Applied new sonographic scoring system in early diagnosis of ectopic pregnancy

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Abstract: Objective: To test the applicability a simply designed new sonographic scoring system aiding in the early and proper diagnosis of ectopic pregnancy. **Patients and methods:** 1200 women in early pregnancy with quantitative β-hCG more than 1000 mIU/ml During the period from January,2016 to December, 2016 were subjected to systemic ultrasound scanning for early detection of ectopic pregnancy by trans-vaginal then trans-abdominal ultrasound scanning starting with the uterus at first, adnexa then peritoneal cavity including Douglas pouch. Doppler study with colour flow mapping was done to help in differential diagnosis of confusing pictures of adnexal masses. Sonographic findings were recorded in a designed new sonographic scoring system composed of (0, 1, 2) for each one of uterus, adnexa and peritoneal cavity which means that: 0: Sonographic picture not commonly seen in ectopic pregnancy. 1: Sonographic picture confused with ectopic pregnancy. 2: Typical sonographic picture seen in ectopic pregnancy. **Results:** Among 1200 patients in early pregnancy, 41 cases were proved to have an ectopic pregnancy. 38 cases of the proved ectopic cases were correctly predicted by the ultrasound scoring system with cut-off point (3) (P< 0.000) while the remaining 3 confirmed ectopic cases were previously predicted as non ectopic cases by the ultrasound scoring system. On the other hand, out of 40 cases predicted by the scoring system to have an ectopic pregnancy, only 2 cases were proved to be non ectopic cases. Application of Doppler study with colour flow mapping for differential diagnosis of adnexal masses led to proper diagnosis of ectopic pregnancy cases with highest sensitivity (92.7%), specificity (99.83%), positive predictive value (95%) and negative predictive value (99.7%). **Conclusion:** This new sonographic scoring system helped in early and proper diagnosis of ectopic pregnancy with cut-off point (score 3) with highest sensitivity and specificity. **Recommendation:** Application of this new sonographic scoring system is recommended over wide scale of ultrasound units and gynecologic emergency departments for early diagnosis of ectopic pregnancy to decrease morbidity and mortality.

1. Introduction

Ectopic pregnancy, also known as eccyesis or tubal pregnancy, is a complication of pregnancy in which the embryo implants outside the uterus (**Kirk E. et al., 2014**). Signs and symptoms classically include abdominal pain and vaginal bleeding. Less than 50 percent of women, however, have both these symptoms. The pain may be described as sharp, dull, or crampy. Pain may also spread to the shoulder if bleeding into the abdomen has occurred (**Crochet JR et al.,2013**). Severe bleeding may result in a fast heart rate, fainting, or shock. Risk factors for ectopic pregnancy include pelvic inflammatory disease, often due to Chlamydia infection, tobacco smoking, prior tubal surgery, a history of infertility, and the use of assisted reproductive technology. Those who have previously had an ectopic pregnancy are at much higher risk of having another one. Most ectopic pregnancies (90%) occur in the Fallopian tube which are known as tubal pregnancies. (**Cecchino et al., 2014**). Implantation can also occur on the cervix, ovaries, or within the abdomen. Detection of ectopic

pregnancy is typically by blood tests for human chorionic gonadotropin (hCG) and ultrasound. This may require testing on more than one occasion.

Women with clinical signs of a ruptured ectopic pregnancy who are haemodynamically compromised should not have surgery delayed to have an ultrasound examination performed. Howevere, the early diagnosis of ectopic pregnancy in clinically stable women with transvaginal ultrasonography (TVS) is not only potentially life saving, but also may decrease the number of operative procedures such as diagnostic laparoscopy and dilatation and curettage (**Atri et al,2003**). This early diagnosis of unruptured ectopic pregnancy also allows for consideration of conservative management options such as methotrexate (**Hajenius et al.,1997**) or even an expectant approach (**Korhonen et. al.,1994**).

