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Diagnostic Accuracy of Transvaginal Ultrasound for Tubal Ectopic Pregnancy Using Laparotomy as the Gold Standard

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ABSTRACT

OBJECTIVE: To evaluate the diagnostic accuracy of transvaginal Ultrasound (TVUS) in detecting tubal ectopic pregnancies compared to laparotomy, which is considered the gold standard for diagnosis

METHODOLOGY: This study employed a cross-sectional design and was carried out within the obstetrics and gynecology department of Khyber Teaching Hospital, Peshawar, from February to August 2017. A total of 223 women aged 15 to 45 years were included in the study. Consecutive patients suspected of having an ectopic pregnancy were enrolled. All participants underwent transvaginal Ultrasound (TVUS), followed by laparotomy for the definitive diagnosis of ectopic pregnancy. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of TVUS were calculated based on the comparison with laparotomy findings. Data analysis was performed using SPSS version 22.

RESULTS: The average age of the participants was 29.8 years (SD ± 6.8). Transvaginal Ultrasound detected ectopic pregnancy in 60.1% of patients, while laparotomy identified ectopic pregnancies in 50.2% of patients. The diagnostic accuracy of TVUS was calculated as follows: sensitivity: 90.1%, specificity: 70.3%, positive predictive value (PPV): 75.4%, negative predictive value (NPV): 87.6%

CONCLUSION: Transvaginal Ultrasound, a widely recognized diagnostic tool for ectopic pregnancy, demonstrates high sensitivity and specificity when compared to laparotomy as the gold standard. It serves as an essential radiological tool for the early and accurate diagnosis of tubal ectopic pregnancy, supporting timely clinical decision-making and management.

KEYWORDS: Diagnostic accuracy, Ectopic pregnancy, Laparotomy, Non-invasive diagnosis, Reproductive Health, Trans vaginal ultrasound.

INTRODUCTION

The occurrence of ectopic pregnancies has increased over recent decades. However, the risks to mothers, including illness and death, have decreased, primarily due to better awareness and earlier detection. Identifying ectopic pregnancies is crucial for lowering maternal mortality rates. Although diagnostic laparoscopy is regarded as the most dependable method for diagnosing tubal ectopic pregnancy, it also has certain limitations. Despite its accuracy, diagnostic laparoscopy has a false-positive rate of 5% and a false-negative rate of up to 4% [1]. This means that even though laparoscopy is highly accurate, there are still instances where it might incorrectly suggest the presence or absence of a tubal ectopic pregnancy.

An ectopic pregnancy occurs when a fertilized egg implants and grows outside the uterus, most commonly in the fallopian tubes. This abnormal implantation prevents the fetus from developing typically and can lead to fatal complications if not immediately diagnosed and treated. Only about 50% of patients present with the classic clinical triad symptoms like abdominal pain, amenorrhea, and vaginal bleeding. The rest of the patients present with nonspecific abdominal discomfort or mild bleeding. A history-based diagnosis of ectopic pregnancy should include general, abdominal, and pelvic examinations. The typical findings on examination are syncope, hypovolemic shock, abdominal rigidity, severe tenderness, cervical excitation and adnexal mass palpation.[2]

Timely diagnosis of an ectopic pregnancy is essential to prevent maternal mortality. The initial step involves a positive pregnancy test, accompanied by serum beta HCG levels that rise less than expected in a normal pregnancy. The introduction of high-resolution transvaginal Ultrasound has significantly improved the accuracy of diagnosing ectopic pregnancies. [3]

Over the past few decades, TVS has become the primary method for diagnosing ectopic pregnancies, with a reliability rate of 87% to 99% for detecting tubal pregnancies. The sensitivity of TVS as a standalone test for ectopic pregnancy is 74%, while its specificity is 99.9%. Indeed, ultrasound indicators of ectopic pregnancy can vary considerably. One significant indicator is an empty uterus observed during transvaginal Ultrasound (TVS), especially when serum beta HCG levels exceed the discriminatory cutoff value for a normal intrauterine pregnancy. In such cases, ectopic pregnancy is considered until proven otherwise through further diagnostic evaluation. Laparoscopy should not be used as a diagnostic tool but rather as an operative interventional tool.[4]

Diagnosing ectopic pregnancy should prioritize identifying an extrauterine mass rather than solely relying on the absence of an intrauterine pregnancy. The definitive indication of ectopic pregnancy is the presence of a viable embryo situated outside the uterus. However, clinicians should note that this finding is observed in only 8-26% of ectopic pregnancies detected via transvaginal Ultrasound. [5] Therefore, clinicians must consider various ultrasound findings and clinical factors to make an accurate diagnosis and ensure appropriate management.

