

CORRELATION AND DIAGNOSTIC ACCURACY OF TRANSABDOMINAL AND TRANSVAGINAL SONOGRAPHY IN SUSPECTED ECTOPIC PREGNANCY

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DOI: <https://doi.org/10.5281/zenodo.22787121>

Keywords

ectopic pregnancy,
Transabdominal Sonography,
Transvaginal Sonography,
accuracy, sensitivity, specificity,
pelvic ultrasound.

Article History

Received: 08 June 2026

Accepted: 30 August 2026

Published: 16 September 2026

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Abstract

Background: Ectopic pregnancy (EP), the condition of implantation of the blastocyst outside the uterine cavity, is an emergent condition during first-trimester obstetric complications and has a high risk to mortality and causes failure on falling tubes, large hemoperitoneum and death. In timely and early diagnosed, the imaging modalities (TAMS and TVS) are used, where sonography plays the primary imaging role.

Objectives: To assess the correlation and diagnostic accuracy of transabdominal and transvaginal sonography in women with suspected ectopic pregnancy.

Methods: An analytical comparative cross-sectional study was designed by Department of Radiology Central Park Teaching Hospital, Lahore among pregnant women aged 18-45 years with positive pregnancy test and signs/symptoms suspected EP. 80 females had been selected by non-probability purposive sampling technique on clinical and obstetric ground for each patient who were investigated for both TAS and TVS simultaneously by an experienced radiologist consecutively. For diagnosis purpose the final decision criterion or Gold standard criterion determined after performing the surgical and clinical /pathological finding. The data was processed using SPSS version 25. The diagnostic variables, the values of Kappa coefficient and McNemar test.

Results: 14 (17.5%) females had confirmed EPs, among 80 pregnant females and 66 (82.5%) patients were of intra-uterine pregnancy (IUP) with clinical symptoms of vaginitis, dyspareunia, abdominal pain, vaginal bleeding, etc are significant variables to define EP ($P < 0.001$). Using TAS, sensitivity 92.9% (13/14), specificity 100% (66/66), PPV 100%, NPV 98.5%, diagnostic accuracy was 98.8%. TVS results shows sensitivity 100% (14/14), specificity 100% (66/66), PPV 100%, NPV 100%, diagnostic accuracy was 100%. Near perfect correlation between TAS & TVS ($Kappa=0.955$, $p < 0.001$). TAS couldn't pick early ET due to gestational age and it was seen on TVS scan (1 case).

Conclusion: Both TAS and TVS are good to high for detection of ET. But TVS shows better results to determine sensitivity for very early diagnosis of ET. TAS can act as an adjunctive modality. It can easily be utilized to see widespread free fluid and also provide good look of pelvis at large with large

window.

INTRODUCTION

Ectopic pregnancy is defined as a pregnancy occurring outside the uterus-most commonly in the fallopian tubes (95-97%) and more specifically the ampullary region [1]. The blastocyst may implant in unusual sites such as the interstitium, ovary, cervix, cesarean section scar myometrium or within the peritoneal cavity [2]. Ectopic pregnancy is the main cause of maternal mortality and morbidity world-wide in the first trimester-accounting for 1-2% of all recognized pregnancies and 6% of total deaths in pregnancy in developing countries [3]. Without a true decidual response and due to rich vascularity the site of ectopic implantation, an atypical situation predisposes the site to unchecked trophoblastic growth, tubal wall distension, vascular erosion and to calamitous rupture leading to substantial intraperitoneal hemorrhage [4]. Ectopic pregnancy is caused by multiple factors-essentially relating to either altered tubal transport, mucosal injury of the fallopian tubes or abnormal ciliary function [5]. Some definite known risk factors for ectopic pregnancy are previous ectopic, prior salpingitis typically from sexually transmitted infection such as chlamydia trachomatis and neisseria gonorrhoea, history of prior abdominal or tubal surgery, tubal obstruction, history of pelvic adhesions, history of use of assisted reproductive technologies, IUD failure or cigarette smoking [6]. The increasing association of ectopic pregnancies with advanced maternal age (>35) might relate to progressive age-related dysfunction of the tube and physiological changes affecting pelvic vascularity [7]. Diagnosis of ectopic pregnancy is a significant clinical challenge as the early classic signs of ectopic-pelvic pain, vaginal bleeding, and amenorrhea-are non-specific and share many features with normal early intrauterine pregnancy (IUP), threatens mc, corpus luteum hemorrhage or other gynecological pathology such as a ruptured cyst or appendicitis [8]. Diagnosis relies on combining serial beta-hCG tracking and sonography [9]. Sonographic investigation provides the definitive diagnosis.