Ultrasound (US) probably is the most important tool in diagnosing an extrauterine pregnancy. An ultrasound showing a gestational sac with fetal heart in the fallopian tube has a very high specificity of ectopic pregnancy. Transvaginal ultrasonography has a

sensitivity of at least 90% for ectopic pregnancy. The diagnostic ultrasonographic finding in ectopic pregnancy is an adnexal mass that moves separately from the ovary. In around 60% of cases, it is an inhomogeneous or a noncystic adnexal mass sometimes known as the "blob sign". It is generally spherical, but a more tubular appearance may be seen in case of hematosalpinx. This sign has been estimated to have a sensitivity of 84% and specificity of 99% in diagnosing ectopic pregnancy. In the study estimating these values, the blob sign had a positive predictive value of 96% and a negative predictive value of 95%. The visualization of an empty extrauterine gestational sac is sometimes known as the "bagel sign", and is present in around 20% of cases. In another 20% of cases, there is visualization of a gestational sac containing a yolk sac and/or an embryo. Ectopic pregnancies where there is visualization of cardiac activity are sometimes termed "viable ectopic *(Kirk E. et al., 2014*).

In the past decade, a number of investigators have utilized pulsed and color Doppler ultrasound in the evaluation of the pregnant patient. Taylor and his group described a flow pattern in placental tissues that was typically high-velocity, low impedance flow. This was thought to be related to invasion of the maternal tissues by trophoblastic villi. This characteristic flow can be identified using colour Doppler imaging as an area of increased vascularity surrounding the gestational sac. Dillon et al demonstrated that this placental flow pattern can be seen in an intrauterine pregnancy approximately 36 days after the last menstrual period, reaching a peak at 50 days. As these flow patterns were seen with trophoblastic tissue they could be identified whether the pregnancy was within, or outside of the uterus. Subsequently, investigators have interrogated the adnexa in high risk patients for this characteristic flow pattern as a means of improving the diagnostic accuracy. Several centers have claimed accuracies of 80-95% with the addition of this technique. In addition to searching for a vascular ring in the adnexa, some have utilized measurements of the spectral Doppler pattern to diagnose the presence of an ectopic gestation. A resistive index value < 0.40 is said to be characteristic of an ectopic gestation.

Aim of the study:

To test the applicability of a simplified new ultrasound scoring system upon women in early pregnancy helping in early diagnosis of ectopic pregnancy.

2. Patients and methods:

This study was conducted upon women in early pregnancy complaining of vaginal bleeding and/or abdominal pain with quantitative β -hCG more than (1000 mIU/ml) recruited from the Obstetrics & Gynecology and Radiology departments at Sheben El-Kom Teaching Hospital during the period from January,2016 to December,2016. 1200 Women in early pregnancy were scanned by both trans-abdominal, then trans-vaginal ultrasound. All areas of the pelvis were evaluated sonographically with Optimal visualization of the uterus and adnexa. Detection of free fluid in the peritoneal cavity was a part of the sonographic evaluation of an ectopic pregnancy. Quantitative β -hCG level was done in all patients to confirm the diagnosis.

A systemic approach of trans-abdominal, then trans-vaginal ultrasound scanning technique was applied for each patient (scanning the uterus at first, then the adnexa and cul-de-sac, and finally looking for other areas of peritoneal cavity for free fluid). Doppler study with color flow mapping was done to help in differential diagnosis of confusing pictures of adnexal masses.

Definition of the scoring system according to the sonographic findings will be recorded in a simple designed scoring system composed of (0,1,2)for each one of uterus, adnexa and peritoneal cavity which means that:

Score (0): Sonographic picture commonly seen in normal pregnancy.

Score (1): Sonographic picture confused with ectopic pregnancy.

Score (2): Sonographic picture typically seen in ectopic pregnancy.

1-Assessment of the uterine cavity:

Score (0): True Intra-uterine gestational sac.

Score (1): Pseudo Intra-uterine gestational sac or shadow of a contraceptive device.

Score (2): Empty uterine cavity with decidual reaction (thickness >14mm).

2-Scanning for detection of Adnexal mass:

Score (0): No mass could be detected.

Score (1): Detection of adnexal mass of complex echogenicity.

Score (2): Detection of a cystic tubal ring or an extra-uterine gestational sac with internal fetal echogenic shadow and may show fetal cardiac activity.

Assessment of the echogenic-complex adnexal mass of Score (1) by Colour-Doppler study and multiply by Doppler score: Score (0): No colour uptake or blood flow could be detected.

Score (1): Detection of blood flow with high R.I. > 0.4

Score (2): Detection of blood flow with low R.I. < 0.4

3-Assessment of free fluid in the Intra-peritoneal cavity:

Score (0): No free fluid could be seen.

