratory results: Serum β-hCG levels where available. Management: Conservative, medical, or surgical treatment.

d. Ultrasound Protocol

All ultrasound examinations were performed using high-resolution transvaginal probes (5-9 MHz) on GE Voluson systems. Examinations followed standardized protocols including assessment of uterine cavity, adnexal structures, and pouch of Douglas. Ectopic pregnancies were classified by location (tubal, ovarian, cervical, cornual, or abdominal) and characterized by size, echogenicity, and presence of gestational structures.

e. Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics version 28.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated for all variables, with continuous variables expressed as mean ± standard deviation or median (interquartile range) as appropriate. Categorical variables were expressed as frequencies and percentages.

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Normality of continuous variables was assessed using the Shapiro-Wilk test. Comparisons between groups were performed using independent t-tests for normally distributed continuous variables, Mann-Whitney U tests for non-normally distributed variables, and chi-square tests for categorical variables. Correlation analysis was performed using Pearson or Spearman correlation coefficients as appropriate.

Statistical significance was set at $p < 0.05$. Missing data were handled using listwise deletion, with the denominator for each analysis representing cases with complete data for the relevant variables.

f. Ethical Considerations

This study was conducted as a clinical audit in accordance with NHS guidelines for service evaluation and quality improvement. As the study involved retrospective analysis of routinely collected clinical data without patient identifiers, formal ethical approval was not required. The audit was registered with the hospital's clinical audit department and conducted in compliance with data protection regulations.

3. Results

a. Study Population and Demographics

A total of 140 cases of ectopic pregnancy were diagnosed and managed in the EPU during the 12-month study period. The demographic characteristics of the study population are summarized in Table 1.

The mean maternal age was 31.9 ± 5.3 years (median 31.0 years, range 21-44 years). The largest proportion of patients were in the 30-34 years age group 44 (31.9%), followed by the 25-29 years group 43 (31.2%). Women aged 35 years and above comprised 35 (25.4%) of cases, while those under 25 years represented 16 (11.6%).

Table 1: Demographic and Clinical Characteristics

Characteristic	Value	Test Statistic	p-value
Age (years)			
Mean ± SD	31.9 ± 5.3		
Median (IQR)	31.0 (28.0-35.8)		
Range	21-44		
Age groups, n (%)		$\chi^2 = 12.4$	0.03
<25 years	16 (11.6)		
25-29 years	43 (31.2)		
30-34 years	44 (31.9)		

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Characteristic	Value	Test Statistic	p-value
35-39 years	27 (19.6)		
≥40 years	8 (5.8)		
Gestational age at presentation			
Mean ± SD (weeks)	6.4 ± 2.0		
Range (weeks)	2-18		
Correlation: Age vs Mass Size	r = 0.18		0.04
Correlation: Gestational Age vs Mass Size	r = 0.12		0.24
Total cases	140		

Abbreviations: SD, standard deviation; IQR, interquartile range; χ^2, chi-square statistic; r, Pearson correlation coefficient.

Statistical tests: Chi-square test used for comparing ectopic location distribution across age groups; Pearson correlation used for continuous variable associations.

Note: Percentages calculated based on cases with complete data for each variable (n=138 for age analysis, n=121 for gestational age analysis).

b. Clinical Presentation

The mean gestational age at presentation was 6.4 ± 2.0 weeks (range 2-18 weeks). Most patients presented between 5-8 weeks of gestation 82 (68.2%). Early presentation (≤5 weeks) occurred in 22 (18.2%) of cases, while late presentation (>10 weeks) was observed in 10 (8.3%) of cases (Figure 1).

Figure 1 shows the age distribution of 138 patients diagnosed with ectopic pregnancy. Panel A displays a histogram showing the frequency distribution of patient ages, with ages ranging from 21 to 44 years (mean 31.9 ± 5.3 years). Panel B presents a pie chart illustrating the proportion of patients in different age groups: 16 (11.6%) under 25 years, 43 (31.2%) aged 25-29 years, 44 (31.9%) aged 30-34 years, 27 (19.6%) aged 35-39 years, and 8 (5.8%) aged ≥40 years. The highest incidence was observed in the 30-34 years age group.

c. Ectopic Pregnancy Location and Characteristics

Among the 102 cases with documented ectopic location, fallopian tube involvement was predominant, accounting for 91 (89.2%) of cases (Table 2). The right fallopian tube was affected in 49 (48.0%) of cases, while the left fallopian tube was involved in 42 (41.2%). Ovarian ectopic pregnancies comprised 8 (7.8%) of cases,

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with 5 (4.9%) in the right ovary and 3 (2.9%) in the left ovary. Rare locations included interstitial 2 (2.0%) and adnexal 1 (1.0%) sites (Figure 2).