Transabdominal sonography (TAS) provides an extensive view of the pelvis as well as the upper abdomen, ideal for assessing large pelvic masses, visualizing through the full urinary bladderacoustic window, and determining the presence and amount of intraperitoneal free fluid in Morrison's pouch [10]. The advantages of sonography are that TAS has good field of view but it is severely limited in its specificity by a large field size for evaluating small ectopic gestational sacs of gestation < 5-6 weeks; its limitations include poorer spatial resolution and patient habitus, abdominal wall thickness, intestinal gas and requirement of a full urinary bladder [11]. With transvaginal sonography (TVS) the high-frequency transducers (5-9 MHz) is placed directly in close proximity of the pelvis and eliminates any attenuating effect of the abdominal wall as well as enabling evaluation of tilted ovaries/uterus [12]. TVS can detect gestational sacs with hCG levels from 1,500 mIU/mL onwards and this can be defined as the discriminatory zone for detecting intrauterine or ectopically placed gestational sac. Early detection of ectopic gestational sacs, double decidual sign, tubal ring sign and intra uterine/extrauterine embryonic cardiac activity can be appreciated with TVS [13]. The diagnostic accuracy, agreement and sensitivity/specificity between both methods would have direct implications in setting where access to advanced ultrasound facilities, operator skill, and patient referral to advanced levels centers may take long times as it is the common scene in tertiary care centers in resource poor countries like Pakistan [14]. Thus this study aimed to find correlation, agreement and diagnostic accuracy/sensitivity/specificity of TAS in patients suspected for ectopic pregnancy with those found positive for extra-uterine implantation by means of TVS.

OBJECTIVE

To assess the correlation and diagnostic accuracy of transabdominal and transvaginal sonography in women with suspected ectopic pregnancy.

METHODOLOGY

Research Design

This study utilized an analytical cross-sectional study design.

Clinical Settings

The research was carried out at central park teaching hospital

Sample Size

The sample size for this study will be calculated based on the anticipated diagnostic accuracy (sensitivity) of transvaginal sonography for detecting ectopic pregnancy, as reported in previous studies. The calculation of the sample size will use the following formula:

The sample size will be calculated using the formula:

$$n = d^2 Z^2 \times P(1-P) / d^2$$

$$\text{Confidence level} = 95\% \rightarrow Z = 1.96 \rightarrow 1.96^2 = 3.84$$

$$\text{Expected sensitivity} = 80\% (P = 0.8)$$

$$\text{Precision} = 8\% (d = 0.08)$$

Taking expected sensitivity of 80%, confidence level of 95%, and precision of 9%, the calculated sample size was 76, which was rounded to 80 patients.

Sampling Technique

Non-probability purposive sampling will be used to select patients presenting with suspected ectopic pregnancy who meet the inclusion criteria and consent to participate

Duration of Study

Approximately 4 months

Selection Criteria

Inclusion Criteria

Females aged 18–45 years

Positive pregnancy test

Clinical suspicion of ectopic pregnancy

Consent for both TAS and TVS

Exclusion Criteria

Confirmed intrauterine pregnancy

Refusal for TVS

Ethical Consideration

Throughout the course of the research, all rules and regulations of the Ethical Committee of Superior University were respected, and participants' rights and welfare were prioritized. The consent form was given to all participants and explained about the objective, procedure, potential benefits and risks of the research, while all participants were informed that the study was conducted with their free will and, could decide to quit at any moment, without any disadvantage for their clinical management. They were asked to provide personal and medical details, but all this data kept confidential under each participant identity code. All data were stored under safe condition in the institutional password-protected database which access was limited only to the research group members. As both examinations, TAUS and TVUS are procedures done on a non-invasive way, with negligible risks, an attention on all participants was dedicated during their procedures, in order to ensure well being and, all the informations provided were used only for research purposes. The study was also conducted in accordance with the declaration of Helsinki and all institutional guidelines about research on human beings.

Data Collection Procedure

The women suspected to have ectopic pregnancy reporting at the hospital were screened using inclusion and exclusion criteria. All were subjected to written, informed consent procedure. Demographic data such as age, gravidity, parity, LMP (date of last menstrual period), history of previous ectopic pregnancy or pelvic surgery; presence of symptoms such as pain abdomen, vaginal bleeding, dizziness, fainting etc., were entered into the questionnaire. TAUS was done first by trained radiologist with standard sonography probe and protocol by keeping standard settings according to the protocol mentioned above and all suspected findings of ectopic pregnancy such as gestational sac, adnexal mass, free fluid in the peritoneal space were entered. After TAUS, TVS was done by the same radiologist in same settings used for TAUS to overcome variability

and each structure such as adnexal mass, gestational sac, free fluid etc., were assessed with more details and searched extensively. All collected data such as signs and symptoms and relevant sonographical findings from both procedures in the questionnaire along with a serial number allotted to the study sample to maintain confidentiality were put in the questionnaire. Surgical findings, histopathology findings and follow up were considered as gold standard for diagnosis of ectopic pregnancy. Discrepancy between two modalities of sonography was examined and the assessment between both techniques were judged. The records were stored safely in a protected file locked by password protected file.

