Review Article

A Review of the Correlation between Clinical Diagnosis and Ultrasound Diagnosis in First Trimester Vaginal Bleeding

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Abstract

Background: Bleeding per vaginum is a common first trimester emergency. Accurate diagnosis is very necessary to enable the clinician to institute appropriate and prompt treatment. The implications of false diagnosis include inappropriate treatment and delay in treatment. **Aims and Objectives:** The study evaluated the accuracy of clinical diagnosis of first trimester vaginal bleeding according to the cadre of the care giver using ultrasound as a gold standard. **Methods:** This was a retrospective study of patients referred to a Specialist Diagnostic Clinic in Nigeria with a history of first trimester bleeding from January 2016 to April 2017. Data was collected from the radiologist's report and request forms of patients with the above presenting symptoms. The patients' data retrieved included age, gestational age, parity, clinical and ultrasound diagnosis. All the data collected were analyzed using SPSS version 23 to produce frequency tables and charts. There were cross tabulations to explore relationship between variables at p-value of < 0.005. **Results:** A total of 101 patients participated in the study. The mean age was 30.2 years. The most common clinical diagnosis in patients with first trimester bleeding was threatened abortion (65.3%) which was reduced to 34.7% by ultrasound. The overall concordance was 44.55%. The highest concordance of 66.7% was observed in the ectopic pregnancy group. (0%) The highest concordance rate with regards to the referral pattern was recorded in the Obstetrics and Gynecology specialist group (75%) while the least was observed in the patent medicine and unspecified group. **Conclusion:** Ultrasound should be done early in patients with first trimester bleeding as this will lead to early definitive diagnosis and commencement of appropriate therapeutic intervention aimed at reduction of mortality and morbidity, reduced hospital stays and cost.

Keywords: Vaginal bleeding; Clinical diagnosis; Ultrasound diagnosis; First trimester; Abortion

Introduction

Bleeding per vaginum in early pregnancy is a common presentation in the emergency room. [1] It occurs in up to 25% of pregnancy. [2] About 50% of first Trimester bleeding will lead to miscarriage. [3,4] It is usually associated with anxiety among the patients and their relatives. Causes range from non-life-threatening conditions like threatened miscarriage to emergency conditions with severe hemorrhage such as incomplete induced or spontaneous abortions and molar pregnancies. About 50-70% of case of spontaneous abortions is due to genetic abnormalities. [5]

The diagnosis is usually clinical and is confirmed by ultrasound. Ultrasound is the mainstay in the definitive diagnosis of cases of first trimester bleeding as it removes uncertainties/ambiguities in the clinical diagnosis. [6-9] Life threatening conditions like ectopic pregnancy may present with minimal vaginal bleeding, and when there is no obvious hemodynamic changes the diagnosis may be missed in the absence of ultrasound. [10]

Most of the studies on combination of Clinical evaluation and ultrasonography in the diagnosis of the etiology of vaginal bleeding in pregnancy were done in the emergency department of tertiary centres in developed countries. However, in developing countries like ours different cadre of trained and untrained health care practitioners attend to pregnant women. [11] Some of them do not have the ultrasound machine or clinical acumen to make the diagnosis. Hence they refer the women for evaluation at diagnostic centers. Other reasons for referral include inconclusive diagnosis.

Accurate diagnosis is very necessary to enable the clinician to institute appropriate treatment. The implications of false

How to Cite this Article: Aronu ME, et al. A Review of the Correlation between Clinical Diagnosis and Ultrasound Diagnosis in First Trimester Vaginal Bleeding. Ann Med Health Sci Res. 2018;8:120-124

diagnosis inappropriate treatment. To the best of our knowledge, no study has stratified the accuracy of clinical diagnosis of different cadre of healthcare providers. This study evaluated the correlation between the diagnosis made by clinical evaluation of vaginal bleeding and that made using ultrasonography. It also determined the accuracy of different cadre of healthcare providers in clinical diagnosis of first trimester vaginal bleeding. The aim being to emphasize the importance of ultrasound machines in our emergency rooms.

Subjects and Methods

This was a retrospective comparative study carried in all patients who were referred to a private diagnostic clinic in Awka, Nigeria (Amen Specialist Diagnostic Clinic, Awka) with history of first trimester bleeding.

Study area

This study was conducted in a Specialist Diagnostic Clinic. This is a foremost radio-diagnostic outfit with consultant radiologists that sub serves the specialized needs. This study was carried out by data collected from the radiologist report and request forms of patients with the above presenting symptoms between January 2016 and April 2017. Patient's record was used to retrieve the relevant data. These include age, gestational age, parity, clinical and ultrasound diagnosis.

The inclusion criteria are patients with amenorrhea of 13 weeks or less who presented with clinical history of bleeding per vaginam.

Exclusion criteria included any patient whose pregnancy was more than 13 weeks and those whose records were not complete. We also excluded women with non-obstetrics causes of vaginal bleeding.