Score (1): Detection of free fluid confined only to cul-de-sac.

Score (2): Detection of free fluid extended to hepato-renal space and para-colic gutters.
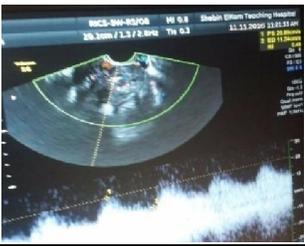
**Table (1): New applied sonographic scoring system.**

Score	0	1	2
1- Uterine cavity	True intrauterine pregnancy.	Pseudo-gesatational sac or I.U.D	Empty uterine cavity + decidual reaction
2- Adnexal mass	No.	Complex echogenic mass	Tubal ring or tubal gestational sac with or without cardiac activity
Colour flow mapping	No Flow.	+ve flow with R.I more than 0.4	+ve flow with R.I 0.4 or less.
3- Intraperitoneal free fluid	No free fluid or very minimal.	Moderate free fluid limited to cul-de-sac.	Severe free fluid extended to hepato-renal space &/or paracolic gutters.

I.U.D means intra-uterine device.   +ve means positive   R.I means (Resistent index)

Score	0	1	2
1- Uterine cavity	True gestational sac	Shadow of I.U.D	Decidual reaction
2-Adnexal mass	No mass	Complex echogenic mass	Adnexal sac
Colour flow Doppler R.I.	No flow	+ve flow with R.I > 0.4	+ve flow with R.I<0.4
3- Peritoneal cavity	No free fluid	Moderate F.F limited to Douglas pouch	Severe F.F
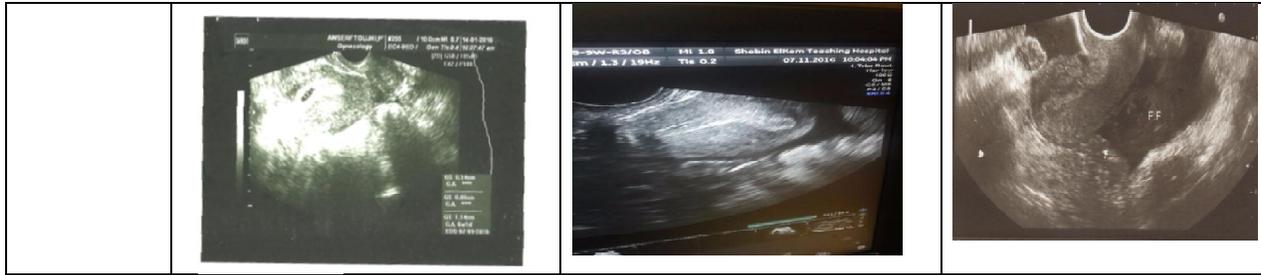
3. Results:

Table (2): the total sonographic scoring among all cases.

Final Diagnosis total score		Frequency	Percent	Valid Percent	Cumulative Percent
non ectopic Valid	0	1079	93.1	93.1	93.1
	1	31	2.7	2.7	95.8
	2	47	4.1	4.1	99.8
	3	1	.1	.1	99.9
	4	1	.1	.1	100.0
	5	0	0	0	100.0
	6	0	0	0	100.0
	Total	1159	100.0	100.0	
ectopic Valid	0	0	0	0	0
	1	0	0	0	0
	2	3	7.3	7.3	7.3
	3	10	24.4	24.4	31.7
	4	10	24.4	24.4	56.1
	5	15	36.6	36.6	92.7
	6	3	7.3	7.3	100.0
	Total	41	100.0	100.0	

The ROC curve **(Fig. 1)** of the sonographic scoring system in diagnosis of ectopic pregnancy was as follows.

Case Processing Summary

Final Diagnosis	Valid N (listwise)
Positive[a]	41
Negative	1159

Larger values of the test result variable (s) indicate stronger evidence for a positive actual state.
a. The positive actual state is ectopic.