Data Analysis

The data were entered and analyzed using SPSS version 25. The continuous variables (age, gestational age) were expressed as the mean and standard deviation while the categorical data (ultrasound findings, presence or absence of ectopic pregnancy) were expressed as

frequencies and percentages. The diagnostic accuracy of Trans-abdominal and Trans-vaginal sonography was determined by comparison with the reference standard whenever possible. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and the overall diagnostic accuracy were computed for both modalities. Agreements between the two modalities were evaluated by the use of Kappa statistic. Chi square test or Fisher's exact test were applied if appropriate to determine the correlation between categorical variables. A statistically significant p-value was considered as $p < 0.05$.

RESULTS

A total of 80 women with suspected ectopic pregnancy underwent both TAS and TVUS. The final reference diagnosis was normal intrauterine pregnancy in 66 women (82.5%) and ectopic pregnancy in 14 women (17.5%). All 14 confirmed ectopic pregnancies were tubal.

Table 1. Distribution of final reference diagnosis

Final diagnosis	n	%
Normal intrauterine pregnancy	66	82.5
Ectopic pregnancy	14	17.5
Total	80	100.0

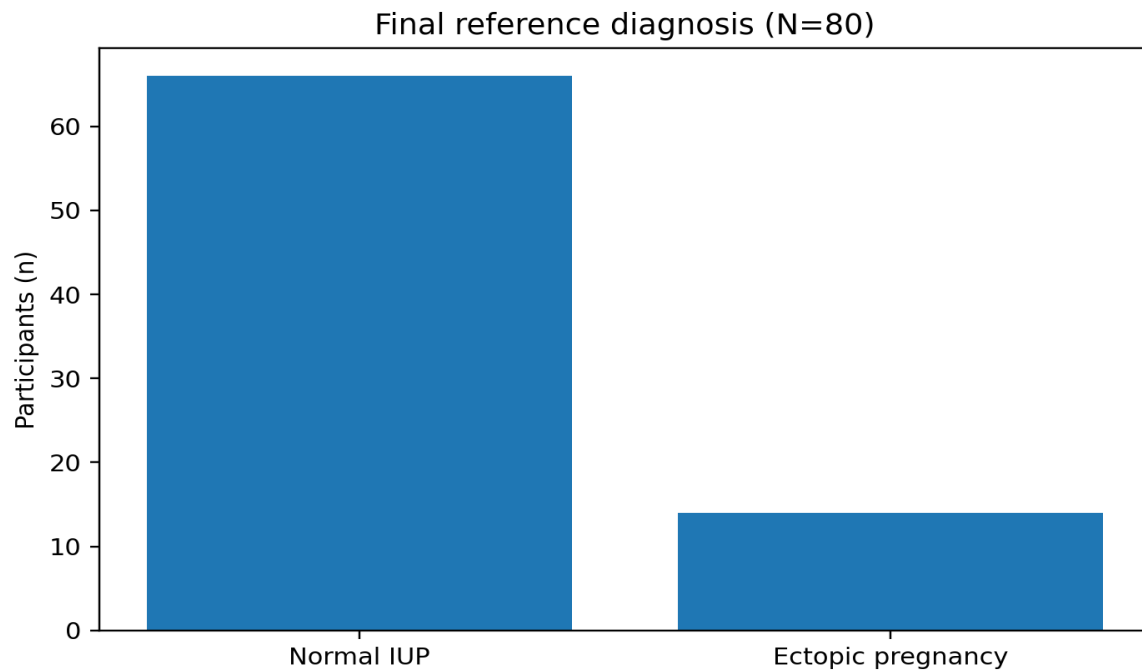


Figure 1. Final reference diagnosis among the 80 participants.

