



INSTITUTE OF OBSTETRICIANS
& GYNAECOLOGISTS
ROYAL COLLEGE OF PHYSICIANS OF IRELAND

ULTRASOUND DIAGNOSIS OF EARLY PREGNANCY MISCARRIAGE

CLINICAL PRACTICE GUIDELINE

**Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland
and**

Directorate of Quality and Clinical Care, Health Service Executive

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1.0 Purpose and Scope

The purpose of this guideline is to assist all healthcare professionals in the management of first trimester spontaneous miscarriage.

2.0 Background and Introduction

Spontaneous miscarriage is the commonest complication of pregnancy. It occurs in up to 20% of clinical pregnancies equating to approximately 15,000 miscarriages per annum in Ireland.

This guideline provides information relating to the diagnosis of early pregnancy loss defined as a loss, within the first 13 weeks of pregnancy. It specifically addresses the ultrasound diagnosis of miscarriage. This guideline is intended to be primarily used by health personnel working in the area of early pregnancy which includes obstetricians, midwife sonographers, radiographers, radiologists and general practitioners. All of the groups should be familiar with the various diagnostic tools necessary to help delineate a viable from a non-viable pregnancy.

3.0 Methodology

A search was conducted of current international guidelines in the UK, USA, Canada, Hong Kong, New Zealand / Australia. In addition, a review of literature through Medline and the Cochrane Library was carried out. The search words used were miscarriage, spontaneous abortion, ultrasound and diagnosis.

Acknowledgements:

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4.0 Clinical Guideline

4.1 Terminology

The recommended medical term for pregnancy loss less than 24 weeks should be “miscarriage”. The inadvertent use by healthcare professionals of inappropriate terms such as ‘pregnancy failure’ or ‘incompetent cervix’ may, in some circumstances, contribute to a woman’s negative self perceptions and aggravate any sense of failure, guilt and insecurity related to the miscarriage. The terms abortion, anembryonic pregnancy and blighted ovum should be abandoned.

4.2 Ultrasound and Embryo Development

It is important that all relevant health personnel are familiar with the chronological ultrasound features of early pregnancy. The first ultrasound evidence of pregnancy is the gestational sac within the thickened decidua. This sac which represents the chorionic cavity is a small anechoic fluid collection surrounded by an echogenic ring that represents trophoblasts and decidual reaction. It is possible to identify the sac with transvaginal ultrasound by 4 weeks and 2 days when the mean diameter is 2-3 mm.

The yolk sac is the first structure often seen within the gestational sac and it confirms an intrauterine pregnancy. The yolk sac is first seen by transvaginal ultrasound when the mean gestational sac diameter is ≥ 5 mm, and should always be visualised when the mean gestational sac diameter is >7 mm. The amnion is a thin, rounded membrane surrounding the embryo and is completely enveloped by the thick echogenic chorion. The yolk sac is situated between the amnion and the chorion. The amnion is thin and difficult to visualise and is best seen when perpendicular to the ultrasound beam. The amnion grows rapidly during pregnancy and fuses with the chorion between 12 and 16 weeks gestation. The embryo can be identified by transvaginal ultrasound when as small as 1–2 mm in length. At 5–7 weeks gestation both the embryo and gestational sac should grow at approximately 1 mm per day. Cardiac activity immediately adjacent to the yolk sac indicates a live embryo but may not be seen until the embryo measures 5 mm. From 5 ½ - 6 ½ weeks gestation a fetal heart rate of less than 100 beats per minute is normal. During the following 3 weeks there is a rapid increase up to 180 beats per minute.

