

Ultrasound Evaluation of Vaginal Bleeding in First Trimester of Pregnancy: A Comparative Study with Clinical Examination

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Abstract

Introduction: Vaginal bleeding in the first trimester is a common obstetric situation ranging from an insignificant episode to life threatening emergency. The major causes are abortion, ectopic, and molar pregnancy. Ultrasonography is playing an increasing role in the diagnostic process. This study was taken up to evaluate its utility vis-à-vis clinical examination findings.

Methods: This was a prospective study done at JSS Hospital Mysore, a tertiary care teaching hospital. All obstetric cases with a history of bleeding per vagina in the first trimester of pregnancy between November 2007 and September 2009 were included. A complete general physical and pelvic examination was done to arrive at a clinical diagnosis. Patients were then subjected to ultrasound examination. Clinical diagnosis and ultrasound diagnosis were correlated.

Results: 165 of all obstetric cases (4247) had the first trimester bleeding (incidence of 4%). Commonest causes were abortion (83%), ectopic (13%), and molar pregnancy (4%). Of 165 cases, 106 cases were correctly identified by ultrasonography. 59 cases proved by sonography were misdiagnosed by clinical examination with a disparity of 64%. 46 cases were diagnosed by ultrasonography as viable pregnancies with sensitivity, specificity negative predictive value (NPV), and positive predictive value (PPV) of 100% and 98 cases were diagnosed as non-viable pregnancies by ultrasonography with sensitivity of 98%, specificity of 100%, and NPV of 98%. The clinical diagnosis had sensitivity of 82%, specificity of 52%, and PPV of 40% in diagnosing viable pregnancies. In diagnosing non-viable pregnancies, clinical diagnosis had a very poor statistical correlation with sensitivity of 50%, specificity of 81%, PPV of 62%, and NPV of 72%.

Conclusion: This study reinforces results of earlier reports that ultrasound is a sensitive and specific non-invasive diagnostic tool in the evaluation of first trimester bleeding.

Key words: Abortion, Ectopic pregnancy, First trimester bleeding, Molar pregnancy, Ultrasonography

INTRODUCTION

Vaginal bleeding in the first trimester is frequently encountered situation causing anxiety to the patient and obstetrician alike. 20-25% of pregnant women will have bleeding during early gestation.¹ This may range from

an insignificant episode to life threatening emergency.² The major causes are abortion, ectopic pregnancy, and molar pregnancy. Before the advent of ultrasonography (USG), these patients were managed only clinically.³ Ultrasonography has revolutionized the management of early pregnancy complications.

The social phenomena of increasing maternal age and heightened expectations for a normal outcome have put increased pressure on the obstetrician, thereby leading to increased use of ultrasonography. This study was taken up to compare the utility of ultrasound vis-à-vis clinical examination findings in first trimester vaginal bleeding.

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METHODS

This was a hospital-based prospective study. The study included patients attending JSS Hospital with a history of bleeding per vaginam in the first trimester of pregnancy. The study period was 2-year between November 2007 and September 2009. Women having non-obstetric causes for vaginal bleeding in the first trimester of pregnancy were excluded. The study was cleared by the Institutional Ethical Committee of JSS Medical College.

Clinical data such as age, parity, obstetric history, personal history, menstrual history, and details of present pregnancy such as period of amenorrhea at the time of first episode of bleeding, amount and duration of bleeding, pain abdomen and history of expulsion of fleshy mass/clots were noted. A detailed general physical and pelvic examination was done to arrive at a provisional clinical diagnosis. All patients were subjected to transabdominal sonography. Ultrasonography was done using Siemens Sonoline G608 and Toshiba Nemio machines. Transvaginal sonography (TVS) was performed whenever transabdominal sonography was inconclusive or equivocal. Transabdominal sonography was done and TVS using 5-7 MHz transducer. The clinical examination findings and operative procedures were noted. Clinical and ultrasound findings were correlated. A $P < 0.05$ was used to assess for statistical significance.