The mean ectopic mass size was 22.6 ± 11.8 mm (median 19.0 mm, range 3-80 mm). Size distribution analysis revealed that masses ≤20 mm comprised 45.6% of cases, 38.8% were 21-40 mm, and 15.5% were >40 mm. There was no statistically significant correlation between mass size and gestational age at presentation (r = 0.12, p = 0.24).

Table 2: Ectopic Pregnancy Location and Ultrasound Findings

Finding	Result	Test Statistic	p-value
Ectopic pregnancy location, n (%)	n = 102		
Right fallopian tube	49 (48.0)		
Left fallopian tube	42 (41.2)		
Right ovary	5 (4.9)		
Left ovary	3 (2.9)		
Interstitial	2 (2.0)		
Other locations	1 (1.0)		
Ectopic mass size (mm)			
Mean ± SD	22.6 ± 11.8		
Median (IQR)	19.0 (14.0-27.5)		
Range	3-80		
Mass size comparison (with vs without free fluid)		t = 2.95	0.003
With free fluid (n=33)	28.4 ± 14.2 mm		
Without free fluid	20.1 ± 9.8 mm		
Mass size and fetal heart activity		t = 2.31	0.02
With fetal heart activity (n=8)	31.2 ± 15.8 mm		
Without fetal heart activity	21.8 ± 10.9 mm		
Ultrasound findings, n (%)			

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Volume 4 | Number 1 | March 2026 |

Finding	Result	Test Statistic	p-value
Gestational sac visible	34/34 (100.0)		
Yolk sac visible	12/12 (100.0)		
Embryo visible	9/9 (100.0)		
Fetal heart activity	8/8 (100.0)		
Free fluid in pelvis	33 (23.6)		

Abbreviations: SD, standard deviation; IQR, interquartile range; t, t-statistic

Statistical tests: Independent t-tests used for comparison of mass sizes between groups with and without free fluid and between groups with and without fetal heart activity; Pearson correlation used for correlation between mass size and gestational age.

Note: Percentages calculated based on cases with complete data for each variable. Ultrasound findings represent cases where specific structures were documented as present when specifically assessed.

Figure 2 illustrates the anatomical distribution and size characteristics of ectopic pregnancies. Panel A shows a horizontal bar chart displaying the location distribution among 102 cases with documented sites: 49 (48.0%) in the right fallopian tube, 42 (41.2%) in the left fallopian tube, 5 (4.9%) in the right ovary, 3 (2.9%) in the left ovary, and 1 (1.0%) in the right interstitial tube. Panel B presents a box plot showing the size distribution of ectopic masses (n=103), with a mean size of 22.6 ± 11.8 mm, median of 19.0 mm, and range of 3-80 mm. The box plot displays the median (red line), interquartile range (box), whiskers (1.5×IQR), and outliers (circles).

d. Ultrasound Findings

Ultrasound visualization of ectopic gestational structures varied considerably. Among cases with documented findings, gestational sacs were visible in 34 cases, representing the most commonly identified structure. Yolk sacs were visualized in 12 cases, while embryonic structures were identified in 9 cases. Fetal heart activity was detected in 8 cases, indicating viable ectopic pregnancies requiring immediate intervention.

The presence of free fluid in the pelvis, suggestive of hemoperitoneum, was documented in 33 (23.6%) of cases, indicating tubal rupture or bleeding. These cases were associated with larger mass sizes (mean 28.4 ± 14.2 mm vs. 20.1 ± 9.8 mm, p = 0.003) and were more likely to require surgical management.

e. Diagnostic Accuracy and Clinical Correlation

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Volume 4 | Number 1 | March 2026 |

The primary diagnosis of "ectopic pregnancy" was established in 55 (39.9%) of cases, with various specific diagnostic terms used to describe location and characteristics. Suspected ectopic pregnancy was diagnosed in 8 (5.8%) of cases, which were subsequently confirmed through clinical follow-up and repeat imaging.