Ultrasound Features of Early Pregnancy

Gestational Age	Anatomical Landmarks	Comments
4 weeks 2 days	Eccentrically placed gestational sac with MGSD 2-3mm	May represent pseudosac 10-20% of ectopic pregnancies have an intrauterine pseudo GS
5 th week	MGSD 5mm Yolk sac (YS) Size varies from 3-8mm (average 5mm)	Confirms IUP Large YS > 10mm – poor prognosis
6 th week	MGSD 10mm Embryo 2-3mm Cardiac activity (remove CA)	Confirms IUP Confirms viability (97% of embryos with cardiac activity have a normal outcome)
7 th week	MGSD 20mm Head and trunk distinguishable	Poor prognosis if MGSD >20mm and no yolk sac or embryo
8 th week	MGSD 25mm Head size = YS Limb buds Midgut herniation Rhombencephalon	
9 th week	Choroid plexus, spine, limbs	
10 weeks	Cardiac chambers, Stomach, bladder, Skeletal ossification	
11 weeks	Gut returning Most structures identified	

GSD Gestational Sac Diameter

DDS Double Decidual Sign

IUP Intrauterine Pregnanc

4.3 Ultrasound Determination of Pregnancy Loss

If on transvaginal ultrasound, the mean gestational sac diameter is less than 20mm with no yolk sac or embryo, or if the fetal pole is less than 8mm with no cardiac activity identified within 30 seconds, then the diagnosis of pregnancy of uncertain viability may be made. A repeat ultrasound examination should be arranged after 7-10 days to clarify the diagnosis.

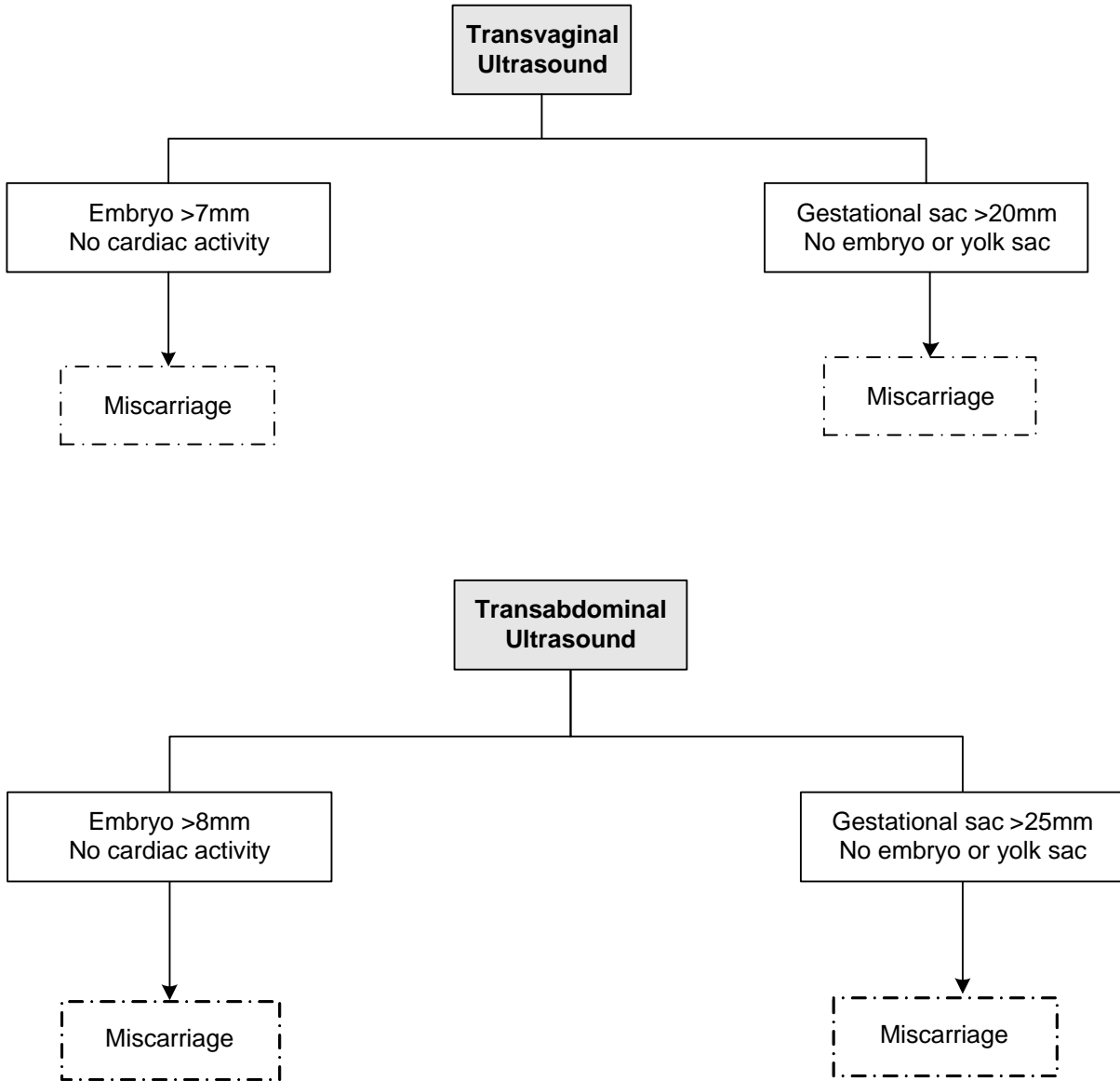
An ultrasound diagnosis of fetal demise may be made when there is no fetal heart in a fetus with fetal pole >7mm when using transvaginal ultrasound. A diagnosis of pregnancy loss may also be made if the mean gestational sac diameter exceeds 20 mm in the absence of a yolk sac or embryo. Particular care should be taken to scan all of the sac in a longitudinal and vertical plain. The mean sac diameter should be measured in 3 diameters and averaged. The area of the fetal heart should be observed for a prolonged period of at least 30 seconds to ensure that there is no cardiac activity. The use of transvaginal ultrasound should be encouraged as better visualisation is nearly always possible.

