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Diagnostic Accuracy of Transabdominal Ultrasound in the Diagnosis of Ectopic Pregnancy Taking Transvaginal Ultrasound as the Gold Standard

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ABSTRACT

Background: The diagnostic accuracy of transabdominal ultrasound in the diagnosis of ectopic pregnancy has rarely been studied in our population. Hence, the study has been planned. **Objective:** This study aimed to determine the accuracy of transabdominal ultrasound in the diagnosis of ectopic pregnancy, transvaginal ultrasound was used as the gold standard. **Materials and Methods:** This cross-sectional study was carried out at the Department of Radiology, Northwest General & Research Centre, Peshawar, from 12th June 2022 until 12th December 2022. Patients aged 15--45 years presenting with signs and symptoms of ectopic pregnancy were enrolled. Transabdominal ultrasound was performed, and the diagnostic accuracy was compared with that of transvaginal ultrasound to determine the diagnostic accuracy. The data were analysed via SPSS version 25. **Results:** A total of 143 patients were enrolled. The mean age of the patients was 30.01 ± 5.518 years. The majority of the patients were aged less than 30 years ($n = 84$, 58.7%). The sensitivity, specificity, PPV, NPV and accuracy of transabdominal ultrasound were 93.9%, 100.0%, 100.0%, 57.8% and 94.4%, respectively. **Conclusion:** The clinical spectrum of ectopic pregnancy is very wide. Transabdominal ultrasound is a useful noninvasive diagnostic tool for the diagnosis of ectopic pregnancy.

INTRODUCTION

EP constitutes a major source of maternal morbidity and mortality, particularly in the first trimester of pregnancy. It happens when a fertilised ovum implants outside the uterine cavity, typically in the fallopian tube (1). Ectopic pregnancy occurs in 1–2% of all pregnancies around the world, and the risk is greater among women with the risk factors of pelvic inflammatory disease, prior tubal surgery, or the use of assisted reproductive technologies (2). Early and accurate diagnosis of ectopic pregnancy will prevent life threatening complications such as tubal rupture and hemorrhage and also maintain future fertility.

However, because TVUS has better resolution and can image pelvic structures in greater detail

than other imaging options, it is considered to be the gold standard for the diagnosis of ectopic pregnancy (3, 4). However, access to TVUS is not universally available; in particular, TVUS is not available in low resource settings and rural areas where there may be limited or no access to trained personnel and specialized equipment. In these situations, transabdominal ultrasound (TAUS) is frequently the first line imaging approach employed when ectopic pregnancy is suspected. This, compared to TVUS is noninvasive, widely available, and does not necessitate specialized training. However, studies continue to question TAUS diagnostic accuracy with respect to diagnosing ectopic pregnancy since the sensitivity



and specificity would differ from study to study. (5, 6).

There are several factors affecting the diagnostic performance of TAUS; such as the operator's expertise, body habitus of the patient, and the gestational age at the time of evaluation. Although TAUS is adequate for diagnosing intrauterine pregnancies and large adnexal masses, it is not as reliable for diagnosing small or early ectopic pregnancies compared with TVUS (7, 8). This diagnostic gap provides the impetus for a systematic assessment of the accuracy of TAUS in diagnosing ectopic pregnancy, especially in its CFG it remains prohibitive.

The utility of TAUS for the diagnosis of ectopic pregnancy has been previously examined with inconsistent results. Few studies have demonstrated high sensitivity and specificity for TAUS in detecting ectopic pregnancy; however, others have noted its lack of performance in delineating subtle or atypical ectopic locations (8, 9). These differences may explain the discrepancies among these studies in study design, patient populations and diagnostic criteria. In addition, the available data for the comparison of diagnostic accuracy of TAUS and TVUS are limited to the assessment in a nonstandardized fashion which does not allow for generalized evidence.

The purpose of the present study is to fill this gap by systematically assessing the diagnostic accuracy of transabdominal ultrasound for the diagnosis of ectopic pregnancy as the gold standard is transvaginal ultrasound. This study seeks to provide robust evidence on utility of TAUS in clinical practice by comparing the sensitivity, specificity, positive predictive value, and negative predictive value of TAUS compared to TVUS. This study carries the potential to inform clinical guidelines and guide improved management of ectopic pregnancy, especially in resource limited settings with limited access to TVUS.