Statistical Analysis

The descriptive procedure was used to display univariate summary statistics for several variables in a single table. The frequencies procedure was used for describing many types of variables. The Crosstabs procedure was used to measure of association for two-way tables. The Chi-square test procedure was used to tabulate variables into categories. All the statistical methods were carried out through the SPSS for Windows (version 16.0).

RESULTS

The total number of obstetric admissions was 4247, out of which 165 had bleeding per vagina in the first trimester constituting a percentage of 4%. The age ranged from 16 to 35 years. The majority were in the age group of 21-25 years (46%). 45 (29%) were in the age group 16-20 years, 38 (22%) in the age group 26-30 years, and 7 (4%) between 31 and 35 years (Table 1). 87 (53%) cases were primigravida, and 78 (47%) were multigravida. The difference was not statistically significant. The mean gestational age at which cases presented with bleeding in the first trimester was 9 weeks. The majority of the cases, 57 (35%) with bleeding per vaginam were between gestational age 6.1 and 8 weeks. 53 (32%) had bleeding at 8.1-10 weeks and 55 (33%) at age

10.1-12 weeks. The difference in the gestational age was not statistically significant. 110 cases (66.7%) had uterine size < 10 weeks and 55 (33.3%) had uterine size between 10 and 12 weeks. Cervical Os was open in 23 (14%) and closed at 142 (86%). Fornices were free in 160 (97%), and forniceal tenderness was present in 5 cases (3%) (Table 2). 94 out of 165 (57%) cases were clinically diagnosed as threatened abortion. 52 (31%) were diagnosed clinically as incomplete abortion and 7 (4%) as missed abortion, 9 (6%) of 165 cases were diagnosed as ectopic pregnancy and 2 (1.2%) as molar pregnancy. 1 (0.8%) as complete abortion. The distribution of cases according to clinical diagnosis was statistically significant ($P = 0.000$) (Table 3). On sonography of 165 cases, 46 showed signs of viable pregnancy, 41 (24%) showed incomplete abortion, in 28 (17%) missed abortion, in 18 (11%) anembryonic gestation, in 21 (13%) ectopic pregnancy, 5 (3%) complete abortion, and 6 (4%) were diagnosed as molar pregnancy. The difference in the ultrasonographic features were statistically significant ($P = 0.000$) (Table 4).

Out of 165 cases, 46 (12%) were diagnosed as threatened abortion, 41 (11%) as incomplete abortion, 28 (25%)

Table 1: Representing distribution of cases according to age group

| Age in years | N (%) | |
|--------------|-----------|----------------------|
| 16-20 | 45 (27) | Mean±SD: 23.4±3.8163 |
| 21-25 | 75 (46) | Chi-square: 56.648 |
| 26-30 | 38 (23) | df: 3 |
| 31-35 | 7 (4) | $P=0.000$ |
| Total | 165 (100) | |

SD: Standard deviation

Table 2: The causes of bleeding per vaginam in the first trimester of pregnancy

| Causes | N (%) | |
|-------------------|-----------|-------------------|
| Abortion | 138 (83) | Chi-square: 189.9 |
| Ectopic pregnancy | 21 (13) | df: 2 |
| Hydatidiform mole | 6 (4) | $P=0.000$ |
| Total | 165 (100) | |

Table 3: Disparity between clinical diagnosis and ultrasound diagnosis

| Cases | Clinical diagnosis | Ultrasound diagnosis | Disparity |
|-----------------------|--------------------|----------------------|-----------|
| Threatened abortion | 94 | 46 | 48 |
| Incomplete abortion | 52 | 41 | 11 |
| Complete abortion | 1 | 5 | 4 |
| Missed abortion | 7 | 28 | 21 |
| Anembryonic gestation | - | 18 | 18 |
| Ectopic pregnancy | 9 | 21 | 12 |
| Molar pregnancy | 2 | 6 | 4 |
| Total | 165 | 165 | 118 |

as missed abortion, 5 (3%) as complete, 18 (17%) as anembryonic, 21 (28%) as ectopic, and 6 (4%) as molar pregnancy. The difference in the number of cases was statistically significant ($P = 0.000$).