**Table (3): Area under the curve in the ROC curve of the scoring system.**

Test Result Variable (s): Total Score

Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.998	.001	.000	.996	1.000

The test result variable (s): Total Score has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.
a. Under the nonparametric assumption
b. Null hypothesis: true area = 0.5
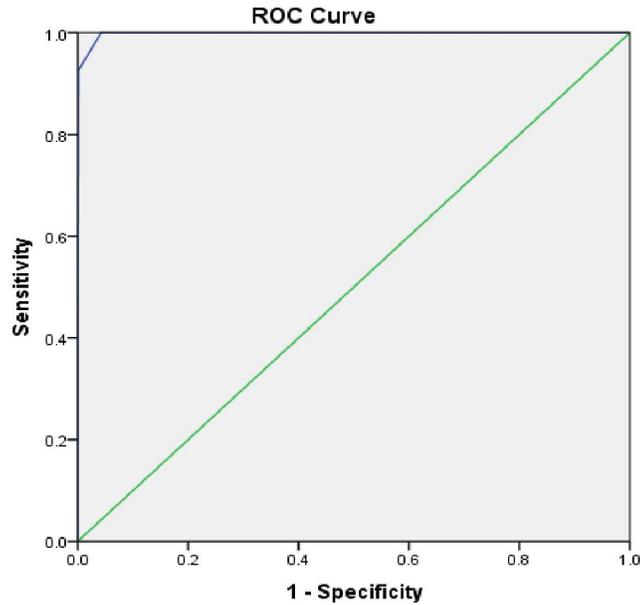
Fig. 1: ROC curve of sonographic scoring in diagnosis of ectopic pregnancy

Table (4): Coordinates of the curve

Test Result Variable (s):

Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
-1.00-	1.000	1.000
.50	1.000	.069
1.50	1.000	.042
2.50	**.927**	**.002**
3.50	**.683**	**.001**
4.50	.439	.000
5.50	.073	.000
7.00	.000	.000

By performing ROC curve of sonographic scoring as a diagnostic marker, Score 3 was found to be the best cut-off point to diagnose ectopic pregnancy.

Table 5: Predicted diagnosis by US * Final Diagnosis Crosstabulation (for sensitivity & specificity).

			Final Diagnosis		Total
			ectopic	non ectopic	
Predicted diagnosis by sonographic scoring system	Predicted Ectopic (score 3 or more)	Count	38	2	40
		% within Final Diagnosis	38/41 **(92.7%)**	2/1159 (0.2%)	
	Predicted non ectopic (score less than 3)	Count	3	1157	1160
		% within Final Diagnosis	3/41 (7.3%)	1157/1159 **(99.8%)**	
Total		Count	41	1159	1200
		% within Final Diagnosis	100.0%	100.0%	100.0%

The sensitivity of (score 3) as a cut-off point for diagnosis of ectopic pregnancy was 92.7% while the specificity was 99.83%.

Table 6: Predicted diagnosis by US * Final Diagnosis Crosstabulation (for positive & negative predictive values).

			Final Diagnosis		Total
			ectopic	non ectopic	
Predicted diagnosis by US	Predicted Ectopic	Count	38	2	40
		% within Predicted diagnosis by US	38/40 **(95.0%)**	2/40 5.0%	100.0%
	Predicted non ectopic	Count	3	1157	1160
		% within Predicted diagnosis by US	3/1160 0.3%	1157/1160 **(99.7%)**	100.0%
Total		Count	41	1159	1200
		% within Predicted diagnosis by US	3.4%	96.6%	100.0%

Positive predictive value was (95%) while negative predictive value was (99.7%).

4. Discussion:

Ultrasonography is an important tool for emergency medicine clinicians and other acute care clinicians to use in assessing patients' risk for potential ectopic pregnancy. Early diagnosis can be very valuable in lessening morbidity and mortality. Diagnosis before tubal rupture can prevent life-threatening hemorrhage and increase the probability that the patient may be managed medically or by laparoscopic surgery. Definitive ultrasonographic diagnosis of an ectopic pregnancy is made in only about 20% of cases, when an extra-uterine pregnancy is clearly identified (ie, an extra-uterine gestational sac with a yolk sac or fetal pole is visualized). There exist, however, numerous findings that are highly suggestive of ectopic pregnancy, including an empty uterus in a patient with a β-hCG level above the discriminatory zone, an adnexal mass other than a simple cyst, echogenic fluid in the cul-de-sac, or anything more than a small amount of fluid in the cul-de-sac (*ACOG,2009*).