Correlation analysis revealed a significant association between patient age and ectopic mass size ($r = 0.18$, $p = 0.04$), with older patients tending to present with larger masses. However, no significant correlation was found between gestational age and mass size ($r = 0.12$, $p = 0.24$).

f. Statistical Analysis Results

Chi-square analysis demonstrated significant differences in ectopic location by age group ($\chi^2 = 12.4$, $p = 0.03$), with ovarian ectopic pregnancies more common in women over 35 years. The presence of fetal heart activity was significantly associated with larger mass size (mean 31.2 ± 15.8 mm vs. 21.8 ± 10.9 mm, $p = 0.02$).

Logistic regression analysis identified maternal age >35 years (OR 2.3, 95% CI 1.1-4.8, $p = 0.03$) and mass size >30 mm (OR 3.1, 95% CI 1.4-6.9, $p = 0.005$) as independent predictors of requiring surgical management.

4. Discussion

This comprehensive clinical audit of 140 ectopic pregnancy cases provides valuable insights into the demographic patterns, clinical characteristics, and ultrasound findings in a UK EPU setting. Our findings are consistent with published literature regarding the epidemiology and presentation of ectopic pregnancy, while highlighting specific patterns relevant to contemporary clinical practice.

1) Demographic Patterns

The mean maternal age of 31.9 years in our cohort aligns with national trends showing increasing maternal age at conception [16]. The predominance of cases in the 30-34 years age group reflects broader demographic shifts and may be associated with delayed childbearing and increased prevalence of risk factors such as previous pelvic infections and assisted reproductive techniques [17]. The relatively low proportion of very young women (11.6% under 25 years) differs from some international studies, possibly reflecting socioeconomic and healthcare access factors specific to our population [18].

2) Clinical Presentation and Timing

The mean gestational age at presentation of 6.4 weeks demonstrates the effectiveness of early pregnancy services in facilitating prompt evaluation of women with first-trimester symptoms. This early presentation is crucial for optimal outcomes, as delayed diagnosis increases the risk of tubal rupture and associated morbidity [19].

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Journal Homepage: https://jurnal.agdosi.com/index.php/IJHS/index
Volume 4 | Number 1 | March 2026 |

The range of presentation (2-18 weeks) highlights the importance of maintaining clinical suspicion for ectopic pregnancy beyond the typical early pregnancy period.

3) Location and Morphological Characteristics

The predominance of tubal ectopic pregnancies (89.2%) is consistent with established literature, reflecting the anatomical predisposition of the fallopian tubes to abnormal implantation [20]. The slight predominance of right-sided involvement (48.0% vs. 41.2%) has been reported in some studies, though the clinical significance of this laterality remains unclear [21].

The mean ectopic mass size of 22.6 mm provides important benchmarking data for clinical decision-making. The wide size range (3-80 mm) reflects the spectrum of disease presentation, from early unruptured masses to large complex lesions. The correlation between larger mass size and presence of hemoperitoneum supports current guidelines recommending surgical management for larger ectopic pregnancies [22].

4) Ultrasound Diagnostic Capabilities

The variable visualization of gestational structures reflects the challenges inherent in ectopic pregnancy diagnosis. The identification of gestational sacs in 34 cases, yolk sacs in 12 cases, and embryonic structures in 9 cases demonstrates the spectrum of ultrasound findings possible in ectopic pregnancy. The detection of fetal heart activity in 8 cases highlights the importance of immediate management to prevent maternal complications [23].

These findings emphasize the critical role of experienced sonographers in EPU settings and the importance of standardized ultrasound protocols. The ability to identify specific gestational structures can influence management decisions, particularly in cases suitable for conservative or medical management [24].

5) Clinical Implications and Quality Improvement

The correlation between maternal age and mass size suggests that older women may present with more advanced disease, possibly due to delayed recognition of symptoms or different presentation patterns. This finding has implications for clinical assessment protocols and may support age-stratified approaches to early pregnancy evaluation [25].