Procedure

All the patients were scanned using a Siemen Siena Ultrasound. These studies were done using either a 3.5MHz probe Trans abdominally. Transvaginal ultrasonography was done using 4.2 – 6.5 MHz endocavitory probe when the gestational week was 8 weeks or less and when the transabdominal ultrasound result was equivocal.

Data analysis

All the data collected were analyzed using SPSS version 20 manufactured in Chicago, USA to produce frequency tables and charts. There were cross tabulations to explore relationship between variables.

Ethical approval

Ethical approval was sought for and obtained from the ethical committee of Chukwuemeka Odimegwu Ojukwu Teaching Hospital Awka. The study protocol conformed to the provisions of the Declaration of Helsinki.

Definition of terms

These are definition of some of the terms applied to this study. [12,13]

Anembryonic Gestation: Presence of gestational sac larger than 18 mm without embryonic tissues

Embryonic demise (missed abortion): Embryo larger than 5 mm without cardiac activity

Ectopic Pregnancy: Pregnancy outside the uterine cavity

Hydatidiform mole: Placental proliferation in the absence of fetus.

Complete Abortion: Passage of all products of conception

Incomplete Abortion: This occurs when some products of conception are within the endometrial cavity with the OS open.

Results

Vaginal bleeding in the first trimester accounted for 101 out of 1132 number of pregnant women that had ultrasound scan in the diagnostic center. The mean age of patients was 30.18 years ±5.38 while the median age was 30 years. The modal age range was 27 to 31 years and the age range of people involved in the study was between 17 and 50 years. Table 1 shows the age distribution of the subjects.

The most frequent clinical diagnosis in women with first trimester bleeding was threatened abortion 66/101 (65.37%) and the least was anembryonic gestation 1/101 (1%). Table 2 shows the pattern of clinical diagnosis. The most common ultrasound diagnosis in patients with first trimester bleeding was abortion (94.1%) with threatened abortion being the most frequently diagnosed entity. Only 35/66 (53.0%) patients clinically diagnosed as having threatened abortion was confirmed by ultrasound. In contrast, the number of patients diagnosed as having complete abortion clinically was 9/101 (8.9%) which is far lower than 27/101 (26.7%) made by ultrasound. Of the three molar pregnancies clinically diagnosed, only one was

Table 1: Age distribution of patients with first trimester bleeding.

Age Range	Frequency	Percent
<20	1	1.0
20-24	11	10.9
25-29	34	33.7
30-34	34	33.7
>35	21	20.8
Total	101	100.0

Table 2: Frequency distribution by clinical diagnosis.

Clinical Diagnosis`	Frequency	Percent
Anembryonic Gestation	1	1%
Complete Abortion	9	8.9%
Cyesis?	3	3.0%
Ectopic Gestation	3	3.0%
Incomplete Abortion	7	6.9
Missed Abortion	6	5.9
Molar Pregnancy	3	3.0
Spontaneous Abortion	3	3.0
Threatened Abortion	66	65.3

correct. Table 3 shows the pattern and correlation of clinical and ultrasound diagnosis.

Table 4 shows concordance between clinical and ultrasound diagnosis. The overall concordance was 44.55%. The highest concordance of 66.7% was observed in the ectopic pregnancy group. The highest concordance rate with regards to the referral pattern was recorded in the Obstetrics and Gynecology specialist group (75%) while the least was observed in the patent medicine and unspecified group.

Discussion

The mean age of patients in this study was 30.18 years. This agrees with findings reported in similar studies done in other places. [14,15] Our study showed that abortion was the commonest cause of first trimester vaginal bleeding with threatened abortion contributing the highest frequency. [16,17] This similar trend was observed in other studies by Gupta et al. and Vidya et al. [18,19]

In correlating the clinical and ultrasound diagnosis, it was found that there was a significant variation between the clinical and ultrasound diagnosis in patients with first trimester bleeding. The overall concordance of 44.55% was poor. This agrees with the findings by Shivanagappa et al. which noted that the accuracy of clinical diagnosis of first trimester miscarriage was poor. [20] The implication of the poor concordance is that relying on clinical diagnosis alone would have missed the diagnosis in more than 50% of the cases. This brings to the fore the need to have ultrasound machines in emergency rooms where pregnant women with bleeding are evaluated and treated. The use of ultrasound early in complicated pregnancy will reduce length of hospitalization, reduce cost and risk of management or even avoid hospitalization entirely. [21]

In our study, a clinical diagnosis of 65% (66/101) for threatened abortion contrasted with the ultrasound diagnosis of 34.7% (30/101). The factors that could have contributed to this observation include the timing between clinical diagnosis

Table 3: Clinical diagnosis versus ultrasound diagnosis.