Therapeutic options for ectopic pregnancy include expectant, methotrexate and surgical intervention based on the clinical scenario of the patient. In one study involving 100 women highly suspected of having ectopic pregnancies (EP), 94% were diagnosed with EP.[6] Another review reported that transvaginal Ultrasound (TVS) has a sensitivity of 81.1% and a specificity of 79.5% for detecting EP.[7]

This study aimed to identify a rapid and reliable diagnostic marker for ectopic pregnancy (EP) within our specific population, especially in cases with high clinical suspicion. Given the relatively high prevalence of EP in our population, early diagnosis and timely management are

essential to minimizing maternal morbidity and mortality. Significant findings from this research will be shared with local obstetricians to inform clinical practice and guide future research efforts.

METHODOLOGY

This study employed a cross-sectional design and was conducted within the obstetrics and gynecology department of Khyber Teaching Hospital, Peshawar, from February to August 2017. This study received approval from the Registration and Research Cell of the College of Physicians and Surgeons, Pakistan. A total of 223 patients were recruited using non-probability consecutive sampling. The sample size was calculated with a 95% confidence level, a prevalence of ectopic pregnancy of 56%, a sensitivity of 81.1%, a specificity of 79.5%, and an 8% margin of error. Inclusion criteria were age above 15 to 45 years, women presenting in their first trimester with high suspicion of ectopic pregnancy (women with positive pregnancy tests having abdominal pain, regional bleeding and beta HCG level of more than 25 IU per liter). Exclusion criteria were confirmed intrauterine pregnancies and molar pregnancies. Confirmation was achieved by performing transabdominal Ultrasound and serum beta HCG. Women with tubo-ovarian masses on Ultrasound were also excluded. These conditions were excluded to minimize confounding and reduce potential bias in the study results. All patients who arrived at the department with a high suspicion of ectopic pregnancy, as defined by the study's inclusion criteria, were enrolled in the research. The patients were informed about the study's objectives and potential advantages. They were also made aware of any associated risks. It was clarified that their participation was solely for research purposes and data publication. If they agreed to participate, both partners provided written informed consent; this ensured that patients understood the study's goals, potential benefits, and risks and voluntarily consented to contribute their data.

All patients were subjected to TVS. Upon completion of TVS, all patients were subjected to laparotomy. All laparotomies were performed by an expert obstetrician with a minimum experience of five years. All transvaginal sonography (TVS) procedures were performed under the supervision of a single expert radiologist with a minimum of five years of experience. All relevant information was systematically recorded using a predefined form. Strict exclusion criteria were adhered to to minimize confounding factors and bias in the study results.

Collected data were entered into SPSS version 22 for analysis. Study variables included TVS findings and laparotomy reports. We calculated the mean and standard deviation (SD) for numerical variables such as age, gravidity, and parity. Frequency and percentage were computed for categorical variables such as previous history of ectopic pregnancy. To assess the diagnostic performance of TVS, sensitivity, specificity, positive predictive value, and negative predictive value were determined using laparotomy findings as the gold standard.

RESULTS

The research involved 223 women who were suspected to have ectopic pregnancy. The ages of the participants ranged from 15 to 45 years. The mean age of the participants was 29.8 years, with an SD±6.8 years.

When the participants were grouped into different age categories, it was found that 25.6% of them were between 15 and 25 years old, 45.7% were between >25 and 35 years old, and 28.7% were between >35 and 45 years old.

While distributing the information to the patients about gravidity, 25.6% were gravida 1, 64.6% were gravida 2-4, and 9.9% were gravida 5 or higher.

Ultrasound examination revealed ectopic pregnancies in 60.1% of the patients. The sensitivity of Ultrasound was determined to be 90%, indicating its ability to identify true positive cases correctly using standard statistical calculations. The specificity of Ultrasound, indicating its ability to identify true negatives correctly, was 70.3%. Furthermore, the positive predictive value of Ultrasound, which shows the likelihood that a positive ultrasound result truly indicates ectopic pregnancy, was calculated at 75.4%. Conversely, the negative predictive value (NPV), representing the likelihood that a negative ultrasound result correctly excludes ectopic pregnancy, was calculated as 87.6% (**Table I**).

Tables II and **III** elaborate on the sensitivity and specificity in different age and gravidity groups.