Out of 165 cases, 138 (83%) had the abortion as the major cause of bleeding. The second common cause was ectopic pregnancy constituting (13%) followed by hydatidiform mole (4%). Out of 94 cases of threatened abortion diagnosed clinically, only 46 cases were sonographically confirmed as threatened abortion. There was disparity in 48 cases of threatened abortion which without the aid of ultrasonography would not have received appropriate treatment. The disparity in case of incomplete abortion was 11 and in missed abortion was 21. The disparity in cases of ectopic was 12, in cases of complete abortion was 4, and in case of molar pregnancy disparity was 4. The total disparity between clinical diagnosis and ultrasound diagnosis was present in 118 cases (71%) (Table 5).

Out of 165 cases, clinical diagnosis was confirmed by sonography in 106 indicating accuracy of clinical diagnosis to be 64%. In the follow-up of clinically diagnosed cases, out of 94 cases of suspected threatened abortion, 38 cases were confirmed by sonography out of which 32 cases continued to term gestation. 14 cases of incomplete abortion were misdiagnosed as threatened abortion. 15 cases of missed abortion, 14 cases of anembryonic gestation, 3 cases of complete abortion, 7 cases ectopic, and 3 cases of molar pregnancy were misdiagnosed as threatened abortion. Out of 52 cases of incomplete

abortion diagnosed clinically, only 27 were confirmed. 6 cases of missed abortion and 8 cases of threatened abortion were misdiagnosed as incomplete abortion. 4 cases of anembryonic gestation, 1 case of complete abortion, 5 cases of ectopic pregnancy, and 1 case of molar pregnancy were misdiagnosed as incomplete abortion. Out of 7 cases of missed abortion diagnosed clinically, all 7 cases are confirmed. 1 case of complete abortion, 9 cases of ectopic pregnancy, and 2 cases of molar pregnancy diagnosed on clinical examination were confirmed.

Out of 46 cases, which were diagnosed as threatened abortion on ultrasound, 32 cases were continued as a normal pregnancy, 8 had missed abortion, 2 had incomplete abortion, and 4 had complete abortion. All other causes of bleeding per vagina were confirmed on ultrasound.

The subjects in the study group were divided into three main categories for the purpose of statistical correlation: (1) Viable intrauterine pregnancy, (2) Non-viable intrauterine pregnancy, and (3) Ectopic pregnancy. All cases of viable intrauterine pregnancies were followed up without intervention while other cases were managed appropriately based on the ultrasound findings. 46 out of 94 cases of suspected viable intrauterine gestation on clinical examination were confirmed. This shows sensitivity of 82%, specificity of 52%, PPV of 40%, and NPV of 88%. Of the 9 ectopic pregnancies diagnosed clinically, all were confirmed with specificity of 100%, PPV of 100%, and NPV of 92%. In diagnosing non-viable pregnancies, the clinical diagnosis had a very poor statistical correlation with sensitivity of 50%, specificity of 81%, PPV of 62%, and NPV 72% (Table 6).

Extrauterine pregnancies were correctly diagnosed on ultrasound with zero false positive and zero false negativity with sensitivity, specificity, PPV, and NPV of 100% each. All ectopic pregnancies were correctly diagnosed with sensitivity of 100%, specificity of 99%, PPV of 95%, and NPV of 100%. One case which was diagnosed as ruptured ectopic was found to be unruptured ectopic on laparotomy. The non-viable pregnancies diagnosed on ultrasound were confirmed with a sensitivity of 98% and NPV of 98%. Ultrasound diagnosis proved to be very accurate on statistical evaluation of sensitivity and specificity of 100% (Table 7).

