The natural course of spontaneous miscarriage: analysis of signs and symptoms in 188 expectantly managed women

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SUMMARY

Background: *Expectant management is an alternative for curettage in women with a miscarriage.*

Aim: *To assess the pattern of vaginal bleeding and pain in expectantly managed women with a miscarriage, and to analyse the factors predictive of a relatively quick spontaneous loss of pregnancy.*

Design of study: *Part of a study comparing expectant management with surgical evacuation.*

Setting: *Two hospitals in Amsterdam.*

Method: *In expectantly managed women with a miscarriage, the pattern of vaginal bleeding and pain and the probability of a spontaneous loss of pregnancy was analysed.*

Results: *Of the 188 expectantly managed women 95 (51%) experienced a spontaneous loss of their pregnancy. In women with bleeding at inclusion, 52% had a completed miscarriage loss, while of the women without bleeding but with a coincidentally diagnosed non-viable pregnancy during routine ultrasonographic examination, 46% had a completed miscarriage. In the multivariate analysis an increasing bleeding pattern at inclusion was predictive of a relatively quick spontaneous loss of pregnancy. The median daily levels of bleeding and pain were the most prominent during the first 8 days after the start of the bleeding and decreased thereafter.*

Conclusions: *Expectant management is effective in 51% of unselected women with a miscarriage. An increasing bleeding pattern is predictive of a relatively quick spontaneous loss of pregnancy in first-trimester miscarriages. The graphical representation of our findings can be used to inform women about the natural course of miscarriages and a well-informed treatment choice.*

Keywords: *First-trimester pregnancy; pregnancy complications; haemorrhage; spontaneous abortion.*

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Introduction

TWO out of ten pregnant women suffer a period of vaginal bleeding during the first trimester of their pregnancy. In 50% of these cases the pregnancy is viable, despite the fact that the bleeding continues for a variable period of time. The remaining 50% will miscarry sooner or later.[1] In places where scans are easily available, ultrasonography, the gold standard to predict whether the pregnancy is viable or not, will be used to establish the diagnosis.[2]

In the case of a non-viable pregnancy expectant management is increasingly accepted as a safe alternative to surgical evacuation.[3,4] However, the availability of data on the natural course of miscarriages, which is needed to inform these women about what to expect in order to make an 'informed, shared-management decision', is only limited.[6] This study tries to provide the missing information by studying patterns of bleeding and pain during expectant management, and analysing the factors predictive of a quick completed miscarriage in first-trimester miscarriages.

Method

This study was part of a larger study conducted between April 1998 and September 2000 in two Amsterdam hospitals: the Academic Medical Center and the Onze Lieve Vrouwe Gasthuis. Women with a non-viable pregnancy or an incomplete miscarriage were asked if they would participate in a randomised, controlled trial to compare the safety and effectiveness of expectant management and surgical evacuation.[4,7,8] Women who refused randomisation were managed according to their own choice. Enrolment took place among women who attended the emergency department or the outpatient clinic of one of the two hospitals because of first-trimester vaginal bleeding, after referral by their GPs. Women without vaginal bleeding, but with a non-viable pregnancy that had been diagnosed coincidentally during ultrasonographic examination for other purposes, were also included. Inclusion criteria were an established diagnosis of a non-viable pregnancy or an incomplete miscarriage at a gestational age of less than 16 weeks of pregnancy. Transvaginal sonographic criteria for this diagnosis were a mean gestational sac diameter of more than 15 mm without a measurable embryonic pole; an embryo without cardiac activity; or a gestational sac diameter of less than 15 mm, not showing any growth after a 7–day interval.[9,10] An incomplete miscarriage was diagnosed where there was ultrasonographic evidence of retained products of conception of more than 15 mm (anterior–posterior diameter). All transvaginal scans were performed by trained physicians using a transvaginal

HOW THIS FITS IN

What do we know?

Expectant management is an alternative for surgical evacuation in miscarriages.

What does this paper add?

An increasing bleeding pattern is predictive of a relatively quick completed miscarriage in first-trimester miscarriages. In the case of a completed miscarriage, median blood loss and pain were heaviest on the third day of vaginal bleeding and steeply decreased after day eight. The graphical representation of the natural course of miscarriages can be used to inform women (Figure 2).

6.5 MHz sonographic probe (Hitachi Corporation, Tokyo, Japan). All women who were randomly assigned to expectant management or had chosen this treatment option participated in this study. Exclusion criteria were an inability to understand the Dutch or English informed consent form, or severe bleeding, pain or fever necessitating immediate surgical evacuation. The study was approved by the medical ethics committees of both hospitals.