Table I: Ectopic pregnancy on Ultrasound and confirmed by laparotomy (n = 223)

Ectopic Pregnancy on Ultrasound	Positive (Laparotomy)	Negative (Laparotomy)	Total
Positive (Ultrasound)	101 (TP)	33 (FP)	134
Negative (Ultrasound)	11 (FN)	78 (TN)	89
Total	112	111	223

Sensitivity of US: TP/TP + FN = 90.1%
Specificity of US: TN/TN+FP=70.3%
Positive Predictive Value US: TP/TP + FP = 75.4%
Negative Predictive Value US: TN/TN+FN=87.6%
Overall Accuracy: TP + TN / Sample size = 80.3%

Table II: Sensitivity and specificity of Ultrasound in different age groups

Age Groups	Ectopic Pregnancy on US	Ectopic Pregnancy on LAP	Sensitivity of US	Specificity of US	PPV	NPV
15 to 25years	34 (+)	23 (+)	100%	100%	100%	100%
	0 (-)	0 (-)				
25 to 35years	58 (+)	47 (+)	76.6%	60%	62.1%	75%
	44 (-)	55 (-)				
35 to 45years	42 (+)	31 (+)	100%	66.7%	73.8%	100%
	22 (-)	33 (-)				

Table III: Sensitivity and specificity of ultrasound indifferent gravidity groups

Parity Groups	Ectopic Pregnancy on US	Ectopic Pregnancy on LAP	Sensitivity of US	Specificity of US	PPV	NPV
Gravidity 1	34 (+)	23 (+)	100%	100%	100%	100%
	0 (-)	0 (-)				
Gravidity 2-4	89 (+)	78 (+)	85.9%	51%	75.3%	80%
	55 (-)	66 (-)				
Gravidity 5 or above	11 (+)	0 (+)	NA	NA	NA	NA
	11(-)	22 (-)				

DISCUSSION

In the late 1960s, ultrasound technology began to show promise in improving the diagnosis of ectopic pregnancy when an intrauterine pregnancy was not visualized. It was considered a possible non-invasive alternative to laparoscopy. The significant cohort study in this area dates back to the 1980s, spanning from 1966 to 1976, when abdominal Ultrasound was used to scan women suspected of having ectopic pregnancies. Data analysis from three hundred forty-two women revealed moderate reliability, with Ultrasound having a sensitivity of 81% and specificity of 77%.[8]

Technological advancements led to the development of smaller ultrasound transducers, replacing older bulky probes and allowing for their vaginal insertion. This innovation reduced the distance between the probe and the target area, overcoming previous limitations and substantially enhancing the resolution of high-frequency Ultrasound. Consequently, smaller intrauterine and ectopic pregnancies could be visualized with greater clarity.[9]

Over the following decades, transvaginal Ultrasound (TVS) has become the primary method for diagnosing ectopic pregnancy. TVS can diagnose between 87% and 99% of tubal pregnancies today. Typical ultrasound findings include about 60% of ectopic pregnancies appearing as an irregular mass (known as the "BLOB sign") near the ovary, 20% showing a hyperechoic ring (the "Bagel sign"), and 13% presenting with a visible gestational sac containing a fetal pole, sometimes with fetal cardiac activity.[10]

Our findings revealed that a single initial transvaginal ultrasound scan performed by general sonographers in a radiology department within a tertiary hospital has demonstrated high sensitivity (90.1%) and specificity (70.3%) in diagnosing ectopic pregnancy. Similar results have been reported in other extensive studies, where sensitivity ranged between 73.9% and 90.9% and specificity between 99.8% and 99.9%. [11-14]

With the vast majority of ectopic pregnancies (EPs) successfully diagnosable by initial transvaginal Ultrasound (TVUS), some women may require clinical reassessment, repeat beta-HCG testing, and follow-up ultrasound examinations. Missed EP cases (false negative ultrasound results) are initially classified as pregnancies of unknown locations (PULs) [15-17]. The addition of a second follow-up ultrasound moderately improves the diagnostic performance of the Ultrasound. Combining both trans-abdominal Ultrasound (TAS) and TVUS enhances diagnostic accuracy.

In developing countries such as Pakistan, it is challenging to provide sophisticated medical equipment and specialized expertise to every pregnant woman. Additionally, cultural and religious constraints and limited availability of facilities and expertise make it impractical within our healthcare system. Conversely, Ultrasound (US) is more accessible, and convenient, and does not require specific gender considerations, which are often problematic in our society. Potential strategies to address these challenges include training community healthcare workers in basic ultrasound techniques, deploying mobile ultrasound units, and adopting cost-effective technologies to enhance accessibility.