The present study was done to help the early diagnosis of ectopic pregnancy by ultrasound with colour Doppler. The applied new sonographic scoring system was designed in a simple sonographic manner using trans-abdominal first then tran-vaginal ultrasound with systemic scanning starting with the uterus, then the adnexa and lastly peritoneal cavity including Douglas pouch composed of (0,1,2) for each parameter according to sonographic findings. The study was conducted upon 1200 women in early pregnancy over one year. Total sonographic score (3) was found statistically to be the best cut-off point for the early diagnosis of an ectopic pregnancy with sensitivity (92.7%) and specificity (98.83%). The results were statistically significant (P< 0.0001). positive predictive value of score (3) as a predictor of

ectopic pregnancy was (95%) while its negative predictive value was (99.7%).

A retrospective study of 585 women over a 2.5-year period concluded that the sensitivity and specificity of ultrasound for the detection of ectopic pregnancy was 88.5% and 96.5%, respectively on the first ultrasound set and 93.1% and 95.7%, respectively after a second scan *(Young L, et al., 2017)*.

This new applied sonographic scoring system was found to be beneficial in early diagnosis of ectopic pregnancy.

A systemic approach of abdominal then vaginal ultrasound scanning technique was applied for each patient (scanning uterus at first, adnexa then Cul-de-sac and finally looking for other areas in peritoneal cavity free fluid). Scoring was recorded in a simple design based on scanning of uterus, adnexa and peritoneal cavity including Douglas pouch and composed of (0, 1, 2) which means that:

Score (0): Sonographic picture commonly seen in normal intrauterine pregnancy.

Score (1): Sonographic picture confused with ectopic pregnancy.

Score (2): Sonographic picture typically seen in ectopic pregnancy.

1-Assessment of the uterine cavity:

Score (0): True Intra-uterine gestational sac.

Score (1): Pseudo Intra-uterine gestational sac or shadow of contraceptive device.

Score (2): Empty uterine cavity with decidual reaction (thickness >14mm).

The first developmental structure big enough to be visualized by transvaginal ultrasonography is the gestational sac, which appears in the endometrial cavity at around 4.5-5 weeks' gestation (corresponding to a β-hCG level of 1000-1500 mIU/mL). Measurement of the mean sac diameter (MSD) is

important for estimating the gestational age, as well as for confirming subsequent normal embryonic development *(Yadav P, et al., 2017)*.

According to *(Richardson A, et al., 2015)* in a first-trimester study of ultrasound features for diagnosis of ectopic pregnancy, an empty uterus was found to predict an ectopic pregnancy with a sensitivity of 81.1% and a specificity of 79.5%. Sensitivity and specificity for a pseudosac were 5.5% and 94.2% respectively.

2-Scanning for detection of Adnexal mass:

Score (0): No mass could be detected.

Score (1): Detection of adnexal mass of complex echogenicity.

Score (2): Detection of a cystic tubal ring or an extra-uterine gestational sac with internal fetal echogenic shadow and may show fetal cardiac activity.

Assessment of the echogenic-complex adnexal mass of Score (1) by Colour-Doppler study and multiply by Doppler score:

Score (0): No colour uptake or blood flow could be detected.

Score (1): Detection of blood flow with high R.I. > 0.4.

Score (2): Detection of blood flow with low R.I. < 0.4.

According to *(Richardson A, et al., 2015)*, Sensitivity and specificity for adnexal mass in ultrasound features for diagnosis of ectopic pregnancy were 94.2% and 63.5% respectively.

The diagnostic yield of endovaginal colour and pulsed Doppler ultrasound (US) in conjunction with endovaginal sonography was compared with endovaginal sonography alone in patients prescreened to be at increased risk for ectopic pregnancy by *(Emerson DS et al, 1992)*. Pelvic structures were evaluated for overall vascularity and for the presence of characteristic pulsed Doppler US velocity waveforms. The diagnostic sensitivity of the initial endovaginal sonographic examination increased with the addition of color and pulsed Doppler US, from 71% to 87% for ectopic pregnancy. Specificities for endovaginal sonography with color and pulsed Doppler US ranged from 99% to 100.

In the present study, colour Doppler was used to assess adnexal masses only which led to improvement of the early diagnosis of ectopic pregnancy.