Clinical	Ultrasound								
	AG	CA	EG	IA	MA	MP	No pregnancy	TA	Total
Anembryonic Gestation (AG)	0	0	0	0	0	0	0	1	1
Complete Abortion (CA)	0	7	0	2	0	0	0	0	9
Cyesis	0	0	1	1	0	0	0	1	3
Ectopic Gestation (EG)	0	0	2	0	0	0	0	1	3
Incomplete Abortion (IA)	0	2	0	4	0	1	0	0	7
Missed Abortion (MA)	1	1	0	0	-0	1	1	2	6
Molar Pregnancy (MP)	1	0	0	0	1	1	0	0	3
Spontaneous Abortion	0	1	0	1	1	0	0	0	3
Threatened Abortion (TA)	6	13	0	8	4	1	1	33	66
Total	8	24	3	16	6	4	2	38	101

Chi Square: 203.71, P-Value<0.00; AG: Anaembryonic Gestation, CA: Complete Abortion,EG: Ectopic Gestation, IA: Incomplete Abortion; MA: Missed Abortion, MP: Molar Pregnancy, TA: Threatened Abortion

Table 4: Concordance of clinical diagnosis and ultrasound diagnosis of first trimester vaginal bleeding.

Clinical diagnosis	Ultrasound diagnosis		Total	Percentage concordance
	Yes	No		
Anembroyic Gestation	0	1	1	0.00
Complete Abortion	7	2	9	63.00
?Cyesis	0	3	3	0.00
Ectopic Gestation	2	1	3	66.67
Incomplete Abortion	4	3	7	57.114
Missed Abortion	1	5	6	16.67
Molar Pregnancy	1	2	3	33.33
Spontaneous Abortion	0	3	3	0.00
Threatened Abortion	30	36	66	45.45
Total	45	56	101	--

Table 5: Cross-tabulation of pattern of referral and accuracy of diagnosis.

Pattern of referral	Concordance of clinical and USS diagnosis		Total	Percentage Concordance
	Yes	No		
Consultant Ob/Gyn	3	1	4	75.00
Other consultants	21	19	40	52.50
GP	5	14	19	26.32
Not specified	0	2	2	0.00
Self	16	19	35	45.71
Patent medicine dealer	0	1	1	0.00
Total	45	56	101	44.55

and ultrasound evaluation. Abortion is a process which can quickly progress from threatened to incomplete and complete abortion. This could contribute to the reduction of the number of threatened abortion and increase in the number of complete miscarriage and incomplete abortion. However, different studies where ultrasound was in emergency rooms reported the same trend. L10, [21] another reason that could possibly have contributed to the discrepancy is that an embryonic gestation is an ultrasound diagnosis. [13] This may be part of the reason for the large discrepancies noted in our study.

The implications of low concordance and wrong diagnosis is that without the confirmation of the result, some diagnosis like molar pregnancy and ectopic pregnancy would have been missed. This will invariably lead to increased morbidities and possible mortalities. The over diagnosis of threatened abortion (which is mainly managed conservatively) would mean that some cases which could have benefitted from surgical or medical evacuation would have been missed leading to delayed treatment or no treatment. Instituting treatment based on the clinical diagnosis alone could lead to unnecessary treatment of complete abortion as incomplete abortion. Some cases of missed abortion would have been missed leading to delay of treatment; some viable pregnancies may also be terminated inadvertently. Ultrasound also identified two cases of vaginal bleeding in women that were not pregnant.

One of the strengths of our study was stratifying the cadre of referring health personnel with the concordance of clinical diagnosis and the ultrasound diagnosis. This has led to the discovery of specific gaps in knowledge. It showed varied accuracy of diagnosis with the cadre of the referring health care practitioner. As is expected, highest concordance was observed in Obstetrics and Gynecology specialist group. It also showed that both skilled and unskilled care givers attend to pregnant women in our clime. The low accuracy of diagnosis among the general practitioners is worrisome considering that they manage the bulk of the cases in every day practice. This calls for continuous medical education on clinical evaluation and management of first trimester vaginal bleeding among the general practitioners [Table 5].

Despite the obvious strengths of our study, it has some limitations, one was the high rate of self-referral, and this is worrisome and places the burden of proper counselling on the radiologist or sonographer. These women need to be encouraged to consult a trained care giver with the ultrasound report. The nature of the study did not allow us to determine whether these women were referred orally by health care providers or requested for the ultrasound evaluation on their own. Further study will be needed to determine the actual reason for self-referral. In addition, the clinical and ultrasound assessment were not done at the same time, since some of these conditions belong to a spectrum which may progress from clinical condition to another. This could have tilted the result of the study. However, our findings were consistent with the findings from other studies. [22,23]

Conclusion

In conclusion, our study has shown the poor accuracy of clinical diagnosis of vaginal bleeding in the first trimester of pregnancy. It also highlighted the need for availability of ultrasound machines and trained sonographers in the emergency rooms of our health facilities. The authors suggest that whenever possible, every woman with vaginal bleeding in first trimester should be subjected to ultrasound evaluation. [24]

Author Contributions

The study arose from an original idea from, MEA, COO and USI. All authors contributed to the study's design. MEA, USI, LO and IIM collected the data while IIM performed the analysis with the help of CIO. MEA AND IIM wrote the first draft. All authors contributed to the discussion and conclusion. All authors contributed significantly to, and are in agreement with, the content of the manuscript.

Conflict of Interest

All authors disclose that there was no conflict of interest.

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