Expectant management involved scheduled visits every other week to the outpatient clinic. Further management in this group depended on clinical development. Women who became impatient while being managed expectantly and requested surgical evacuation straight away were scheduled to undergo a curettage within a week.

All women were assessed clinically and sonographically during the appointments until complete evacuation of the uterus had occurred after either surgical evacuation or a completed miscarriage during expectant management. Evacuation was considered as completed if the uterine contents were smaller than 15 mm (anterior–posterior diameter) at ultrasonography. Women had access to a telephone consultation at all times, and emergency admission could be arranged whenever necessary.

During the first visit, the attending physician collected baseline data on clinical signs and symptoms, obstetric history, and gestational age. Additional information on symptoms and sociodemographic data was collected by means of a patient questionnaire.

All patients were asked to report the amount of bleeding and the degree of abdominal pain in a standardised diary. Bleeding was registered daily on a validated pictorial blood-loss assessment chart. Women were asked to register the number and degree of saturation of tampons and towels used per day. We gave a score of 1 ml for each lightly stained tampon, 5 ml for a moderately soiled tampon and 10 ml for a completely saturated tampon. The scores for towels were 1, 5 and 20 ml respectively; scores for small and large blood clots were 1 and 5 ml respectively.[11,12] Pain was scored daily on a visual analogue scale from 0–100. During the visits the diaries were taken in, and instructions about the diary for the next interval were given to the patients.

We estimated the daily bleeding and pain profile of women with a spontaneous loss of products of conception. Daily blood-loss scores were estimated with the use of the pictorial chart. The scores were categorised according to a study in which measured daily menstrual loss and subjective ratings of volume were compared. Although there was a wide variation, the categories gave an indication of the amount of bleeding: spotting (2.5 ml), light (5.7 ml), moderate (16.1 ml) and heavy (22 ml).[13] Characteristics and time until completed miscarriage of women who completed a diary were compared with those who did not. We regarded the date of self-reported tissue loss as the true date of completed miscarriage whenever this was confirmed ultrasonographically during the next visit to our unit.

Characteristics and complaints at inclusion were compared between women who received expectant management according to randomised treatment allocation and those women who refused randomisation and were managed expectantly according to their own choice. Furthermore, we compared characteristics and complaints at inclusion between women who had experienced a completed miscarriage, and those undergoing surgical evacuation later on at their own request or as an emergency procedure (unscheduled curettage). This analysis was divided in two groups, those with and those without bleeding at presentation (we expected the clinical course to be different between these groups). A survival analysis was used to describe the cumulative probability of a spontaneous loss of pregnancy; statistical testing of potential predictors was done by applying the log-rank test. Women undergoing surgical evacuation (vacuum curettage) were censored in this analysis at the date of curettage. Women undergoing surgical evacuation as an emergency procedure were included in two ways: either censored or analysed in the completed miscarriage group. Variables associated with a completed miscarriage in univariate analyses ($P < 0.10$) were checked for correlation. The selected set of potential predictors was included in a multivariate survival analysis (Cox's proportional hazards model). Age and gestational age were treated as categorical and continuous variables respectively. The multivariate analysis was restricted to women with bleeding at inclusion as explained in the text. The Statistical Package of the Social Sciences (SPSS, version 10.07) was used for all analyses.

Results

Of 1101 women who visited our unit with first-trimester pregnancy problems, 215 (20%) had already miscarried completely, 439 were excluded because of a viable pregnancy (and other diagnoses such as ectopic pregnancy), and 447 (42%) had an incomplete miscarriage or a non-viable pregnancy. Of this group of 447, 22 women were excluded from the study because of severe bleeding or pain necessitating an immediate curettage. Of the remaining 425 women, 188 (44%) were managed expectantly (Figure 1).

Table 1 shows the characteristics and clinical signs at inclusion of the various groups. There were no differences between the group randomised to expectant management and the group that had chosen to undergo this treatment.

