Bleeding in the first trimester of pregnancy
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CHAPTER 1
General introduction

Introduction

Two out of every ten pregnant women experience an episode of vaginal bleeding during the first trimester. In 50% of these women the pregnancy is viable and the bleeding will stop after a certain period of time without further consequences. In the remaining 50% of women, however, the pregnancy is non-viable and the bleeding period heralds a miscarriage. \(^1\) In most countries surgical evacuation is the preferred treatment for miscarriages. \(^2\) Some observational studies and one randomised trial have also described expectant management as a realistic alternative to surgical evacuation. \(^3-5\)

The guideline on imminent miscarriage of the Dutch College of General Practitioners (first issued in 1989, revised in 1997) advises women in the Netherlands to first await the natural course of the bleeding, and to withhold from further diagnostic investigations, i.e. ultrasonography. \(^6,7\) After one week, if the diagnosis is still unclear, these women are referred for an ultrasonographic assessment. In case of a non-viable pregnancy, the guideline then propagates expectant management. The restrictive use of ultrasonography is based on the premise that in either case, whether the bleeding results from a viable or a non-viable pregnancy, the ultrasonographic findings will have no therapeutic consequences whatsoever.

The first Dutch guideline was based on a study, initiated by the Dutch College of General practitioners in the late 1950s, which resulted in two theses published in 1964 and 1966. \(^6,8,9\) This study was performed in a primary care setting and included more than 1500 women with a miscarriage. The diagnosis was solely based on patient histories. Spontaneous expulsion of products of conception was verified by the GPs' inspection of any lost tissue. In the absence of both a urinary pregnancy test and transvaginal ultrasonography, currently the gold standard for establishing the cause of first-trimester bleeding, considerable diagnostic errors were probably made. Clearly, a guideline to be used today cannot validly be based on the evidence from this study.

In the revised version of the guideline, the results of a recently performed randomised controlled trial were incorporated. \(^7\) This hospital-based trial compared expectant management with surgical evacuation in women with ultrasonographically confirmed miscarriages, and suggested the outcomes to be similar. \(^5\) However, the duration of expectant management in that study was restricted to only three days, while the majority of included women had an incomplete miscarriage. Three days of follow-up cannot seriously be
regarded as 'true expectant therapy', neither from a practical nor from an empirical point of view. The over-representation of women with an incomplete miscarriage, thus excluding the vast majority of women with a non-viable pregnancy, also limits the generalisability of these findings from this study for every-day practice.

In contrast to the Dutch GP guideline, the Dutch Society of Obstetrics and Gynaecology advises a sonographic assessment in all women with first-trimester bleeding, enabling a distinction between viable and non-viable pregnancies. In case of a non-viable pregnancy the advice is 'to prevent prolonged bleeding and infection'. Consequently, curettage is often the preferred treatment in these cases.

Both recommendations are neither evidence-based nor representative for current practice. In fact, a recent study showed no adherence of GPs to the guideline in 56% of cases of threatened miscarriage. First-trimester bleeding, being a problem which affects two out of every ten pregnant women, needs management based on scientific evidence. The combination of unsatisfactory evidence from the literature, the high incidence of this clinical problem, and the conflicting recommendations with respect to its management, were the reasons to start the study presented in this thesis.

The aim of the present study

The aim of the study presented in this thesis is to answer the following questions:

1. What is the value of patient's medical history and physical examination in diagnosing the underlying cause of first-trimester bleeding during pregnancy?
2. Which treatment is preferable in the management of first-trimester miscarriage: expectant management or surgical evacuation?
3. Are there any differences in health-related quality of life between expectant or surgical management in the treatment of miscarriages?
4. Which treatment do women prefer in first-trimester miscarriage?
5. What is the natural course of a first-trimester miscarriage?

Terminology

We have used the term miscarriage instead of spontaneous abortion. First-trimester miscarriage is defined as 'a miscarriage occurring before the gestational age of 16 completed weeks following the first day of the last menstrual period'.
General introduction

Study design

We performed an observational study (to answer questions 1 and 5) as well as an intervention study (questions 2 to 4). In order to cover the whole range of women with first-trimester bleeding we not only enrolled women attending the outpatient clinics or the emergency departments because of pregnancy complications in the first trimester, but we also asked general practitioners and midwives to refer all consecutive women with first-trimester vaginal bleeding for an ultrasound assessment. All GPs/midwives working in the health district covered by two Amsterdam hospitals, the Academic Medical Center and the Onze Lieve Vrouwe Gasthuis, were asked to participate in the study during a specially organised seminar about first-trimester bleeding during pregnancy. The GPs/midwives were visited by the researcher and received information about the study. Ultimately 74 GPs and 8 midwives agreed to participate and included one or more patients in the study. During the consultations of eligible patients, the participating GPs/midwives used structured questionnaires and registered signs and symptoms and findings of gynaecological examinations. Referral of eligible patients was facilitated by direct telephone access to the researchers. A special daily ultrasonographic facility was created, enabling referral to our unit within two days. To inform the participating GPs/midwives about our project, and to remind them to send in patients, a newsletter was sent out every four months.

The flow of participants is presented in the Figure below. Between April 1998 and September 2000 we enrolled 1101 women in the study. For the observational part of the study we registered signs, symptoms and the final diagnosis of all women. Women with a confirmed diagnosis of a viable preg-

![Flow of participants](image)

**Figure 1.1.** Flow of participants.
nancy were referred back to their GP or midwife. These women received a questionnaire at term to check the outcome of the index pregnancy. Women with a complete miscarriage, an ectopic pregnancy, or a molar pregnancy, were managed according to the hospital protocol. Women with a non-viable pregnancy or an incomplete miscarriage were asked to participate in the intervention study. Consenting women took part in the randomised controlled trial comparing expectant and surgical management. Women who refused to be randomised were managed according to their own treatment choice, and were asked to participate in the observational study.

Outline of this thesis

Chapter 2 gives an overview of the history of the management of first-trimester miscarriage.

Chapter 3 analyses the diagnostic accuracy of the patient’s medical history and physical examination in predicting the underlying cause of the first-trimester vaginal bleeding. In addition, we analysed the accuracy of the GPs/midwives in making a provisional diagnosis based on their clinical impression before referral (question 1).

Chapter 4 and 5 describe a randomised controlled trial comparing expectant management and surgical evacuation in terms of safety, complications and success rates (chapter 4). Health-Related Quality of Life issues are analysed in chapter 5. The outcomes of the trial are compared with those of women treated according to their own preference (question 2 and 3).

Chapter 6 provides information on treatment preferences for surgical evacuation or expectant management in women with first-trimester bleeding or a non-viable pregnancy (question 4).

Chapter 7 describes the natural course of miscarriages (question 5).

Chapter 8 discusses the results of the study. Implications for guidelines and for future research are indicated.

Chapter 9: Summary, samenvatting.

References


