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Transrectal ultrasound and 3D transabdominal ultrasound in comparison to vaginoscopy in virgins with suspected genital tract lesions: A comparative diagnostic accuracy study

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SUMMARY

AUTHORS' CONTRIBUTION: (A) Study Design · **(B)** Data Collection . **(C)** Statistical Analysis · **(D)** Data Interpretation · **(E)** Manuscript Preparation · **(F)** Literature Search · **(G)** No Fund Collection

Background: In many cultures, Hymen preservation during the investigation of virginal gynecological problems is of utmost importance

Aim: to assess the diagnostic performance and acceptability of sonographic modalities (3D transabdominal and Transrectal ultrasound) compared to vaginoscopic hysteroscopy during the diagnostic workup of virginal gynecological lesions

Patients and methods: Virgin patients with different presentations (Bleeding, Amenorrhea, pelvic pain and chronic discharge) were recruited from outpatient clinic and ER. After detailed history and clinical examination, they were assigned to have a 3D transabdominal and transrectal ultrasound followed by a confirmatory vaginoscopy under anesthesia. Patients were then assessed for discomfort and satisfaction by visual analog scale

Results: 41 consented to participate and have a vaginoscopy however five patients (13%) refused to have a transrectal ultrasound. Transrectal ultrasound showed higher concordance with vaginoscopic hystoscopy in detection of different lesions where 94% of patients were correctly diagnosed by transrectal ultrasound on the other hand 3D Transabdominal ultrasound correctly diagnosed 65% of the patients. Still significantly more patients expressed their dissatisfaction with transrectal ultrasound in comparison to 3d transabdominal ultrasound and vaginoscopy

Conclusion: Although transrectal ultrasound had high accuracy in detecting different genital tract lesions in concordance with vaginoscopy more patients expressed their dissatisfaction towards it.

Keywords: Transrectal ultrasound; 3D Transabdominal ultrasound; Vaginoscopy; Virgins; Genital tract lesions

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INTRODUCTION

Many cultures, due to tradition, religion or social beliefs, put heavy pressure behind virginity, as a symbol of purity that must be protected by all means. The physical evidence of virginity is an intact hymen, so many virgin patients refuse any intervention that could damage their hymen, some would even rather suffer through serious situations that could be life threatening as a result of delayed diagnosis and management [1]. The issue of virginity must be respected by medical professionals. But when a vaginal examination is necessary, virginity might be a limiting factor for the gynaecologist [2].

Vaginal discharge or bleeding is the symptom most commonly reported by adolescent girls. The most common cause of vaginal discharge at these ages is infection due to a hypoestrogenized vagina, although other potential causes, such as congenital anomalies of the genitalia, trauma, foreign bodies, sexual abuse, and malignant disease, must also be excluded [3].

This highlights the importance of hymen preserving diagnostic modalities such as the transabdominal ultrasound, which was the first to be used and is still the most widespread [4]. Transrectal and transperineal ultrasounds have been continuously studied and offered to patients as alternatives to transvaginal ultrasound & vaginoscopy which serves as a means for both diagnosis and treatment. But the acceptance and satisfaction of those patients has never been properly assessed. Though vaginoscopy is considered the golden standard modality for diagnosis of different lesions and although the possibility of hymen preservation is high, virgins are highly resistant to this procedure [1]. Also, the patient will be forced to undergo an invasive procedure and could be found free of an actual genital tract lesion. Thus, proper examination by ultrasonography as a non-invasive and less costly method is of outmost importance.

AIM

To assess the diagnostic performance and acceptability of sonographic modalities (3D transabdominal and Transrectal ultrasound) compared to vaginoscopic hysteroscopy during the diagnostic workup of virginal gynecological lesions.

PATIENT AND METHODS

This comparative cohort diagnostic test accuracy study was conducted at Ain Shams University Maternity Hospital. After ethical committee approval on June 2019, recruitment of cases started on June 2019 and ended on April 2021. The study included 41 virgin patients with suspected genital tract lesions by history (complaining of abnormal vaginal bleeding, abnormal discharge or pelvic pain), examination, or a pelvic ultrasound. They were recruited from either the outpatient gynecology clinic or the emergency room. All patients who didn't consent to a vaginoscopy or could not communicate effectively were excluded from the study. The sonographers were blinded to all images obtained from the initial pelvic ultrasound and those obtained from the alternative sonographic modality. Also, all sonographic images were concealed from the physician performing the vaginoscopy procedure.