Of the 188 expectantly managed women 95 (51%) experienced a completed miscarriage (52% of the women with bleeding and 46% of the women without bleeding) and 93 (49%) ultimately underwent surgical evacuation. Of this latter

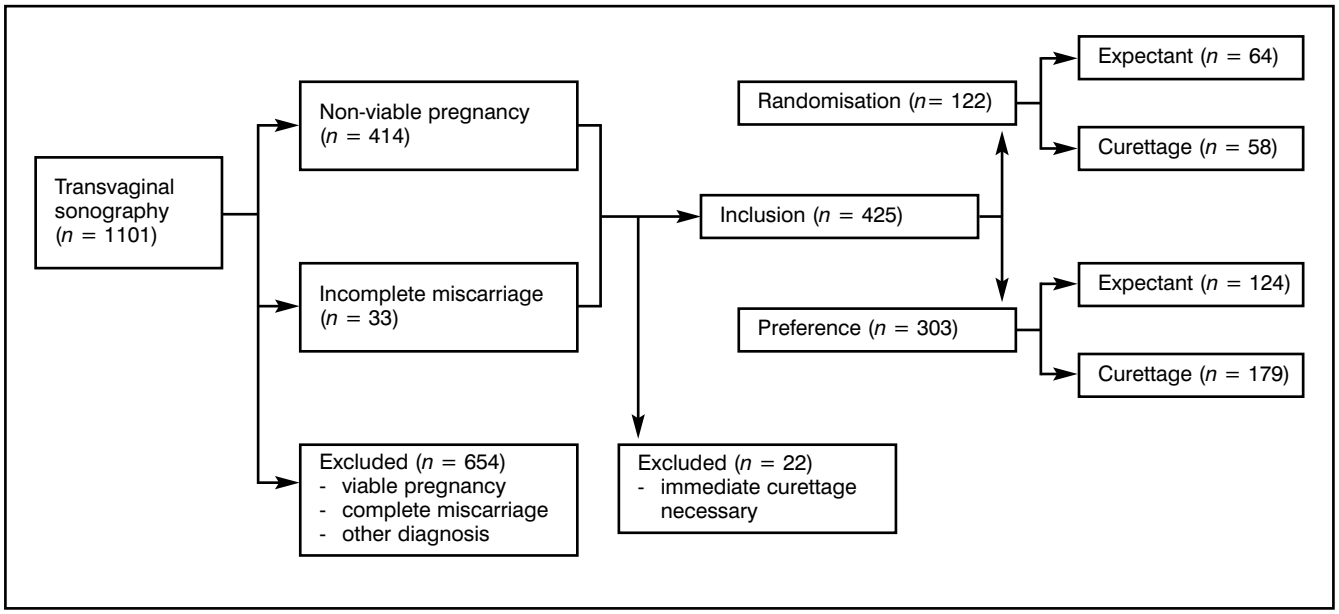

Figure 1. Trial profile.

Table 1. Characteristics and complaints at inclusion of women with a complete miscarriage, of randomised women and of women managed according to their own preference.

		Randomised groups		Preference groups	
Characteristics and complaints at inclusion	Complete miscarriage (*n* = 215)	Expectant management (*n* = 64)	Curettage (*n* = 58)	Expectant management (*n* = 124)	Curettage (*n* = 179)
Bleeding at inclusion	n.a.[a]	49 (76.6)	43 (74.4)	93 (75.0)	127 (70.9)
Mean age (years)	31.2	32.1	33.4	32.3	32.2
Parity					
0	115 (53.5)	32 (50.0)	22 (37.9)	58 (46.8)	89 (49.7)
1	100 (46.5)	32 (50.0)	36 (62.1)	66 (53.2)	90 (50.3)
Prior experience at baseline					
No previous miscarriage or legal abortion	130 (60.5)	37 (57.8)	32 (55.2)	72 (58.1)	97 (54.2)
Prior curettage	52 (24.2)	17 (26.6)	19 (32.8)	32 (25.8)	56 (31.3)
Prior expectant management	20 (9.3)	7 (10.9)	5 (8.6)	11 (8.9)	9 (5.0)
Prior curettage and expectant management	8 (3.7)	3 (4.7)	2 (3.4)	5 (4.0)	14 (7.8)
Unknown	5 (2.3)	-	-	4 (3.2)	3 (1.7)
Gestational age					
< 8 wk	79 (36.7)	9 (14.1)	8 (13.8)	10 (8.1)	20 (11.2)
8–12 wk	88 (40.9)	35 (54.7)	29 (50.0)	66 (53.2)	91 (50.8)
12–16 wk	28 (13.0)	16 (25.0)	18 (31.0)	40 (32.3)	50 (27.9)
Uncertain	20 (9.3)	4 (6.3)	3 (5.2)	8 (6.5)	18 (10.1)
Intact gestational sac	n.a.	59 (92.2)	54 (93.1)	112 (90.3)	167 (93.3)
Gestational sac diameter, median	n.a.	23.1	24.9	23.6	25.1
Bleeding before inclusion, median days[b]	4 (2–8)	6 (3–10)	4 (2–8)	4 (2–8)	4 (1–12)
Pain before inclusion, median days[b]	3 (1–6)	3 (1–8)	3 (1–6)	3 (1–7)	3 (1–9)

[a]not applicable. [b]Median time until inclusion following Kaplan-Meier estimation. In parentheses the 25% probability and 75% probability respectively.

group, 70 women were treated on their own request and 23 women underwent an emergency procedure.

