

## **EDITORIAL**

### **SPONTANEOUS MISCARRIAGE AMONG 325 VIABLE PREGNANCIES COMPLICATED BY VAGINAL BLEEDING IN THE FIRST TWENTY WEEKS OF GESTATION**

. Faisal M. S. Basama<sup>(1)</sup>, Fiona crossfill<sup>(2)</sup>

1.Consultant Obstetrician and Gynecologist  
Lancaster Infirmary, UK

2.Consultant Obstetrician and Gynecologist  
Sharoe green Hospital,  
U.K.

[E-Mail: fbasama@hotmail.com](mailto:fbasama@hotmail.com)

#### **ABSTRACT**

##### **THE OBJECTIVES:**

To confirm or refute that when the fetal cardiac activity is demonstrated on scan at less than 7 weeks gestation, the risk of miscarriage is not significantly different from the natural-background risk

To ascertain the outcome of threatened miscarriage

##### **Methods**

###### **The setting:**

The early pregnancy assessment unit at Sharoe Green Hospital, Preston, England, U. K.

###### **Design:**

The study was prospective and observational.

###### **The subject:**

325 pregnant women who presented with viable pregnancies and vaginal bleeding in the first 20 weeks of pregnancy.

###### **The intervention:**

Transabdominal or transvaginal ultrasonography.

###### **Statistics:**

The statistical package, SPSS 9.0 for windows, was used and Pearson's Chi-square test was selected to compare the groups.  $P \geq 0.05$ .

###### **Results:**

Higher parity and recurrent miscarriages were associated with higher rate of miscarriage. Women presenting with viable pregnancies and moderate to heavy vaginal bleeding had a significantly higher rate of miscarriage (24.1%) compared with (9.0%) in women presenting with mild bleeding (Pearson Chi-square test = 17.516, df = 2, Asymp.sig. (2-Sided) = 0.000). In 37.5% of the women, there were significant differences in the gestational age as calculated by the scan from that calculated by the first day of the Last-Menstrual Period (LMP). The rate of miscarriage (17.5%) amongst women with gestational age of less than 7 weeks was significantly higher than (9.2%) amongst women with gestational age of more than 7 weeks (Pearson Chi-square test = 7.065, df = 2, Asymp.sig. (2-Sided) = 0.029). Hematomas were associated with significantly higher rates of miscarriages (25.8%) in contrast to a rate of 10.2% amongst women

## **EDITORIAL**

without hematomas (Pearson Chi-square test = 6.990, df = 2, Asymp.sig. (2-Sided) = 0.030).

### **Conclusions**

Moderate to heavy vaginal bleeding, a gestational age of less than 7 weeks and the demonstration of a haematoma on ultrasound scan are associated with significantly higher rates of miscarriage. Higher parity and recurrent miscarriages are associated with increased risk of miscarriage.

### **Key words:**

Viable pregnancy, vaginal bleeding, first twenty weeks, gestation, spontaneous miscarriage.

### **Synopsis**

#### **Title:**

Spontaneous miscarriage among 325 viable pregnancies complicated by vaginal bleeding in the first twenty weeks of gestation

#### **Authors:**

Mr. F. M. S. Basama and F. Crosfill

#### **Synopsis:**

Moderate to heavy vaginal bleeding, a gestational age of less than 7 weeks and the demonstration of a haematoma on ultrasound scan were associated with significantly higher rate of miscarriage. The findings suggest that perhaps there is a need to rationalize the timing of scans in early pregnancy.

## **INTRODUCTION**

Vaginal bleeding and abdominal pain are common symptoms in early pregnancy and may complicate up to 30% of such pregnancies [1] and the risk of miscarriage can range between 15 to 25% [2, 3]. Understandably, this can be a source of considerable anxiety to the pregnant woman whose pregnancy is complicated by vaginal bleeding therefore; the reassurance offered by early ultrasound is welcome and desirable.