Before being admitted to the clinical study, written consent was obtained from the patients to participate after the nature, scope, and possible consequences of the clinical study had been explained. For all 41 women, a detailed history and physical examination were done, followed by a 3D transabdominal ultrasound and a vaginoscopy. 36 patients also underwent a transrectal ultrasound, while five patients refused the test. For the 3D transabdominal Ultrasound, we used the Samsung WS80 ultrasound scanner and its convex 3D probe (multiple frequencies 1-6 MHz).

The Transrectal ultrasonography procedure was explained to the patient. The vaginal probe was covered with the customary plastic sheath and richly lubricated with KY gel. The probe was then slowly advanced into the rectum. The transvaginal probes (multiple frequencies 1-8 MHz) were those of the Samsung WS80 ultrasound scanner. The scanning technique was similar to that of transvaginal sonography.

A vaginoscopic hysteroscopy was done under general anesthesia to reach an accurate diagnosis. The procedure used a rigid hysteroscope (kalstorz, Tuttlingen, Germany) (Telescope: rigid, 30° Hamou II lens system). The sheath had a 5-mm outer diameter, with 2.9 mm rod lens. A high-intensity light source and fiber optic cable (Germany) (Xenon nova, model 20 13 15 20 manufactured by Storz) was used to illuminate the uterine cavity. Procedures were performed by an expert gynecologist with a vaginoscopic approach under general anesthesia without utilizing a speculum or applying traction to the cervix with a tenaculum.

Finally, patients' acceptance and satisfaction were assessed by a questionnaire using visual Analogue Scale. VAS was used for grading levels of patient pain and discomfort and overall satisfaction by giving a range of potential scores (0-10) with a score 0 reflecting least discomfort and greatest satisfaction.

Primary outcomes

- Feasibility of 3D pelvic ultrasound, Transrectal ultrasound and vaginoscopy in Virgin Patients.
- Test performance of 3D pelvic ultrasound and Transrectal ultrasound in the detection of local lesions in the uterus, cervix and vagina compared to the final diagnosis confirmed by vaginoscopy as a golden standard modality of diagnosis in Virgin Patients.

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Patients' acceptance and satisfaction with visual Analogue Scale. VAS will be used for grading levels of patient pain and discomfort and overall satisfaction by giving a range of potential scores (0-10) with a score 0 reflecting least discomfort and greatest satisfaction.

Sample size justification: Up to our knowledge, up till beginning of the work no published articles on this topic, this study is preliminary, assuming the agreement kappa would be 0.5 and assuming the α=0.05 and power=0.80, and by using PASS 11th release the minimal sample size against null hypothesis of agreement kappa=0.0 is 35 cases.

Data Analysis: Data were analyzed using IBM© SPSS© Statistics version 26 (IBM© Corp., Armonk, NY) and XLSTAT© Version 2016.02.28451 (Addinsoft©, Paris, France). Categorical variables are presented as counts and percentages and numerical variables as mean and standard deviation. The paired samples t-test was used to compare paired numerical data. Repeated numerical data were compared using one -way anova. The Bonferroni method was used to adjust the level of significance for multiple post hoc pairwise comparisons.

RESULTS

A total number of 76 patients were assessed for eligibility to participate in the study. 19 patients were excluded from the study after not meeting the inclusion criteria and 8 patients refused to participate, 9 patients (12% of assessed patients) refused to undergo vaginoscopy. 41 consented to participate but 5 patients (13% of consenting patients) refused to have a transrectal ultrasound done for them.

The mean BMI of the patients was 21.7 ± 2.6 kg/m^2, and the mean age of patients was 24.1 ± 11.2 years (15 patients were from 10-17 years, 21 patients were from 18-40 years and 5 patients were from 40-50 years. (Data not tabulated)

As regards clinical presentation, 25 patients (62.5%) presented with bleeding, 5 patients (12.2%) presented with chronic pelvic pain, 4 patients (9.7%) presented with amenorrhea, and 6 patients (14.6%) with discharge.

Final Diagnosis (confirmed by vaginoscopic hysteroscopy and pathology)

- Normal findings: 4 Patients (9.7%)
- Thick endometrium: 6 Patients (14.6%)

- Endometrial polyp: 7 Patients (17%)
- Cervical polyp: 5 Patients (12.2%)
- Submucous myoma: 4 Patients (Patients (9.7%)
- Malignancy: 3 Patients (7.3%)
- Vaginal cyst: 1 Patient (2.4%)
- Distal vaginal atresia: 4 Patients (9.7%)
- Obstructed hemivagina and ipsilateral renal anomaly (OHVIRA):5 Patients (12.2%)
- Non communicating cornua with hematometra: 1 Patient (2.4%)

Patients that had 3D transabdominal Ultrasound complained of discomfort due to the pressure applied by the probe while having full bladder especially those originally complaining of pelvic pain. On the other hand, patients that had TRUS complained of discomfort and a considerable degree of pain while placing the vaginal probe into the rectum (**Tab. 1.**).