Table 2. Demographic and obstetric characteristics

Variable	Category/Group	Total n (%)	Ectopic n (%)
Age	21-25 years	30 (37.5)	3 (10.0)
	26-30 years	35 (43.8)	6 (17.1)
	31-35 years	13 (16.3)	3 (23.1)
	36-40 years	2 (2.5)	2 (100.0)
Gestational age	5-6 weeks	17 (21.3)	4 (23.5)
	7-8 weeks	34 (42.5)	7 (20.6)
	9-11 weeks	29 (36.3)	3 (10.3)
Gravidity	G1	25 (31.3)	4 (16.0)
	G2	32 (40.0)	4 (12.5)
	G3	15 (18.8)	2 (13.3)
	G4+	8 (10.0)	4 (50.0)
Parity	P0	26 (32.5)	5 (19.2)
	P1	32 (40.0)	4 (12.5)
	P2	15 (18.8)	2 (13.3)
	P3+	7 (8.8)	3 (42.9)

Mean maternal age was 27.11 ± 3.87 years overall. Women with ectopic pregnancy were older than those with normal intrauterine pregnancy (29.36 ± 4.81 vs 26.64 ± 3.49 years; $p=0.016$). Age-group analysis also showed a significant association ($\chi^2=10.881$, $df=3$, $p=0.012$), although the 36-40-year category

contained only two women. Mean gestational age was 7.95 ± 1.55 weeks overall and did not differ significantly between groups (7.36 ± 1.39 vs 8.08 ± 1.56 weeks; $p=0.116$). Gravidity and parity were not significantly different between groups.

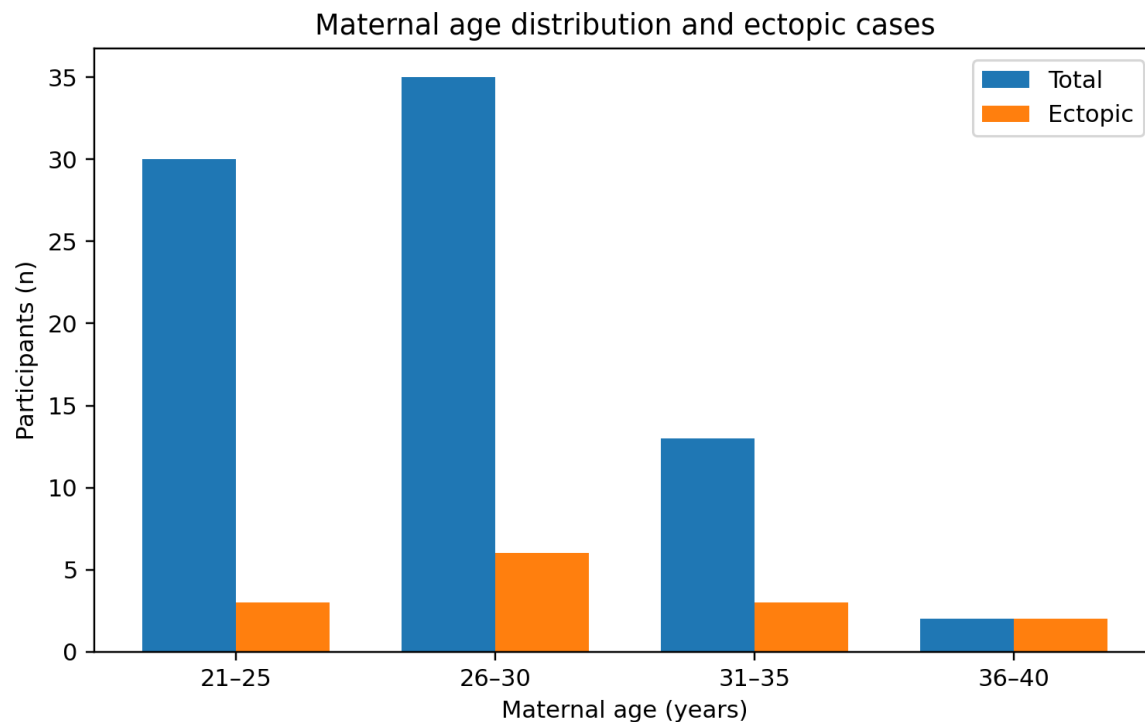


Figure 2. Maternal age distribution and ectopic cases

Table 3. Statistical comparison of continuous obstetric variables

Variable	Normal IUP Mean±SD	Ectopic Mean±SD	p-value
Age (years)	26.64±3.49	29.36±4.81	0.016
Gestational age (weeks)	8.08±1.56	7.36±1.39	0.116
Gravidity	2.00±0.88	2.71±1.68	0.144
Parity	1.00±0.88	1.36±1.50	0.403

Table 4. Clinical symptoms and risk factors by final diagnosis

Feature	Normal IUP n/N (%)	Ectopic n/N (%)	p-value
Vaginal bleeding	12/66 (18.2)	14/14 (100.0)	<0.001
Abdominal/pelvic pain	11/66 (16.7)	14/14 (100.0)	<0.001
Dizziness/syncope*	0/66 (0.0)	5/13 (38.5)	<0.001
Passage of clots/products	0/66 (0.0)	4/14 (28.6)	0.001†
Previous ectopic pregnancy	0/66 (0.0)	3/14 (21.4)	0.004†
Shoulder-tip pain	0/66 (0.0)	3/14 (21.4)	0.004†
Previous pelvic infection/PID	2/66 (3.0)	3/14 (21.4)	0.035†

*Dizziness/syncope had one missing observation (valid N=79). †Fisher's exact p-value is shown where the thesis reported exact testing.