Undeniably, ultrasonography in early pregnancy has allowed the assessment of viability with great accuracy. It has been claimed that once the viability is ultrasonographically confirmed 87% to 98% of these pregnancies will have a normal outcome [4, 5, 6, 1, 7, 8, 9]. However, this optimism is not universal and threatened miscarriage appears to associate with significant risk of subsequent spontaneous miscarriage and adverse perinatal outcome [10, 7].

### **The rationale:**

The viability and prognosis of pregnancy complicated by vaginal bleeding is the prime concern of women attending the early pregnancy assessment unit. Through long experience of dealing with early pregnancy problems, we felt that there is a need to ascertain the rate of miscarriage in two distinct gestational age groups; the less than 7 completed weeks gestation group and the greater than 7 (actually 7 – 20) weeks gestation group, which will allow us to provide valid information to our patients.

The hypothesis is that when the gestation age is less than 7 weeks; the risk of miscarriage is not significantly different from the frequently quoted risk of 15 to 25% even when the fetal cardiac activity is demonstrated on scan. Therefore, by confirming viability on an early scan we could not, confidently, reassure the women that their risk of losing the pregnancy is lower than the natural-background risk.

### **The aims and objectives:**

## **EDITORIAL**

The main objective of the study is to test the hypothesis; however, the study would also aim to ascertain the outcome of the viable pregnancies complicated by vaginal bleeding in the first twenty weeks of gestation.

### **Pilot study:**

A pilot project studied the outcome of 182 women with threatened miscarriage (Basama and Crosfill, 2004). The overall rate of miscarriage was 14.3%; the rate was higher in the first trimester (15%) and with recurrent vaginal bleeding (21%) than in the second trimester (5.6%) or if the bleeding was not recurrent (12.4%). The rate was 29% in the 5 – 6 weeks + 6 days gestation group, which was significantly higher than 8.2% in the 7 – 12 weeks gestation group. The study suggested that early scans, less than 7 weeks gestation, were falsely reassuring for the woman with threatened miscarriage.

### **The setting:**

The setting was the early pregnancy assessment unit in a general district hospital; Sharoe Green Hospital, Preston, U. K. In an average year the unit deals with 2500 early pregnancy complications.

### **Design:**

The study was prospective and observational.

### **Materials and methods:**

Women presenting with vaginal bleeding with or without abdominal pain and who had the fetal heart activity confirmed on the ultrasound scan in the first 20 weeks were included. The amount and duration of the vaginal bleeding were noted; based on the patient's history and the observation of the assessing gynecologist.

### **The intervention:**

Transabdominal or transvaginal sonography was employed. The ultrasound-scan machine used was an EUB 420 Hitachi with a 6.5 MHz transvaginal probe and a 4 MHz transabdominal probe. The scan was performed by one of two associate specialist doctors who ran the unit. The fetal **Crown-Rump Length (CRL)** and/or the **Bi-Parietal Diameter (BPD)** were used to confirm the gestation age as appropriate. The routine observations also included the fetal cardiac activity, size and shape of the gestation sac, uterus and adnexae. Any fluid collection suggestive of haematoma was measured and recorded and a repeat scan would be offered in two weeks if a haematoma was present. Routine-laboratory investigations included full-blood count, blood group and Rhesus factor.

### **The measured outcomes:**

These were; termination of pregnancy, miscarriage, or continuing pregnancy. These were evaluated against multiple factors that include; age, gravidity, parity, history of previous miscarriage, presenting symptoms of vaginal bleeding with or without abdominal pain, the ultrasonographic gestational age and the presence or absence of haematoma.

### **The inclusion criteria are:**

- Single, viable-intrauterine pregnancy.
- Pregnancy of twenty-week gestation or less.
- Known last-menstrual date.
- Regular periods.
- Signs of threatened miscarriage; vaginal bleeding with or without abdominal pain.

### **The exclusion criteria:**

## **EDITORIAL**

- Multiple pregnancies.
- Women with uncertain dates.
- Irregular periods.
- Women with incompetent os.
- Hydatidiform mole.
- Pregnancies complicated by congenital fetal malformation.
- Women with serious medical conditions such as renal failure, chronic hypertension, and diabetes.