Beyond its clinical implications, this study aimed to fill gaps in the diagnostic pathway of ectopic pregnancy for a topic of broader public health relevance. Accurate and timely diagnosis of ectopic pregnancy is important for reducing maternal morbidity and mortality and also for improving patient outcomes and limiting healthcare resource use. As an evaluation of the diagnostic performance of TAUS in line with

global efforts in maternal health and the Sustainable Development Goals, that of reducing maternal mortality, TAUS should be referred to as a screening test (10).

MATERIALS AND METHODS

The study was cross-sectional validation study in Department of Obstetrics and Gynecology, Northwest General Hospital & Research Centre, Peshawar from 12th June 2022 to 12th December 2022. With a 95% confidence interval, ectopic pregnancy prevalence of 19.7%, and an absolute precision of 15%, 143 patients were included in the study and achieved 79.5% sensitivity, 83.3% specificity. Participants were recruited by means of consecutive non-probability sampling.

Inclusion criteria were appropriate female patients, age 15–45 years, with signs and symptoms of ectopic pregnancy and who were willing to give informed consent. The study excluded patient's who had a history of uterine, or fallopian tube surgery, had normal transvaginal ultrasound findings, or had lower abdominal symptoms due to other etiologies. This study was approved ethically by both the ethical committee and the institutional review board of Northwest General Hospital & Research Centre, and the ethical approval was taken from the College of Physicians and Surgeons Pakistan (CPSP).

The data collection was made by evaluating all eligible patients who presented with suspected ectopic pregnancy to the Diagnostic Radiology Department. Each patient was given informed written consent, and after having done so then received a transabdominal ultrasound and the findings were recorded. A confirmatory transvaginal ultrasound was performed (the gold standard diagnosis method). Patient details (name, medical record no., age, serial no., date) were documented and findings from both transabdominal and transvaginal ultrasound automatically recorded onto a structured questionnaire.

IBM SPSS, version 21 was used to analyze the collected data. Categorical variables included age groups, previous ectopic pregnancies, and ultrasound findings; frequencies and percentages were calculated. Diagnostic parameters were calculated including Sensitivity, Specificity, Positive predictive value (PPV), and Negative

predictive value (NPV), stratified across age groups using transvaginal ultrasound as the reference standard.

RESULTS

The age distribution pattern among the study groups with ectopic pregnancy is shown in Figure 1. A total of 143 participants aged 15 to 45 years participated in the analysis. Participants had a mean age of 29.1 years ($SD \pm 8.9$). A relatively normal age distribution was seen, with a preponderance of cases in the range from 20 to 35 years of age. Of note was a slight predominance in ages in 25-30 years age group, supporting the normal reproductive age range in which an ectopic pregnancy would present. A pattern of distribution shows risk of ectopic pregnancy occurring over the entire reproductive age spectrum with different frequencies in different age groups.

Figure 1

Age-wise distribution of participants

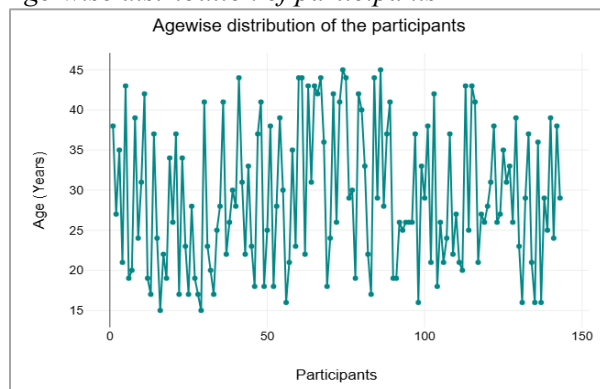


Table 1 provides the descriptive summary of nominal variables such as diagnosis, imaging modality and outcome. An analysis of the data shows that 67.13% of cases or subject were diagnosed as 'NO', ectopic pregnancy and 32.87% as 'YES'. More transvaginal ultrasound was done than transabdominal (50.35% VS. 49.65%). Finally, the outcomes are consistent with the diagnosis distribution: 67.13% being labeled as 'Excluded' versus 32.87% of cases labeled as 'Confirmed'. Ultimately, these results add even more support to the notion of proportional diagnostic outcomes across all the studied cases, and the fact that both procedures have near equal reliance. The congruence of transvaginal and transabdominal ultrasound as diagnostic tools in the management of ectopic pregnancy is

highlighted by the balanced use of these two procedures, and the outcome distribution accurately corresponds to diagnostic accuracy and the prevalence of the problem in the study cohort.