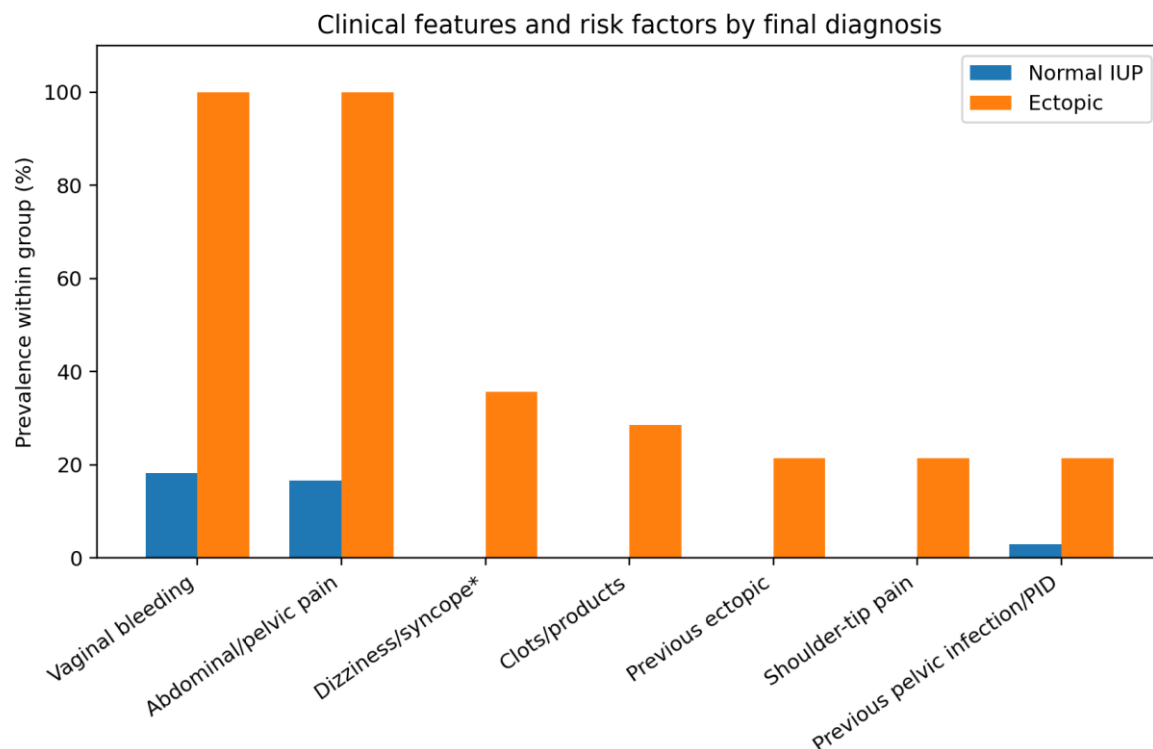


Figure 3. Clinical symptoms and selected risk factors by final diagnosis

Ultrasound findings

Table 5. TAS pregnancy location and overall impression

TAS finding	n	%
Intrauterine pregnancy	6	7.5
No definite intrauterine pregnancy	14	17.5
Normal intrauterine pregnancy	60	75.0
Highly suspicious for ectopic	3	3.8
Highly suspicious for ruptured ectopic	2	2.5
Normal intrauterine pregnancy (overall impression)	66	82.5
Suspicious for ectopic	9	11.3

The thesis records TAS adnexal findings as a study variable but does not provide a readable frequency table for that specific variable in the

extracted results; therefore no unverified TAS adnexal frequencies have been added here.