More patients expressed their dissatisfaction with transrectal ultrasound in comparison to 3D transabdominal ultrasound and vaginoscopy mostly due to a considerable degree of pain and discomfort notified by a significant number of patients (**Tab. 2.**).

We found that misdiagnosed lesions were more common with transabdominal US compared to transrectal US after confirmation with a vaginoscopy (**Tab. 3.**) where;

- Bicornuate uterus with hematometra in obstructed right cornu in a patient was not detected by 3D transabdominal ultrasound it was visualised as bicornuate uterus
- In 2 patients with malignancy, the Necrotic mass in cervix was visualised as a myoma in one patient and was not detected in the other patient by 3D transabdominal ultrasound
- Foreign body was detected by 3D transabdominal ultrasound in one patient which was proven to be a false finding by transrectal ultrasound and vaginoscopy
- 2 patients were misdiagnosed by 3D transabdominal ultrasound one to have thickened endometrium and the other to have endometrial polyps but were found to be free by transrectal ultrasound and confirmed by vaginoscopy
- 2 patients which refused to have a transrectal ultrasound ultrasound one was misdiagnosed to have a thickened endomtrium and one to have had endometrial polyps by 3D transabdominal ultrasound which was confirmed by vaginoscopy and found to be free
- 2 patients were misdiagnosed by transrectal ultrasound one patient with thick endometrium and the other had endometrial polyp

DISCUSSION

Abnormal vaginal discharge and vaginal bleeding which may be associated with pelvic pain are relatively common problems causing patients to seek medical attention. These symptoms may be caused by serious conditions such as genital tract malignancies, foreign bodies, infections or genital tract malformations. Optimal evaluation of the endometrium generally requires transvaginal ultrasonography or hysterosonography, which enables physicians to detect intrauterine abnormalities. Unfortunately, this usually faces much rejection from virgins even at the risk of being misdiagnosed [5].

Vaginoscopy combined with pathological examination is the standard gold test for the evaluation of intrauterine lesions and anomalies in virgins as it allows a means of both diagnosis and treatment. However, it is an invasive procedure with likely chances of a negative yield. Even though vaginoscopy has a high possibility of hymen preservation, prepubertal and virginal patients are highly resistant to the intervention and have many apprehensions that may result in a delayed diagnosis and improper treatment [6]. These points to the importance of offering alternative hymen preserving non-invasive modalities to patients refusing the traditional transvaginal ultrasound and vaginoscopy as the 3D transabdominal and transrectal ultrasound.

The principal finding of this study was that Transrectal ultrasound is an effective imaging method for the

Tab. 1. Discomfort and dissatisfaction score associated with 3D transabdominal Ultrasound (TAUS), transrectal ultrasound (TRUS) and Vaginoscopy.

Variable	TAUS		TRUS		Vaginoscopy		F (df 2,78)	P-value*
	Mean	SD	Mean	SD	Mean	SD		
Discomfort score	2.9**	1.4	6.4	2.6			17.009	<0.001
Dissatisfaction score	4.2†	1.6	6.1	2.7	3.5‡	1.9	17.009	<0.001

SD = standard deviation, F = F-statistic, df = degrees of freedom. *. One-way anova, †. P = 0.001 versus TRUS (Bonferrni-adjusted), ‡. P < 0.001 versus TRUS (Bonferrni-adjusted). **. Paired samples t-test P

Tab. 2. The recommended method as rated by the patient after the procedure.

Variable		Count	Percentage
Recommended method: 3D transabdominal Ultrasound (TAUS) or transrectal ultrasound (TRUS)?	TAUS	32	80.0%
	TRUS	8	20.0%
Recommended method: 3D transabdominal Ultrasound (TAUS) , transrectal ultrasound (TRUS) or vaginoscopy?	TAUS	10	25.0%
	TRUS	4	10.0%
	Vaginoscopy	26	65.0%

Tab. 3. Correct final diagnosis by 3D transabdominal Ultrasound (TAUS) and transrectal ultrasound (TRUS) in comparison to vaginoscopy (the gold-standard for diagnosis).