Table 1

Demonstrated the descriptive statistics of nominal variables

Variables	Details	Frequency	Percentages
Diagnosis	No	96	67.13%
	Yes	47	32.87%
Imaging	Transvaginal	72	50.35%
Modalities	Transabdominal	71	49.65%
Outcomes	Excluded	96	67.13%
	Confirmed	47	32.87%

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Table 2

Diagnostic Accuracy Of Transabdominal Ultrasound

USG* TVS Findings				
		TVS Findings		
		Positive	Negative	Total
USG	Positive	124 (100.0%)	00 (0.0%)	124 (100.0%)
	Negative	08 (42.1%)	11 (57.9%)	19 (100.0%)
Total		132 (92.3%)	11 (7.7%)	143 (100.0%)

Sensitivity = 93.9%
Specificity = 100%
PPV = 100%
NPV = 57.8%
Accuracy = 94.4%

Table 3 presents the age-stratified analysis of diagnostic accuracy for transabdominal ultrasound (USG) compared to transvaginal ultrasound (TVS),

with patients categorized into two age groups: ≤ 30 years and >30 years. Transabdominal ultrasound showed a sensitivity of 91.0% and a specificity and PPV of 100%, but a NPV of only 46.1% (in patients ≤ 30 , $n=84$). Overall diagnostic accuracy in this age group was 91.7%. Of the 71 positive USG findings in this age group, all were confirmed positive by TVS, as also the seven out of the 13 negative findings, where they were false negatives.

In patients >30 years ($n=59$), characteristics of diagnostic performance were slightly different: sensitivity 92.9%, specificity 100%, PPV 100%, and NPV 33.3%. In this group the overall accuracy was 93.2%. Of the 53 positive USG findings all were confirmed by TVS and 4 out of 6 negative findings were false negatives. Both age groups maintained 100% specificity and PPV, thus excellent reliability in confirming positive cases across age groups. This is supported by the fact that NPVs are already lower in both groups, especially among patients >30 years of age (33.3% vs 46.1%), meaning that a false negative result is more likely; USG negative findings should be considered with reservation, especially in older patients.

Table 3

Stratification of Diagnostic accuracy w.r.t to the age of the patient

Patients USG* TVS Findings		TVS Findings			Sensitivity = 91.0% Specificity = 100% PPV = 100% NPV = 46.1% Accuracy = 91.7%
Age (years)		Positive E	Negative E	Total	
≤ 30 years	US G	Positive	71 (100.0%)	00 (0.0%)	71 (100.0%)
		Negative E	07 (53.8%)	06 (46.2%)	13 (100.0%)
		Total	78 (93.8%)	06 (6.2%)	84 (100.0%)
>30 years	USG	Positive	53 (100.0%)	00 (0.0%)	53 (100.0%)
		Negative	04 (66.7%)	02 (33.3%)	06 (100.0%)
		Total	57 (96.6%)	02 (3.4%)	59 (100.0%)

after taking a dedicated history, doing a clinical examination and reserving a diagnosis. Of these patients, 47 (39.5%) were primigravida. Sixty eight women had no living children. Optimization of further reproductive outcomes of these women is important as such, and selection of appropriate management is equally important. A sterilized patient with the maximum last childbirth stated was 19 years. Of the ectopic pregnancies, 47.1% occurred in the time period after 2–5 years of last child birth of the couple. 9.8% of ectopic pregnancies occurred in within 1 year of delivery (11).

All women had the three investigations—urine pregnancy test, serum β -hCG and transvaginal ultrasound. Mean β -hCG in ruptured ectopic was 18,629 vs mean β -hCG in unruptured ectopic: 6889. The results were statistically significant (p value 0.008). And the Iranian study in prognostic value of maternal serum β -hCG concentration in ruptured tubal ectopic pregnancy ($p = 0.03$) also confirmed that higher β -hCG correlated with ruptured ectopic pregnancy. Transvaginal ultrasound was diagnostic in all except one patient. Her case was of cervical pregnancy which was a case of hemorrhage referred to us late since the patient was unbooked (12). Ectopic pregnancy is a critical gynecological condition that can be life threatening and requires an urgent, immediate medical attention (8). This paper concentrates on one type of ectopic pregnancy and discusses the in process controversy regarding the best method to detect and make a diagnosis of tubal ectopic pregnancy (13).