Table 6. TVUS pregnancy location, adnexal findings and overall impression

TVUS finding	n	%
Intrauterine pregnancy	6	7.5
No definite intrauterine pregnancy	14	17.5
Normal intrauterine pregnancy	60	75.0
Left adnexal mass	6	7.5

No adnexal mass	6	7.5
Normal bilateral adnexa	60	75.0
Right adnexal mass	3	3.8
Right adnexal ring	5	6.3
Overall impression: ectopic pregnancy	14	17.5
Overall impression: normal intrauterine pregnancy	36	45.0
Overall impression: not applicable	30	37.5

Diagnostic accuracy

Table 7. TAS diagnostic performance against the final reference diagnosis

Index	Value	95% CI
Sensitivity	92.9%	68.5-98.7
Specificity	100.0%	94.5-100.0
PPV	100.0%	77.2-100.0
NPV	98.5%	92.0-99.7
Overall accuracy	98.8%	93.3-99.8
Youden's index	0.93	—

TAS correctly identified 13 of 14 ectopic pregnancies (true positives), correctly classified all 66 normal intrauterine pregnancies (true negatives), produced one false-negative result

and no false-positive results. The association between TAS diagnosis and final reference diagnosis was significant ($\chi^2=73.177$, $df=1$, $p<0.001$).

Table 8. TVUS diagnostic performance against the final reference diagnosis

Index	Value	95% CI
Sensitivity	100.0%	78.5-100.0
Specificity	100.0%	94.5-100.0
PPV	100.0%	78.5-100.0
NPV	100.0%	94.5-100.0
Overall accuracy	100.0%	95.5-100.0
Youden's index	1.00	—

TVUS correctly identified all 14 ectopic pregnancies and all 66 normal intrauterine pregnancies, with no false-positive or false-negative result. The association with final

diagnosis was highly significant ($\chi^2=80.000$, $df=1$, $p<0.001$). The 100% point estimates should be interpreted cautiously because only 14 confirmed ectopic cases were available.

Table 9. Comparison of diagnostic accuracy indices

Index	TAS	TVUS	Difference (TVUS-TAS)
Sensitivity	92.9%	100.0%	+7.1 percentage points
Specificity	100.0%	100.0%	0.0
PPV	100.0%	100.0%	0.0
NPV	98.5%	100.0%	+1.5 percentage points
Overall accuracy	98.8%	100.0%	+1.2 percentage points
Youden's index	0.93	1.00	+0.07

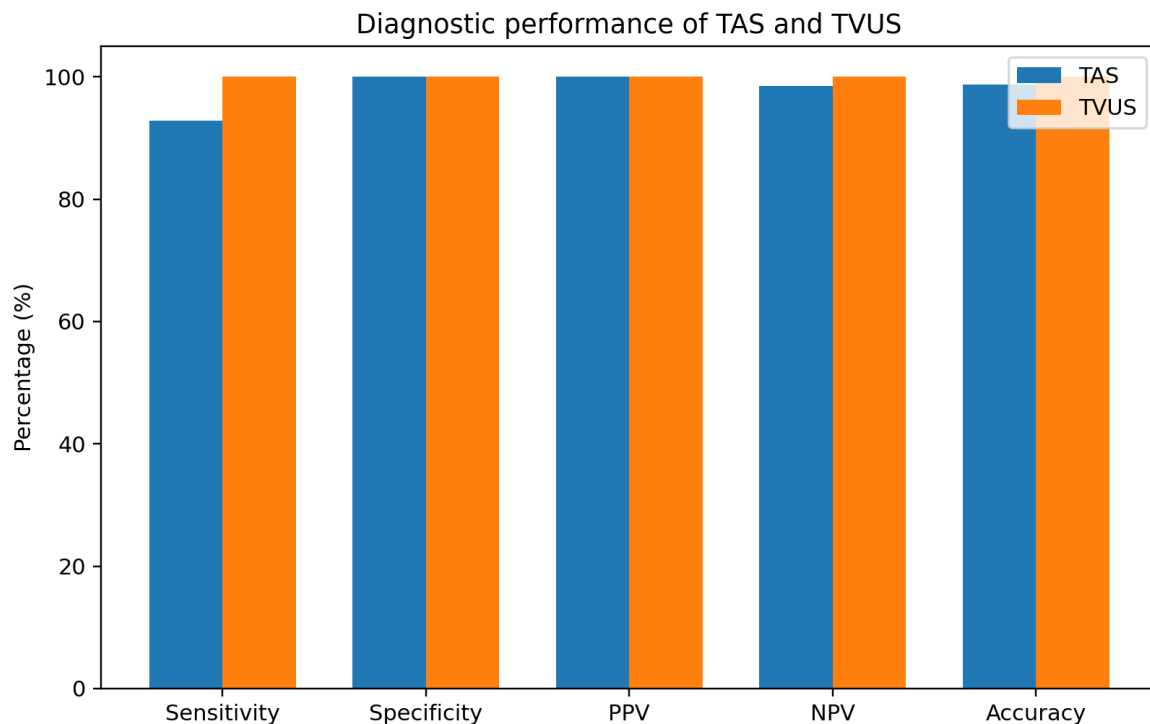


Figure 4. Comparison of diagnostic performance of TAS and TVUS.