Dallas et al. [18] conducted ultrasound examinations on 66 patients suspected of ectopic pregnancy, achieving a clear diagnosis in 69.6% of cases. Similarly, **Chichia et al.** [19] reported a clear diagnosis in 89% of cases using transabdominal sonography for ectopic pregnancy in their study conducted in Tunis. **Ahmed et al.** [20], in their research at Nishtar Hospital Multan, found that Ultrasound detected ectopic pregnancy with a clear diagnosis in 88.2% of cases confirmed on laparotomy, with 11.3% false positive diagnoses. The slight variation in sensitivity compared

to **Dallas et al.** could be attributed to differences in sample size and interpretation of a few cases in their study. Combining both transabdominal and transvaginal sonography has been shown to improve diagnostic accuracy."

In a study by **Zinn et al.,** [21] three patients initially negative on transvaginal Ultrasound (TVUS) were subsequently found to have confirmed ectopic pregnancy (EP) on transabdominal Ultrasound (TAS). **Athey et al.** [22] reviewed 45 consecutive cases of proven EP using both TAS and TVS. TVUS outperformed TAS in 22 cases (49%), was less effective in 3 cases (7%), and provided comparable information in 20 cases (44%). **Braffman et al.** [23] screened 1427 patients for EP using TAS followed by TVUS, successfully diagnosing 81% of patients. They reported sensitivity and specificity rates of 99% and 84%, respectively. Combining sonography with serial beta-HCG measurements or established criteria further improves diagnostic accuracy. **Shaler et al.** [24] assessed 840 pregnancies with TVUS and correlated them with serum beta-HCG levels, achieving a sensitivity of 87% and specificity of 94%. **Naseem et al.** [25] reported perfect sensitivity and specificity of 100% when using transabdominal sonography (TAS) and transvaginal sonography (TVS) correlated with serum Beta HCG. However, their study involved a smaller sample size and utilized several established criteria.

Although Ultrasound has limitations such as operator dependence, the need for a full bladder, and challenges with acoustic windows due to bowel gases, a good clinical approach serves as an essential starting point in managing patients with EP. The importance of clinical history, examination, serial beta-HCG monitoring, and possibly laparoscopy cannot be overlooked. Therefore, there is a need for improved clinical training of healthcare providers in settings where advanced facilities may not be readily available to ensure timely and effective management of patients.

CONCLUSION

Ultrasound is a highly sensitive and specific tool for detecting ectopic pregnancy. Therefore, it serves as a valuable radiological marker for diagnosing ectopic pregnancy, and further studies are recommended to validate its utility.

LIMITATIONS

This study has several limitations that should be considered when interpreting the results. First, the sample size was relatively small, which may reduce the statistical power to detect significant differences in diagnostic accuracy and may not fully represent the broader patient population. Second, the study was conducted at a single institution, which limits the generalizability of the findings to other healthcare settings or populations. Third, this study focused exclusively on transvaginal Ultrasound as the sole diagnostic tool for detecting ectopic pregnancies, comparing it only to laparotomy. Including additional complementary diagnostic methods, such as serum beta-hCG levels or other imaging techniques (e.g., trans abdominal Ultrasound or MRI), could have provided a more comprehensive assessment of diagnostic accuracy and potentially enhanced the overall effectiveness of the diagnostic process.

Future studies with larger, multi-centre samples and the inclusion of additional diagnostic modalities would provide a more robust evaluation of Ultrasound's role in diagnosing ectopic pregnancy.

RECOMMENDATIONS

Although Ultrasound has limitations such as operator dependence, the need for a full bladder, and challenges with acoustic windows due to bowel gases, a good clinical approach serves as an essential starting point in managing patients with EP. The importance of clinical history, examination, serial beta-HCG monitoring, and possibly laparoscopy cannot be overlooked. Therefore, there is a need for improved clinical training of healthcare providers in settings where advanced facilities may not be readily available to ensure timely and effective management of patients.

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AUTHOR CONTRIBUTION

Zeb M:	Concept of the study, Methodology, manuscript writing and Final approval
Robeen K:	Analysis and Interpretation of data, drafting the manuscript, Final approval
Khattak N:	Statistical analysis, revising the manuscript, Final approval
Riaz S:	Editing and reviewing the manuscript, Final approval

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