According to *(Fukami T et al., 2001)*, 34 patients who received surgery for ectopic tubal pregnancies were preoperatively evaluated using TV-CDU. The presence or absence of colour vascularity within the ectopic masses was examined. The relationship between the presence or absence of blood flow in the tubal mass and the corpus luteum cyst, accompanied with the serum β-hCG values, were

evaluated. The study found that Colour vascularity within the adnexal mass was detected in 27 of 34 (79.4%) patients with ectopic pregnancies by TV-CDU. However, it was difficult to identify the blood flow of the adnexal mass in six of the nine (66.7%) patients with a corpus luteum cyst in the ipsilateral ovary. No relationship was observed between the serum β-hCG concentrations and the resistance indices, or the peak systolic velocity. The study concluded that the detection of color vascularity by TV-CDU in patients with an ectopic pregnancy is helpful for diagnosis, especially for patients with either a questionable adnexal mass in B-mode images or lower serum β-hCG concentrations.

In the present study, colour Doppler of adnexal masses was identified in 38 of 41 ectopic cases (92.68%). Resistant index was used to classify adnexal masses giving more chance of patients with adnexal masses having R.I below 0.4 to have an ectopic pregnancy.

According to *(Chew S et al., 1996)*, 71 patients with suspected ectopic pregnancies had transvaginal sonography and colour Doppler imaging performed and 61 ectopic pregnancies were confirmed at surgery. The result found that the use of transvaginal B- mode imaging alone in the diagnosis of ectopic pregnancy achieved a sensitivity of 98% and a positive predictive value of 86%. The use of transvaginal colour flow imaging did not increase detection rates of ectopic pregnancy. The mean RI values for patients with or without ectopic pregnancy were almost identical. The result concluded that colour Doppler imaging failed to improve the results of transvaginal B- mode sonography in the detection of ectopic pregnancy. The study conclusion disagrees with the present study in which the use of colour flow Doppler of adnexal masses among the new applied scoring system was helpful in early diagnosis of ectopic pregnancy and R.I values less than 0.4 were more suggestive of ectopic pregnancy.

3-Assessment of free fluid in the Intra-peritoneal cavity:

Score (0): No free fluid could be seen.

Score (1): Detection of free fluid confined only to cul-de-sac.

Score (2): Detection of free fluid extended to hepato-renal space and para-colic gutters.

According to *(Richardson A, et al., 2015)*, the sensitivity and specificity of free intraperitoneal fluid in sonographic diagnosis of ectopic pregnancy were 47.2% and 92.3%, respectively.

A retrospective medical record review by *(J.L. Thacker & R.F. Reardon, 2004)* of all emergency department (ED) patients diagnosed with ectopic pregnancy during 2000 to 2004 in an urban teaching hospital. 76 stable patients had emergency

endovaginal studies. Radiology studies confirmed the finding of an empty uterus in all cases but noted pelvic free fluid in 58 (88%) patients. This agrees with the present study in which there were 41confirmed ectopic patients. 33 cases (80.4%) of them had a variable amount of free fluid in the peritoneal cavity while only 8 cases (19.5%) had no or very minimal amount of free fluid.

According to (*M. Hesham Anwar, 2009*) In the study,300 clinically suspected ectopic pregnancy cases with positive pregnancy test were scanned by trans abdominal, then trans vaginal U/S according to the same scoring system of the present study. The cut-off point for diagnosis of ectopic pregnancy was sonographic (score3) with sensitivity (98.8%), specificity (87.2%), positive predictive value (98%) and negative predictive value (91.8%). The present study applied the same scoring system upon women in early pregnancy for screening of ectopic pregnancy. The results revealed identical cut-off point of sonographic (score 3) for early diagnosis of ectopic pregnancy with sensitivity (92.7%), specificity (98.83%), positive predictive value (95%) and negative predictive value (99.7%).

The new applied sonographic scoring system with cut-off point (score 3) helped in early diagnosis of ectopic pregnancy with sensitivity (92.7%), specificity (98.83%), positive predictive value (95%) and negative predictive value (99.7%) and is recommended to be used over wide scale at obstetric and gunecological emergency departments to decrease morbidity and mortality.

Conclusion:

This new applied sonographic scoring system with cut – off point (score 3) can be useful in early diagnosis of ectopic pregnancy with highest sensitivity and specificity.

Recommendation:

This sonographic scoring system can help clinicians to make early and poper diagnosis of ectopic pregnancy and this allows early decision making, either conservative medical treatment or intervention with better outcome. The scoring system is recommended to be applied over wide scale of obstetric & gynecologic emergency departments and scanning units.

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