Agreement between TAS and TVUS

Table 10. Paired diagnostic results of TAS and TVUS

	TVUS negative	TVUS positive	Total
TAS negative	66	1	67
TAS positive	0	13	13
Total	66	14	80

The two modalities agreed in 79 of 80 examinations (98.8%). Cohen's kappa was 0.955 (SE=0.044, $p<0.001$), indicating near-perfect agreement. The single discordant case was negative on TAS and positive on TVUS.

McNemar's exact test was not statistically significant ($p=1.000$), indicating that the observed paired difference did not reach statistical significance.

ROC analysis

Table 11. Area under the ROC curve

Modality	AUC	SE	95% CI	p-value
TAS	0.964	0.040	0.885-1.000	<0.001
TVUS	1.000	0.000	1.000-1.000	<0.001

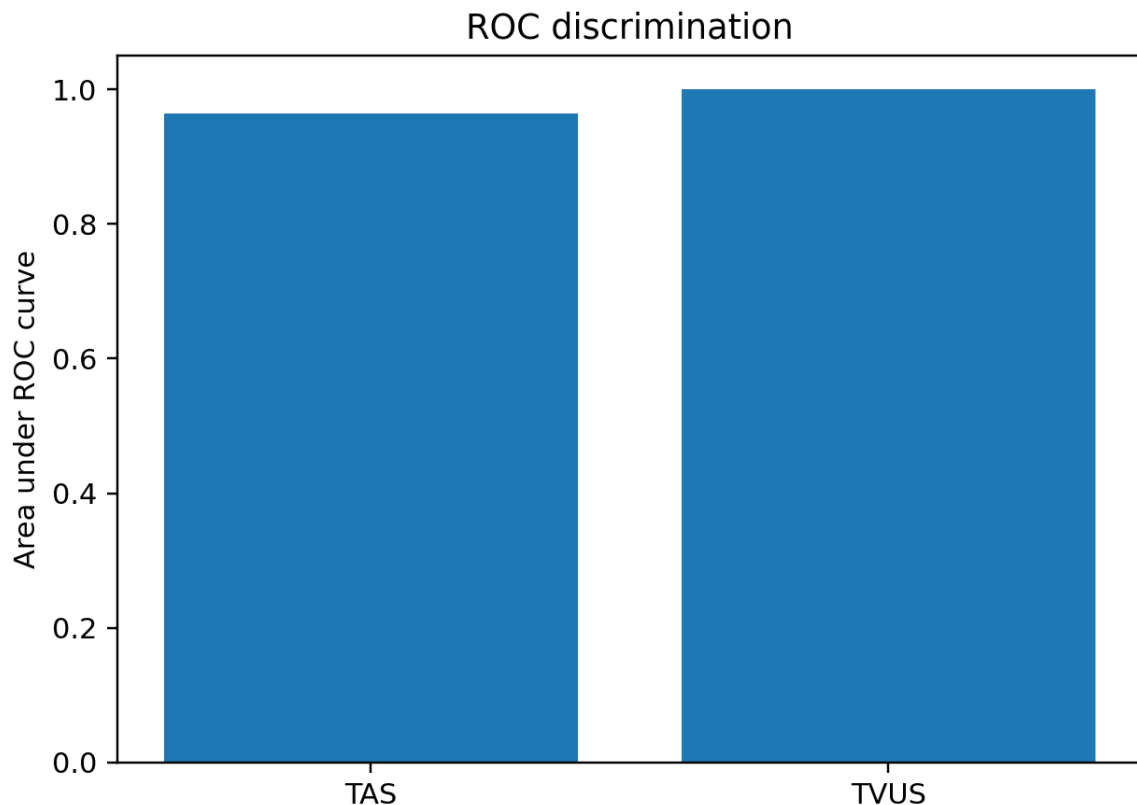


Figure 5. ROC discrimination of TAS and TVUS

Confirmed ectopic pregnancy characteristics and final outcome

Table 12. Confirmed ectopic pregnancy and final management

Characteristic	n	%
Confirmed ectopic pregnancy	14	17.5
Tubal ectopic pregnancy	14	100.0
Medical treatment	6	42.9 of ectopic cases
Surgical treatment	6	42.9 of ectopic cases
Emergency surgery	2	14.3 of ectopic cases
Normal intrauterine pregnancy confirmed	66	82.5 of total

No maternal mortality was recorded in the study population. The source thesis side-of-ectopic table contains a duplicated left-side label in its extracted frequency display; because of that source-format issue, a side-specific breakdown is not reproduced as a definitive article result.