### **Statistics:**

The statistician calculated that at least 300 women were required to achieve a power of 90%, which would allow for some women to drop out or to be excluded from the study; thus, guaranteeing a power of at least 80%. The statistical package, SPSS 9.0 for windows, was used and Pearson's Chi-square test was selected for comparing the groups. A value of less than 0.05 is considered significant.

### **The time scale:**

The study took place from 01/06/2002 to 31/05/2004.

### **Ethical issues:**

There was no added intervention, treatment, or tests. This research will further enable us to counsel and reassure women with threatened miscarriage about their main concern; the possible perinatal outcome of their pregnancies. The local ethical committee approved the study.

### **THE RESULTS:**

The study recruited three hundred and fifty four (354) women. Twenty-nine (29) women were not traceable and the records were complete for three hundred and twenty five (325) women. The women's ages ranged between 15 and 42 years (table 1) with a mean of 28, a median of 29 and a mode of 29. The gestational ages; 97 women (29.8%) were between 4 to 6 weeks plus 6 days gestation, 124 (38.2%) were 7 to 12 weeks gestation and 104 (32%) were 12 weeks plus one day to 20 weeks gestation (table 1). There were 112 (34.5%) primigravidae, 213 (65.5%) multigravidae, 151 (46.5%) nulliparae and 174 (53.5%) multiparae (table 1). One hundred and two (102) of the women (31.3%) had a history of previous miscarriage; 70 (21.5%) had one miscarriage, 23 (7.1%) had two miscarriages and 9 (2.7%) had more than 3 miscarriages (table 1).

Two hundred and sixty seven (267) of the women (82.2%) presented with mild vaginal bleeding, while 58 (17.8%) presented with moderate to heavy bleeding (table 1). The bleeding was associated with pain in 146 of the women (44.9%) (Table 1). The ultrasound scan demonstrated the presence of haematoma in 31 women (9.5%) (Table 1). The volumes of the haematoma ranged between 12 and 166 milliliters. In 122 of the women (37.5%) there were significant differences (7 days or more) in the gestational age as calculated by the scan from that calculated by the first day of the **Last-Menstrual Period (LMP)** (table 1).

Five (5) of the women (1.5%) opted for social **Termination Of the Pregnancy (TOP)**, 38 (11.7%) had spontaneous miscarriages and the pregnancies continued in 282 (86.8%) (Table 2).

The rates of miscarriage were 13.2%, 10.8% and 12.7% for the age groups; 15 – 20, 21 – 30 and 31 – 40 respectively, showing no significant differences (Pearson Chi-square test = 3.539, df = 6, Asymp.sig. (2-Sided) = 0.739) (table 3). The rates of miscarriage were; 11.4% for primigravidae, 12.2% for 2 – 3 gravidity and 11.8%, for 4 gravidity or more and the differences were not