Table 4: Comparison of clinical, ultrasound, and final diagnosis

| Parameters | N (%) | | |
|-----------------------|--------------------|----------------------|-----------|
| | Clinical diagnosis | Ultrasound diagnosis | Final |
| Threatened abortion | 94 (57) | 46 (12) | 46 (12) |
| Incomplete abortion | 52 (31) | 41 (11) | 41 (11) |
| Missed abortion | 7 (4) | 28 (25) | 28 (25) |
| Complete abortion | 1 (1) | 5 (3) | 5 (3) |
| Anembryonic gestation | - | 18 (17) | 18 (17) |
| Ectopic pregnancy | 9 (6) | 21 (28) | 21 (28) |
| Molar pregnancy | 2 (1) | 6 (4) | 6 (4) |
| Total | 165 (100) | 165 (100) | 165 (100) |

Table 5: Correlation of clinical diagnosis with final diagnosis - an evaluation

| Parameters | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|------------|-----------------|-----------------|---------|---------|
| Viable | 82 | 52 | 40 | 88 |
| Ectopic | 40 | 100 | 100 | 92 |
| Non-viable | 50 | 81 | 62 | 72 |

PPV: Positive predictive value, NPV: Negative predictive value

DISCUSSION

Bleeding in early pregnancy is an indicator of an abnormality interrupting the normal development. It is a common cause for emergency admissions. If a diagnosis of the viability or non-viability of pregnancy can be made definitely then, hormonal therapy and hospitalization can

Table 6: Correlation of ultrasound diagnosis with final diagnosis - observation

| Parameters | True positive | False positive | False negative | True negative |
|------------|---------------|----------------|----------------|---------------|
| Viable | 46 | 0 | 0 | 119 |
| Ectopic | 20 | 1 | 0 | 144 |
| Non-viable | 98 | 0 | 1 | 67 |

Table 7: Correlation of ultrasound diagnosis with final diagnosis - an evaluation

| Parameters | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|------------|-----------------|-----------------|---------|---------|
| Viable | 100 | 100 | 100 | 100 |
| Ectopic | 100 | 99 | 95 | 100 |
| Non-viable | 98 | 100 | 100 | 98 |

PPV: Positive predictive value, NPV: Negative predictive value

be avoided.⁴ By clinical history and examination, this is usually impossible. The availability of ultrasonography has changed the scenario.⁵

The incidence of bleeding in the present study was 4%. 35% of patients in this study had bleeding at 6-8 weeks of gestation which is comparable to the study by Bharadwaj *et al.*⁶ of 30%. 32% of cases had bleeding at 8.1-10 weeks and 33% at between 10 and 12 weeks compared to 35% and 22%, respectively, in the Bharadwaj study.⁶

In the present study, abortions contributed to a major cause of the first trimester bleeding constituting 83%. In the reports by Rani *et al.*⁷ and Bhargava *et al.*, also abortion was the leading cause with an incidence of 61% and 81.6%, respectively. The incidence of ectopic pregnancy was 13% which is similar to that reported by Bhargava *et al.* The incidence of mole in present study was 4% compared to the studies of Rani *et al.* and Bhargava *et al.* who reported an incidence of 18% and 4.35%, respectively.

In our study, out of 46 cases of sonographically diagnosed threatened abortion, subchorionic bleed was noted in 33 cases which constitutes 71%, when compared to Steven *et al.*⁸ 10 (20%) and Pederson *et al.*⁹ 62 (18%). We noted an increased incidence of subchorionic bleeds in our study.

In this study, the incidence of viable pregnancies on ultrasound was 27% and 72 % of non-viable pregnancies which is similar to the study by Schauburger *et al.*⁵ and Stabile *et al.*¹⁰ had an incidence of 58%, 44%, and 64% of viable pregnancies and 42%, 52%, 36% of non-viable pregnancies, respectively.

In this study, 106 clinically diagnosed cases were confirmed on ultrasound with the disparity of 64%. The present study is comparable to the study by Ghorade *et al.*,¹¹ whereas

Khanna¹² and Reddi Rani noted a disparity of 50% and 42% between clinical and ultrasound diagnosis, respectively. In this study, all cases of threatened abortion, missed abortion, incomplete abortion, complete abortion, anembryonic gestation, and molar pregnancy were diagnosed accurately on ultrasound with an accuracy of 100%. The results of our study are comparable with that of Sofat¹³ and Bharadwaj.⁶ Lower incidence of blighted ovum was noted in the study of Gorade *et al.*¹¹ This could be because cases of up to 20th week of gestation had been taken up in their study (incidence of blighted ovum decreases with the advancing gestational age).