The association between mass size and surgical management requirements provides evidence supporting current treatment algorithms. The identification of predictive factors for surgical intervention can assist in patient counseling and resource planning within EPU services [26].

6) Comparison with Literature

Our findings are generally consistent with large-scale epidemiological studies of ectopic pregnancy. The demographic profile matches recent UK data, while the

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Journal Homepage: https://jurnal.agdosi.com/index.php/IJHS/index
Volume 4 | Number 1 | March 2026 |

location distribution aligns with international reports [27,28]. The ultrasound findings reflect the diagnostic capabilities expected in contemporary EPU settings, with visualization rates consistent with published series using similar equipment and protocols [29].

7) Strengths and Limitations

a) Strengths

This study presents several notable strengths that enhance the validity and clinical relevance of our findings. The comprehensive nature of our dataset, encompassing 140 consecutive cases over a full calendar year, provides robust statistical power and minimizes selection bias. The single-center design ensures consistency in diagnostic protocols, equipment, and clinical management approaches, reducing inter-observer variability that might confound multi-center studies.

Our EPU maintains high-quality electronic records with standardized ultrasound reporting protocols, enabling detailed extraction of clinical and imaging data. The involvement of experienced sonographers and gynecologists in all cases ensures diagnostic accuracy and appropriate clinical correlation. The use of modern high-resolution ultrasound equipment (GE Voluson systems with 5-9 MHz transvaginal probes) provides optimal imaging capabilities for detecting ectopic pregnancies and their characteristics.

The statistical analysis employed appropriate methodologies for the data types and research questions, including correlation analysis, regression modeling, and non-parametric tests where indicated. The comprehensive demographic analysis provides valuable benchmarking data for other EPU services, while the detailed ultrasound findings contribute to the evidence base for diagnostic protocols.

The audit methodology follows established NHS guidelines for clinical audit and quality improvement, ensuring that findings are directly applicable to clinical practice improvement initiatives. The systematic approach to data collection and analysis provides a model for similar audits in other healthcare settings.

b) Limitations

Despite these strengths, several limitations must be acknowledged when interpreting our findings. The retrospective design inherently limits the completeness and consistency of data collection, as clinical records were not originally designed for research purposes. Some variables of interest, particularly detailed risk factor assessment and symptom duration, were inconsistently documented in clinical records.

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Volume 4 | Number 1 | March 2026 |

The single-center design, while ensuring consistency, may limit the generalizability of findings to other populations with different demographic characteristics, healthcare access patterns, or clinical protocols. Our patient population may not be representative of all UK EPU services, particularly those serving different socioeconomic or ethnic populations.

Missing data for certain variables, particularly ultrasound findings and laboratory results, reflects the challenges of retrospective data extraction and may introduce bias in specific analyses. The proportion of missing data varied considerably between variables, with some analyses based on smaller subsets of the total cohort.

The study period coincided with the COVID-19 pandemic, which may have influenced patient presentation patterns, clinical protocols, and resource allocation. While our EPU maintained consistent diagnostic approaches, the pandemic may have affected patient behavior regarding seeking medical care for early pregnancy symptoms.

The audit focused primarily on diagnostic aspects and did not comprehensively evaluate treatment outcomes, complications, or long-term follow-up data. This limits our ability to assess the clinical significance of various diagnostic findings or to evaluate the effectiveness of different management approaches.

Inter-observer variability in ultrasound interpretation, while minimized through standardized protocols and experienced operators, was not formally assessed. The subjective nature of some ultrasound findings may introduce diagnostic variability that could influence the reported frequencies of specific findings.

5. Conclusions

This audit demonstrates that dedicated Early Pregnancy Units are effective in facilitating early diagnosis and appropriate management of ectopic pregnancies. The findings support the continued use of high-resolution ultrasound as the primary diagnostic tool and emphasize the importance of experienced sonographic assessment. These data provide a framework for ongoing quality improvement and benchmarking within EPU services, supporting evidence-based approaches to patient care and contributing to national standards development.

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Volume 4 | Number 1 | March 2026 |

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Volume 4 | Number 1 | March 2026 |

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Volume 4 | Number 1 | March 2026 |

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