Lesions diagnosed by vaginoscopy		№.† correctly diagnosed by	
Neoplastic Lesions	**№.†**	**Transrectal ultrasound**	**3DTransabdominal ultrasound**
Thick endomerium	6	4*	5
endometrial polyp	7	5*	4
cervical polyp	5	5	3
submucous myoma	4	4	3
Malignancy (necrotic mass by ulrasound)	3	3	1
Vaginal (gartner's) cyst	1	1	0
Congenital Lesions	**№.†**	**Transrectal ultrasound**	**3DTransabdominal ultraound**
Distal vaginal atresia (hematometra and hematocolpus by ultrasound)	4	4	4
OHVIRA (obstructed hemivagina and ipsilateral renal anomaly)	5	5	5
Bicornuate uterus with hematometra in obstructed right cornu	1	1	0
Normal findings	4	2*	2
†№. (Number of patients with lesion); * patients refused modality			

evaluation of vaginal lesions. This agrees with Güdücü N, et al. [7] who investigated the indications and diagnosis in adolescents undergoing transrectal ultrasound in a retrospective study with sample size of 538 Adolescents and found that transrectal Ultrasound provides images superior to Abdominal ultrasound. The study concluded that transrectal ultrasound is a highly acceptable modality with no evident harm to the patient that can be used in adolescents to visualize the pelvic organs and to exclude genital abnormalities and mass lesions [7].

Lopez-Rasines G, et al. [8] also published a preliminary study to assess vaginal pathology by transrectal ultrasonography. The study scanned six women transrectally using a biplanar probe. Three patients had hematocolpos and three had cysts. Thus, it considered this method to be successful in imaging vaginal pathology [8]. This is in accordance with our study.

The research conducted by Timor-Tritsch IE, et al. [9] on a sample size of Forty-two patients with an absolute or a relative contraindication to transvaginal ultrasound, so were scanned transabdominally and transrectally, showed that transrectal ultrasound was clearly superior to transabdominal ultrasound in 31 cases. In nine cases transabdominal ultrasonography furnished some clinical information but transrectal ultrasonography yielded better images. Only in one such case was transabdominal ultrasonography similar in quality to transrectal ultrasonography In four obese patients transabdominal ultrasonography did not reveal sufficient pelvic anatomy to generate a clinical diagnosis, whereas transrectal ultrasonography revealed two sets of normal ovaries and two patients with ovarian cysts. In the two cases with vaginal agenesis transrectal ultrasonography revealed the diagnosis of Rokitansky–Kuster syndrome [8]. These results are similar to our study however, no obese patients were included thus effect of weight couldn't be assessed in our study also they reported that all scans were completed without significant patient discomfort or complaints which disagrees with our results where patients showed significant pain and discomfort during transrectal ultrasonography despite both studies using the same method for performing transrectal ultrasound.

As physicians, we must respect our patients' fears and choices but provide them with a thorough understanding and if possible efficient alternatives. We found that concerning the acceptance of transrectal as a scanning route, some patients initially rejected the 'unaccustomed' modality however with a detailed additional explanation, agreed to perform the scan. All patients who finally agreed felt that it was less discomforting than they had imagined.

We used transrectal ultrasound in a large spectrum of patients from all age groups; however patients' age had no role in patients discomfort or satisfaction. We did not experience any rectal trauma. Also, no hymenal tears occurred during the vaginoscopy procedure.

In conclusion, Transrectal ultrasonography is the superior modality in patients with suspected neoplastic genital tract lesions lesions (mostly found in patients complaining of abnormal uterine bleeding) for the diagnosis of abnormal endometrial thickness, endometrial polyps, cervical polyps, submucous myomas, vaginal cysts and necrotic mass (malignancy) due to its significantly higher accuracy in detection of those lesions in concordance with vaginoscopy. In patients with suspected anomalies transrectal ultrasound and 3D transabdominal ultrasound showed excellent agreement.

RECOMMENDATIONS

Transrectal ultrasound is a feasible diagnostic modality superior to 3D transabdominal ultrasound in the detection of local lesions in the uterus, cervix and vagina. Hence, patients should be routinely offered and properly counseled for transrectal ultrasound when genital tract lesions are suspected especially in patients with suspected neoplastic lesions.

Few studies addressed the possible use of transrectal ultrasound as a diagnostic modality in virgins and almost no study properly assessed patient's satisfaction and

discomfort. The main limitation of our study was the small number of patients per lesion also no patients with high BMI (obese patients) were included thus results couldn't be generalized

We recommend further studies to be done to assess possible methods to reduce patients' pain and discomfort during transrectal ultrasonography. Also, lesion specific studies on a larger number of women to determine the diagnostic accuracy of transrectal Ultrasonography in each lesion. Furthermore, comparative diagnostic accuracy studies with other modalities as MRI should be conducted.

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