An ectopic pregnancy must always be excluded in sexually active women of reproductive age who present with lower abdominal pain, with or without vaginal bleeding (14). Qualitative urinary beta-human chorionic gonadotropin assay is an extremely effective diagnostic test, sensitive to 99% at 25 or more International Units per Liter (IU/L) (15). Urinary pregnancy test is reassuring in its negative form, but a positive form requires subsequent transvaginal ultrasound with high efficiency for definitive diagnosis and localization of ectopic pregnancy (16).

DISCUSSION

Urine pregnancy test, serum β -hCG and ultrasound can make diagnosis certain of ectopic pregnancy

Recent comparative analyses have better delineated optimal diagnostic methods for ectopic pregnancy. Gracia and Barnhart, in their seminal

investigation, showed that together transvaginal ultrasonography and serum beta-human chorionic gonadotropin quantification are more accurate than either ultrasonography alone or clinical examination without image support (17). It is then that Sawyer and Jurkovic's systematic review determined that for the maximal diagnostic precision to be achieved ultrasonographic imaging, serum beta-hCG determinations and histological confirmation by laparoscopic evaluation or dilation and curettage are all essential. As a result, since diagnosis, particularly of ectopic pregnancy in symptomatic patients presenting with abdominal pain and/or vaginal bleeding, is a time critical matter and given that there is usually delay in obtaining biochemical and histological results, transvaginal ultrasonography becomes the best initial diagnostic tool (18).

Symptomatic patients with confirmed urinary beta hCG positivity are subjected to the initial screening protocol consisting of both trans abdominal and trans vaginal ultrasonographic evaluation. The contemporary gold standard diagnostic imaging modality of ectopic pregnancy has already been widely accepted as Transvaginal ultrasonography (TVS). The use of TVS technology has revolutionized how we approach the diagnosis of early pregnancy complications by greatly enhancing the diagnosis and helping us to make decision in the clinical setting (19). As a result, transvaginal ultrasonography has become the definitive diagnostic modality for diagnosis and characterization of ectopic pregnancy, with greater diagnostic accuracy and real time visualization than alternative imaging modalities (20). Recent evidence suggests transabdominal ultrasonography is insufficient to diagnose ectopic pregnancy as a single modality because of its low diagnostic sensitivity and scan field resolution, making it an inadequate tool to evaluate early gestational complications (21). Transabdominal U/S has a diagnostic reliability of approximately 70% under optimal conditions, whereas transvaginal U/S gives superior reliability in excess of 90%, despite the fact that the latter can be useful in the identifying certain suprapubic pathologies (22).

Shalev et al. illustrated that transvaginal

ultrasonography has robust diagnostic parameters in detecting ectopic pregnancy with sensitivity of 87%, specificity of 94% and positive predictive value of 92.5%, therefore is a statistically valid primary means of diagnosis (23). The sensitivity of TVS alone was 93%, the specificity was 99%, and the positive predictive value was 98 pct, according to one study. The incorporation of TVS findings of an adnexal mass together with serum beta-hCG levels increases sensitivity to 97%, with unchanged specificity and positive predictive value (16).

Using ultrasonographic images the presence of a tubal ring, defined as an adnexal mass with an echogenic rim surrounding a hypoechoic ('empty') center, was identified in 68 cases with ectopic but unruptured fallopian tubes using a retrospective analysis (17). Brown and Doubilet's systematic analysis identified four cardinal ultrasonographic features that constitute the diagnostic criteria for ectopic pregnancy: Adnexal mass (with visualization of yolk sac or embryo when possible), characteristic tubal ring sign (echogenic rim surrounding hypoechoic center), pelvic free pelvic fluid, and intrauterine gestational sac not seen (8). Results showed that identification of any noncystic adnexal mass is the most reliable ultrasonographic indicator of ectopic pregnancy. That being said, negative findings by transvaginal ultrasonography alone does not rule out ectopic pregnancy and a further comprehensive diagnostic evaluation requires serial quantitative serum beta hCG measurements (24).

CONCLUSIONS

Ultrasonography has come a long way in providing us with early diagnosis of the ectopic pregnancy. Early detection in hemodynamically stable patients and patients with minimal ectopic involvement allows for conservative treatment, e.g. with methotrexate (MTX) administration. Moreover, shock, collapse, and emergency laparotomy are now rare exceptions in modern practice. The move from diagnostic to therapeutic intervention has been facilitated by the use of transabdominal ultrasonography, relegating the role of laparoscopy to a diagnostic role.

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