## **EDITORIAL**

significant (Pearson Chi-square test = 1.102, df = 4, Asymp.sig. (2-Sided) = 0.894) (table 3). The rates of miscarriage were; 11.9% for nulliparae, 10.3% for Para 1 – 2 and 17.2%, for Para 3 or more (Pearson Chi-square test = 3.497, df = 4, Asymp.sig. (2-Sided) = 0.478) (table 3). The rates of miscarriage were; 11.7% amongst women with no previous miscarriage, 10.8% when there is a history of 1 to 2 miscarriages and 22.2% for 3 or more previous miscarriages (Pearson Chi-square test = 3.372, df = 4, Asymp.sig. (2-Sided) = 0.498) (table 3). Women presenting with moderate to heavy vaginal bleeding have a significantly higher rate of miscarriage (24.1%) in comparison to a rate of 9.0% amongst women presenting with mild bleeding (Pearson Chi-square test = 17.516, df = 2, Asymp.sig. (2-Sided) = 0.000) (table 3). There was no significant difference in the rate of miscarriage (11%) amongst women presenting with vaginal bleeding and abdominal pain versus a rate of 12.3% amongst women presenting with bleeding, but without pain (Pearson Chi-square test = 2.615, df = 2, Asymp.sig. (2-Sided) = 0.270) (table 3). In more than one third of the women (37.5%), there were significant differences in the gestational age as calculated by the scan from that calculated by the first day of the LMP; however, there was no significant difference in the miscarriage rate between the two groups (9.9% v 14.8%) (Table 3). Women with gestational age of less than 7 weeks have a significantly higher rate of miscarriage (17.5%) compared to 9.2% amongst women with gestational age of more than 7 weeks (Pearson Chi-square test = 7.065, df = 2, Asymp.sig. (2-Sided) = 0.029) (table 3). Ultrasonographically demonstrated hematomas were associated with significantly higher rate of miscarriage (25.8%) compared to 10.2% when there was no haematoma (10.2%) (Pearson Chi-square test = 6.990, df = 2, Asymp.sig. (2-Sided) = 0.030) (table 3).

## **DISCUSSION:**

This study has observed an overall miscarriage rate of 11.7% after the demonstration of the fetal cardiac activity on ultrasound scan in pregnancies complicated by vaginal bleeding in the first twenty weeks of gestation, which was higher than in other studies [5, 8, 9]. Generally, the demographic features of the studied population such as; age, parity and gravidity may explain the differences and it is more likely that the more advanced gestational age in the above mentioned studies is the plausible reason for the lower miscarriage rate and this study and in agreement with other observations [11, 12] showed that the rate of miscarriage tend to decrease with increased gestation.

Although, the women's ages and gravidity appeared to have no direct influence on the miscarriage rate, an increased rate of miscarriage (19.2%) was observed in association with higher parity, probably an indirect reflection of higher age, which is a well-known association with higher miscarriage rates [13, 12, 9].

The findings of this study indicate that moderate to heavy vaginal bleeding carries a significantly higher rate of miscarriage (24.1%), which is in keeping with earlier observations [12, 14]; though, this study suggests that the presence or absence of abdominal pain seems to have no influence in the outcome.

The demonstration of the fetal cardiac activity in women presenting with threatened miscarriage is crucial, as both the woman and the clinician are eager for reassurance. The improved ultrasound machines, professional skills and the reassuring earlier studies [15, 16, 11, 17, 9] have all meant an increasing pressure and demand for early scan. It is comprehensible that different studies may infer different emphases; however, any recommendation of early reassuring scans should be carefully evaluated. Cashner et al [16] and Mackenzie et al [11] reported a miscarriage

## **EDITORIAL**

rate of 2 and 3.2% respectively once the fetal heart activity was demonstrated and it is likely that the relatively advanced gestation ages in both studies; 8 to 12 weeks respectively, would explain the low miscarriage rates. Wilson et al [9] also reported a low incidence (2.3%) following ultrasound scans and the rational explanation for the good outcome was that the scans were performed on an essentially normal pregnancies, while Brigham et al [15] was dealing with asymptomatic women; hence, it was not a surprise that a much higher proportion of the pregnancies continued when the fetal heart pulsation was demonstrated. Our study did not confirm the above findings and in contrast, has shown that vaginal bleeding at a gestational age of less than 7 weeks has a significantly higher rate of miscarriage (17.5%) compared to 9.2% when the gestational age is more than 7 weeks.

Our study has also observed a significantly higher rate of miscarriage (25.8%) in association with haematoma, as compared with (10.2%) when it is absent. In general, the demonstration of a haematoma on ultrasound scan is associated with increased risk of adverse pregnancy outcome, including miscarriage [18, 19, 20, 21] and the incidence seems to increase, significantly, when the gestational age was less than 8 weeks [20]. Bennett et al [13] has shown that the fetal outcome is dependent on the size of the haematoma and observed a higher rate (18.8%) of miscarriage with larger collection; however, Jouppila [19] did not find any correlation between the volume of the haematoma and the outcome of the pregnancy.