Univariate and multivariate analyses were only performed in women with bleeding at inclusion, because the non-bleeding group was too small ($n = 46$) for regression analysis.

In the bleeding group we selected the following variables ($P < 0.10$) for the multivariate analysis: presence of gestational sac on ultrasound, course and amount of bleeding (compared to normal period) and presence of abdominal pain.

Table 2 shows that the course of bleeding was the only variable significantly predictive of a quicker completed miscarriage in women with bleeding with a hazard ratio of 0.69 (95% confidence interval 0.52–0.93). After adding women with an emergency curettage to the dataset, both the course of bleeding (hazard ratio: 0.71) and the amount of bleeding (hazard ratio: 0.76) emerged as statistically significant predictors.

Of the 95 women with a completed miscarriage, 60 (63%) completed the diary. For six women the data are not included

Table 2. Multivariate proportional hazards model of factors determining completed miscarriage during expectant management in women with bleeding at inclusion.

Model	Factors	Hazard ratio	*P*-value
Completed miscarriage	Increasing bleeding	0.69 (0.52–0.93)	0.01
Completed miscarriage and emergency curettages	Increasing bleeding	0.71 (0.53–0.94)	0.02
	Increasing amount of bleeding	0.76 (0.58–0.99)	0.04

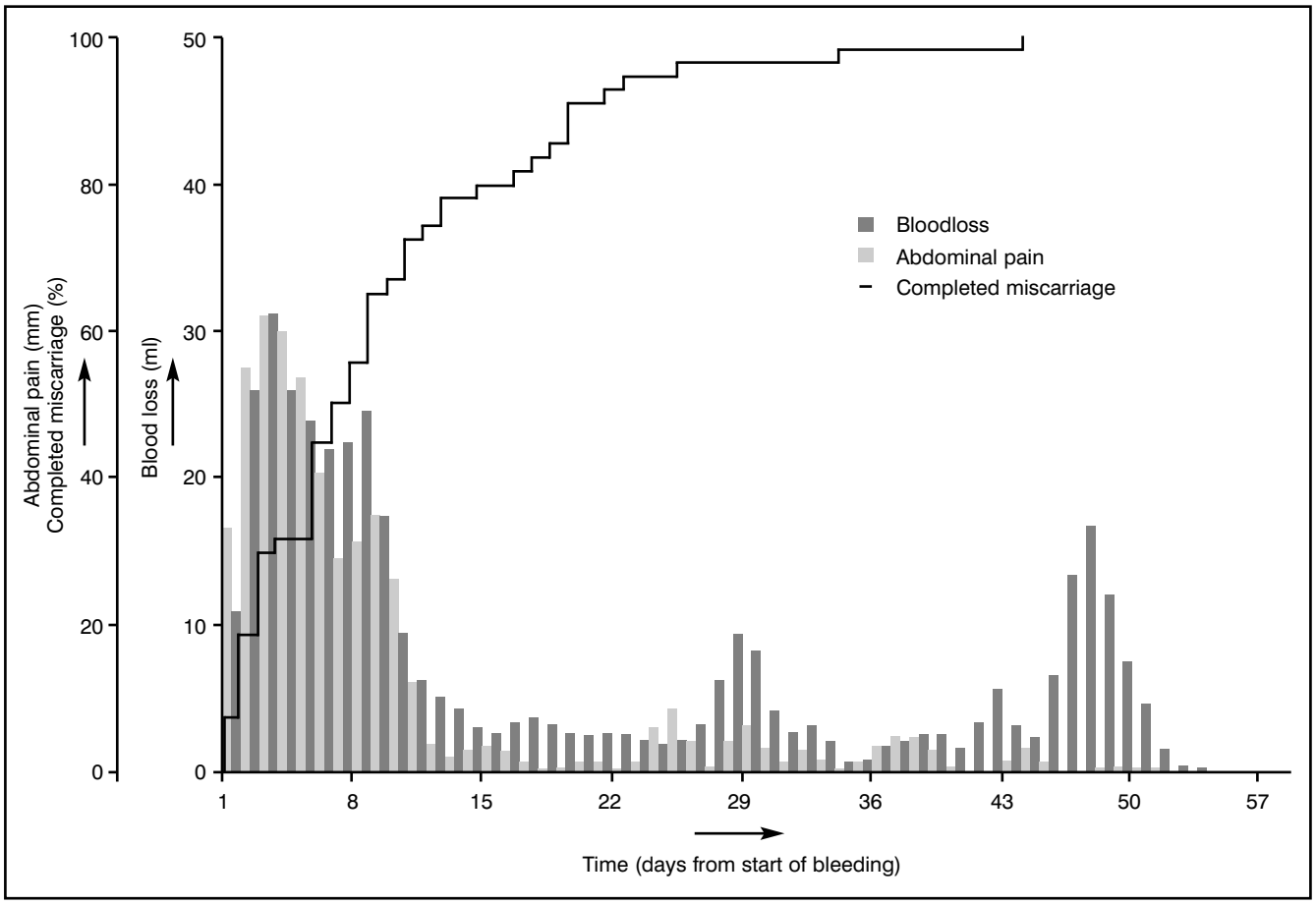

Figure 2. Median daily vaginal blood loss and abdominal pain of expectantly managed women with a completed miscarriage.

because these women could not report the moment of spontaneous loss of pregnancy. Time until event (i.e. completed miscarriage or curettage) was not different for women who completed the diary and those who did not.

Figure 2 describes the median daily amount of bleeding (in ml) and the severity of pain of women who experienced a completed miscarriage. Data are synchronised for the first day of vaginal bleeding and are only included during the period of bleeding. In addition, the cumulative proportion of women experiencing a completed miscarriage is represented in this figure. Median blood loss and pain were heaviest on the third day of vaginal bleeding and steeply decreased after 8 days to a much lower level characterised by slight bleeding and spotting (5–2 ml/day) from day 12 onward. Of the described group, 50% miscarried completely during the first 8 days.

Discussion

In a group of 188 expectantly managed women with a nonviable pregnancy or incomplete miscarriage, about half (n = 95; 51%) of the women experienced a completed miscarriage. Of the women with bleeding at inclusion this was the case in 52%, of the women without bleeding in 46%. If bleeding occurred, further increase of bleeding prompted completed miscarriage. No other characteristics were predictive for a quick spontaneous loss of pregnancy. The daily amount of bleeding and pain on each day were most pronounced during the first 8 days of the vaginal bleeding and steeply declined after this period. The group of women who had no bleeding at inclusion, but were diagnosed at ultrasound examinations, was too small for regression analysis. At inclusion 215 women had already had a complete miscarriage. If we combine these with the cases of completed miscarriage during expectant management the success rate