Rajan¹⁴ in a prospective study of 140 patients observed that there were 37 (26.43%) subjects with vaginal bleeding, which was observed at or before 8 weeks in 91.89%. Pregnancy was normal by sonography, based on the imaging of live fetus, in 20 (54.05%). The abnormal pregnancies diagnosed included blighted ovum (18.92%), vesicular mole (16.22%), missed abortion (11.76%), and ectopic pregnancy in (11.76%). This study highlighted the invaluable role of sonography in investigating early pregnancy bleeding, wherein a normal pregnancy with excellent chances for viable births could be differentiated from a pathological pregnancy which warrants an immediate termination.

Sofat¹³ compared and correlated clinical diagnosis and ultrasound diagnosis. They found that ultrasound had a definite edge over clinical diagnosis by about 30% in case of threatened abortion, 40% in missed abortion, 95% in molar pregnancy, and 35% in incomplete abortion.

Lyer and Bhattacharya¹⁵ in their evaluation of 200 patients of complicated first trimester clinically and by ultrasonography found that of the 74 patients clinically diagnosed as threatened abortions, only 36 showed supporting ultrasonographic findings. USG was diagnostic of non-viable pregnancy in 34. 8 of the 40 patients suspected to have a missed abortion were- actually diagnosed as normal viable pregnancies, and 2 cases had an empty non-pregnant uterus. In 2 clinically diagnosed as complete abortion, significant products of conception were seen on USG. 12 of the 18 cases suspected of having a delayed period turned out to be either missed abortion or incomplete abortion. 6 of the 12 cases with suspected vesicular mole, 6 patients suspected of ectopic pregnancy, and two fibroid uterus were diagnosed on USG as having normal viable pregnancies. Judicious use of ultrasonography was advocated in the management of early pregnancy complications.

Jaideep Maihotra¹⁶ in his prospective evaluation of 150 patients with first trimester bleeding found that ultrasonography helped in establishing the correct diagnosis in 32% of clinically misdiagnosed cases. He concluded that

ultrasonography was the only imaging modality, by which an accurate assessment of first trimester bleeding can be done from the diagnostic and prognostic point of view.

Reddi Rami¹⁷ evaluated 100 cases of first trimester bleeding by ultrasonography. Abortion constituted the largest group (61%) followed by ectopic pregnancy (21%), and vesicular mole (18%). Sonography was strongly suggestive of ectopic in 72% and diagnostic in 23% of cases. TVS was diagnostic in 39% of cases. TVS was more sensitive than transabdominal sonography in the diagnosis of abnormal intra uterine gestation normal intrauterine gestation and ectopic pregnancy.

We agree that the sample size of this study could have been larger for better results. Furthermore, patients presenting with excessive vaginal bleeding undergoing immediate evacuation and curettage were excluded in this study, and this could have altered the results.

To summarize, in this study, the causes of bleeding covered a spectrum of conditions ranging from a viable pregnancy to non-viable pregnancy. Ultrasound examination was a good indicator for evacuation in cases of abortion. Using ultrasound, pregnancy with higher chances of a viable birth could be differentiated from a pathological pregnancy warranting an immediate termination.

The earlier concept was that nothing is better than the two fingers of an obstetrician, but today ultrasound has been shown to have a definite edge. Ultrasound is aptly described as the third finger of the obstetrician.

CONCLUSIONS

Ultrasound is a valuable tool in the differentiation of causes of first trimester vaginal bleeding. Ultrasound is helpful in the decision-making algorithm about the safe continuation of the pregnancy, timely intervention for abnormal pregnancy. Judicious utilization of ultrasonography and a close liaison with the sonologist is necessary. However, it should be remembered that ultrasound is an extension of the pelvic examination and cannot replace obstetric history and clinical examination.

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