Different cutoffs for diagnosing miscarriage apply when using transabdominal ultrasound. If transvaginal ultrasound is not available or not acceptable to a woman, transabdominal ultrasound criteria for fetal demise can be made when there is no fetal heart in an embryo measuring >8 mm. Similarly, if the mean gestational sac diameter is > 25 mm in the absence of a yolk sac or embryo, a diagnosis of fetal demise can be made using transabdominal ultrasound. If there is no sign of either intra or extra-uterine pregnancy or retained products in a woman with a positive pregnancy test, this should be described as a pregnancy of unknown location.

The CRL does not include the yolk sac. If the mean gestational sac is smaller than expected, the possibility of incorrect dates should always be considered, especially when there is no pain or vaginal bleeding. In these circumstances, a repeat transvaginal scan should be arranged after 7-10 days.

It is not essential for a second sonographer to confirm fetal demise, provided that the first sonographer is appropriately qualified and has adhered to the guidelines. It may be distressing for the woman to undergo another unnecessary transvaginal assessment. It should, however, be emphasised that if there is any doubt in the diagnosis, a second opinion should be sought. Also, if a second opinion may benefit a woman psychologically, it should be facilitated. It is important to listen carefully to the views of the woman, particularly in circumstances where she has had a prior pregnancy.

Ultrasound Determination of Nonviable Pregnancy



4.4 Prediction of Early Pregnancy Failure

There are certain ultrasound features which predict but are not diagnostic of early pregnancy failure. These include a fetal heart rate of less than 85 beats per minute at greater than 7 weeks gestation, a small sac size relative to the embryo (difference of less than 5 mm between gestation sac and crown rump length), enlarged or abnormally shaped yolk sac and sub-chorionic haematoma. The latter leads to a pregnancy loss rate of about 9%. This risk would appear to be increased in women older than 35 years and in pregnancies less than 8 weeks gestation.

Any clinical interventions, however, must be based on diagnostic and not predictive features.