would have been 77% (310/403).

The possibility of identifying women for whom expectant management is feasible has previously been explored by Nielsen *et al*.[14] In an randomised, controlled trial they compared expectant and surgical management in women with incomplete miscarriages and developed a logistical model including serum human chorionic gonadotrophin, progesterone levels and intra-uterine volume. In our study, gestational age or intra-uterine volume was not significantly different in women with or without a completed miscarriage during expectant management. Our study differed from Nielsen's on two crucial points. Firstly, we included all women with a miscarriage as they presented in the regular practice, while Nielsen's study restricted the inclusion to women with incomplete miscarriages. Secondly, the duration of expectant management was much longer in the present study, while Nielsen's waited for only 3 days.

Our data were based entirely on self-reported symptoms and, as a result, the study has some limitations. We used the patients' own assessment of vaginal bleeding as substantiated by the pictorial charts. The reliability of our findings therefore strongly depends on the accuracy of this registration. The reliability of pictorial charts, has been criticised in a previous paper studying their use in the evaluation of menorrhagia.[15] However, in our opinion pictorial charts are an easy and patient-friendly method of comparing vaginal bleeding patterns in and among patients and therefore we accepted the limitations of the method.

It is possible that the subjective experience of pain and bleeding varies between randomised and non-randomised women. Although the numbers were too small for a statistical comparison we did not find substantially higher levels of pain or bleeding among randomised or non-randomised women.

We allowed women to use tampons and towels of their own choice, without providing one standard type of towel and tampon, which earlier had been shown to be useful.[16] Following this approach, we may have underestimated the total amount of blood loss, as had been observed by others.[17]

Our data illustrate the natural course of completed miscarriage during expectant management, as registered and experienced by patients themselves. The graphical representation of vaginal bleeding and pain may be useful in counselling women about the expectant management of miscarriage, and in reaching a well-informed treatment choice.

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