In more than one third of the women studied (37.5%) there were significant differences (7 days or more) in the gestational age as calculated by the scan from that calculated by LMP; although, the study recruited, only, women with viable pregnancies, who had regular periods and certain dates! In the presence of skilled professionals and good equipments we feel that the scan dating was accurate and it is more likely that the menstrual age was inaccurate. Chromosomal abnormalities may influence the rate of miscarriage and theoretically this may manifest itself as a small-for-dates at very early gestations; however, this study did not show enough evidence to support such a claim. Falco et al [22] observed a non-optimal prognosis and an increased-miscarriage rate, when the discrepancy between the menstrual and sonographic age exceeded 7 days. The miscarriage rate in our study was 14.8% in the 'inaccurate dates' group was slightly higher than the overall rate of miscarriage (11.7%); however, the difference is not statistically significant.

The influence of recurrent miscarriages on the outcome of future pregnancies is well investigated and those with idiopathic recurrent miscarriages seem to have better prognosis [15, 23]. This study has shown an increased risk of miscarriage of 22.2%, when there is a history of 3 previous miscarriages or more; however, the difference did not reach statistical significance. Clifford et al [23] reported a risk of 29% after 3 consecutive miscarriages and Laufer et al [24] in a retrospective analysis of women with two miscarriages or more reported a miscarriage rate of 22.7%; however, in the latter study it was not clear whether the women were symptomatic or not. In the past, when we counseled women who had undergone ultrasound scanning for threatened miscarriage, we might have been, unduly, optimistic once a fetal heart was demonstrated. This study indicates that caution is required in giving a good prognosis to those women of less than 7 weeks gestation, those in whom a haematoma is demonstrated, or those who had had recurrent miscarriage. These patients should have a repeat scan in the first or early-second trimester (i.e. they should not miss out on their dating scans). We would also suggest that it is inappropriate to scan simply for reassurance prior to 7 weeks gestation as such reassurance would be misplaced.

**CONCLUSIONS:**

## **EDITORIAL**

The women's ages, gravidity and abdominal pain appear to have no effect on the miscarriage rate. Higher parity and a history of three previous miscarriages or more are associated with increased risk of miscarriage. Moderate to heavy vaginal bleeding, a gestational age of less than 7 weeks and the demonstration of a haematoma on ultrasound scan are also associated with significantly higher rate of miscarriage. This study also suggests that the risk of miscarriage decreases with increased gestation age. The menstrual dates were, likely, wrong in one third of the women.

We are very aware of the high demand for the facilities of the early pregnancy assessment units at very early gestations; this study will support the rationalization and timing of early pregnancy ultrasound scans.