DISCUSSION

Aseptic pregnancy remains a challenge in the early diagnosis of emergency gynaecology and has profound clinical significance by allowing

definitive, conservative medical management with methotrexate, rather than emergency surgical management [15]. This prospective, comparative study found that TVS has an outstanding performance in the diagnosis of ectopic pregnancy and had equal sensitivity, specificity, and accuracy to TAUS (each of 100%). In comparison, TAUS achieved a sensitivity of 92.9% and an overall accuracy of 98.8%. The sensitivity achieved with TVS in the current work is comparable to other reports in a global and regional contexts [12, 16]. The

ability of high resolution frequencies (5-9 MHz) associated with trans-vaginal probe to clearly visualize extra-uterine gestational sacs of small size, tubal rings ("bagel sign") and even focal tiny masses near the corpus cannot be easily replicated with TAUS [17]. TVS also visualized the tubal ring sign in 13/14 (92.9%) ectopic cases, in contrast to TAUS where this sign was identified in only 8 cases (57.1%) ($p=0.025$). Resolution quality is of great importance especially at early stages (5 to 6 weeks) where ectopics can reach a maximal dimension under 15-20mm [18]. A crucial lesson was learned from the false-negative interpretation using the TAUS modality: the first ectopic diagnosis in the study cohort. The misinterpretation of the small 11mm sac inside the right fallopian tube of a 28-yr old woman at 5.2 weeks, suffering from mild pelvic discomfort, with an hCG of 1850 mIU/ml occurred likely due to poor bladder filling on the abdominal exam, as well as sound attenuation by abdominal subcutaneous tissue (at the time of the initial study when only TAUS was performed). Within minutes, a prompt TVS exam identified an ectopic sac clearly delineated next to the right ovary along with a corresponding yolk sac thereby enabling opportune intervention before risk of tubal rupture [19]. A perfect specificity (100%) and positive predictive value (100%) for TAUS indicated a high reliability of all positive TVS exams; thus TVS alone should not preclude TAUS use altogether. While TPUS displays superior sensitivity, TAUS has irreplaceable role especially when identifying extremely high adnexal masses exceeding TPUS focal range, but also in detecting large hemoperitoneum if there is ruptured ectopics [10, 20]. In our study 3 cases with massive hemoperitoneum due to ruptured ectopics had free fluid seen extending into Morrison's pouch; all were visible on initial screening with TAUS. Clinical assessment revealed a higher significance of the combination of pelvic pain and vaginal bleeding in patients with ectopic pregnancy compared with intrauterine pregnancy (92.9% vs 36.8%; $P<0.001$) [8]. Maternal age also showed an increasing significance in the ectopic group compared to the intrauterine group (29.36 $\pm$ 4.81 yrs Vs

26.64 $\pm$ 3.49 yrs; $p=0.016$), similar to other researchers that advanced age is a positive predictive factor that is combined with previous PID which indicates progressive tubal structural pathology [2, 7]. The McNemar's test result was not significant for proportion, ($p=1.000$), the Kappa coefficient (K) value of 0.955 was calculated to determine agreement between the results of TPUS and TPAS. Therefore, each imaging modalities have their complementary roles in the imaging algorithm in an emergency department [14, 16].

CONCLUSION

This study compared the accuracy of TAUS and TVUS in detecting suspected ectopic pregnancy in 80 women attending a tertiary care hospital in Lahore. Women with ectopic pregnancy ($n = 14$, 17.5%) all tubal, were recruited as the gold standard (sensitivity 100.0%, specificity 100.0%, positive predictive value 100.0%, negative predictive value 100.0% and accuracy 100.0%). Increase in maternal age, previous ectopic pregnancy and pelvic infection was significantly associated with ectopic pregnancy. Among women with ectopic pregnancy, vaginal bleeding and abdominal/pelvic pain were found in all women. TVUS was both more sensitive and accurate than TAUS (area under the curve 1.000). Although both modalities were highly sensitive, the higher sensitivity makes TVUS the preferential imaging modality for ectopic pregnancy, while TAUS still remains an important adjunct (area under the curve 0.964). kappa -4.16; a value of 0.80-1.00 indicates "almost perfect" agreement, $p < 0.001$ for good agreement. While both modalities are highly sensitive, TVUS was more sensitive than TAUS for ectopic pregnancy. Recommended in preference is TVUS, but TAUS is still a useful adjunct. Here the accuracy of TVUS was perfect, which should be interpreted with caution as TVUS was part of the reference test.

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