### **REFERENCES:**

- 1- Jouppila P: Clinical and ultrasonic aspects in the diagnosis and follow up of patients with early pregnancy failure. *Acta Obstet Gynecol Scand* 1980; 59: 405 – 409.
- 2- Harlap S, Shiono PH and Ramcharan: A life table of spontaneous abortions and the effects of age, parity and other variables. In Porter IH and Hook EB (eds) *Embryonic and fetal deaths*. New York: Academic Press. 1980: 145 – 158.
- 3- Shapiro S, Levine HS and Abromowicz M. Factors associated with early and late fetal loss. *Adv Planned Parenthood* 1963; 6: 45 – 63.
- 4- Christiaens G and Stoutenbeek P: Spontaneous abortion in proven intact pregnancies. *Lancet* 1984; ii: 571 – 572.
- 5- Everett C and Preece E: Women with bleeding in the first 20 weeks of pregnancy: value of general practice ultrasound in detecting fetal heart movement. *Br J Gen Pract* 1996; 46: 7 – 9.
- 6- Gilmore D and McNay M: Spontaneous fetal loss rate in early pregnancy. *Lancet* 1985; i: 107.
- 7- Mantoni M: Ultrasound signs in threatened abortion and their prognostic significance. *Obstet Gynecol* 1985; 65: 471 – 475.
- 8- Stabile I, Campbell S, Grudzinskas J: Ultrasonic assessment of complications during first trimester of pregnancies. *Lancet* 1987; 28: 1237 – 1240.
- 9- Wilson R, Kendrick V, Wittmann B, McGillivray B: Spontaneous abortion and pregnancy outcome after normal first – trimester ultrasound examination. *Obstet Gynecol* 1986; 67: 3, 352 – 355.
- 10- Basama FMS and Crosfill F: The outcome of pregnancies in 182 women with threatened miscarriage. *Arch Gynecol and Obstet* 2004; 270: 86 – 90.
- 11- Mackenzie WE, Holmes DS and Newton JR: Spontaneous abortions rates in ultrasonographically viable pregnancies. *Obstet Gynecol* 1988; 71: 1, 81 – 83.
- 12- Rosati P, Exacoustos C, Masini L and Mancuso S: Usefulness and limits of ultrasonic examination in the diagnosis and prognosis of early pregnancies. *Minerva Gynecol* 1989; 14: 10, 485 – 488.
- 13- Bennett GL, Bromley B, Leiberman F and Benacerraf BR: Subchorionic hemorrhage in the first – trimester pregnancies; prediction of pregnancy outcome with sonography. *Radiology* 1996; 200: 3, 803 – 806.
- 14- Siddiqi TA, Caligaris JT, Miodovnik KM, Holroyde JC and Mimouni F: Rate of spontaneous abortion after first trimester sonographic demonstration of fetal cardiac activity. *Am J Perinatol* 1988; 5: 1, 1 – 4.

**EDITORIAL**

- 15- Brigham SA, Conlon C and Farquharson RG: A longitudinal study of the outcome following idiopathic recurrent miscarriage. *European Society of human Reproduction and embryology* 1999; 14, 11: 2868 – 2871.
- 16- Cashner KA, Christopher CR and Dysert GA: Spontaneous fetal loss after demonstration of a live fetus in the first trimester. *Obstet Gynecol* 1987; 70: 6, 827 – 830.
- 17- Simpson JL, Mills JL, Holmes LB, Ober CL, Aarons J and Javarovic et al: Low fetal loss after ultrasound proved viability in early pregnancy. *JAMA* 1987; 258: 28, 2555 – 2557.
- 18- Ball RH, Ade CM, Schoenbor JA and Crane JP: The clinical significance of ultrasonographically detected Subchorionic hemorrhages. *Am J Obstet Gynecol* 1996; 174: 3, 996 – 1002.
- 19- Jouppila P: Clinical consequences after ultrasonic diagnosis of intrauterine haematoma in threatened miscarriage. *J Clin Ultrasound* 1985; 17: 2, 107 – 111.
- 20- Maso G, D'Ottavio G, De Seta F, Sartore A, Piccoli M and Mondruzzato G: First – trimester intrauterine haematoma and outcome of pregnancy. *Obstet Gynecol* 2005; 105: 2, 339 – 344.
- 21- Nagy S, Bush M, Stone J, Lapiniski Rh and Gardo S: Clinical significance of Subchorionic and retroplacental haematoma detected in the first trimester of pregnancy. *Obstet Gynecol* 2003; 102: 1, 94 – 100.
- 22- Falco P, Milano V, Pilu G, Davis C, Grisolia G and Rizzo et al: Sonography of pregnancies with first – trimester bleeding and a viable embryo: a study of prognosis indicators by logistic regression. *Ultrasound Obstet Gynecol* 1996; 7: 3, 165 – 169.
- 23- Clifford K, Rai R and Regan L: Future pregnancy outcome in unexplained recurrent first trimester miscarriage. *Hum Repord* 1997; 12: 2, 387 – 389.
- 24- Laufer MR, Ecker JL and Hill JL: Pregnancy outcome following ultrasound – detected fetal cardiac activity in women with a history of multiple spontaneous abortions. *J Soc Gynecol Investig* 1994; 1: 2, 138 – 142.