4.5 Common Pitfalls with Ultrasound in Early Pregnancy

Exercise extreme caution with regard to last menstrual period (LMP) on history taking. Up to 50% of women are uncertain of their dates, or have an irregular cycle, or have just stopped the oral contraceptive pill (OCP), or are lactating or did not have a normal last period. Enquire when the women had her first positive pregnancy test (which may be positive 3 days before the missed period).

Visualise all of the uterus. Pan the uterus in sagittal, and then rotate the probe 90 degrees to visualise from cervix to fundus. Failure to visualise all of the uterus will result in missing gestational sacs in multiple pregnancies.

Neglecting to scan the adnexae will result in missing heterotopic pregnancies and ovarian masses which may require surgery.

Avoid labelling subchorionic bleeds as additional gestational sacs. Do not tell a woman that she has a twin pregnancy with one empty sac unless you are very experienced in ultrasound.

Pseudosacs. Exercise caution in labelling intrauterine sac-like structures as gestational sacs unless they have contents i.e. yolk sac or fetus. Pseudosacs will follow the uterine cavity and are more elliptical, while gestational sacs are fundal and eccentrically placed.

Fibroid Uterus. The fundus of a fibroid uterus may not be included in the scan field at TVS. Both TVS and abdominal scans are needed in these women to avoid missing gestational sacs.

5.0 Organisation of Early Pregnancy Unit

All maternity units in Ireland should provide a dedicated outpatient early pregnancy assessment unit (EPAU). The cost-benefits of the EPAU are well established; 40% of patients will completely avoid surgery and hospital stay is shortened. An EPAU should be in a dedicated area and with surroundings that are comfortable and allow for appropriate privacy and dignity. Early pregnancy units should be open during working hours, but as a minimum should work for approximately 2 hours each morning. There should be at least one appropriately furnished room for the ultrasound examination.

5.1 Referral Guidelines

Women who should be assessed at an early pregnancy unit include:

Those with a history of a positive pregnancy test and:

- Vaginal bleeding and / or abdominal pain
- Previous ectopic pregnancy
- Previous tubal surgery
- Previous miscarriage
- Intrauterine contraceptive device in situ
- Persistent bleeding post evacuation of the retained products of conception (ERPC) where there is a suspicion of problems
- Other clinical indications as agreed in each hospital

5.2 Equipment

The ultrasound machines should be of good quality and should be regularly maintained, serviced and checked for safety. Records of maintenance and service should be easily discoverable. Urine pregnancy testing and β -HCG estimation should be available. In addition, access to laboratory facilities for Rhesus antibody testing and full blood counts should be available.

The decontamination of reusable invasive medical devices including transvaginal ultrasound probes should be compliant with the HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices available here:

http://www.hse.ie/eng/services/Publications/services/Hospitals/Code_of_Practice_for_Decontamination_of_Reusable_Invasive_Medical_Devices_.html

5.3 Staffing

Ideally, the EPAU should be staffed by a receptionist / secretary and a midwife sonographer / radiographer, supported by appropriately trained medical personnel. All staff should use clear and consistent language and convey consistent information. This communication should always be carried out in a caring and sympathetic fashion.

Sonographers should be formally trained in both transabdominal and transvaginal ultrasound as both methods are complementary.

5.4 Reporting

The sonographer should produce reports using standardised documentation.

This includes:

- Presence or absence of an intrauterine gestational sac(s)
- Number of sacs and mean gestational sac size
- Presence of haematoma
- Yolk sac
- Fetal Pole
- Crown Rump Length (CRL) with expected gestation
- Fetal heart pulsation present or absent
- Extrauterine observation to include ovaries, adnexal mass / fluid in the Pouch of Douglas

Standardised information leaflets, referral and transfer of care (discharge) letters should also be readily available, utilised and regularly reviewed. Each unit should produce quarterly statistics of the number of women attending the EPAU and the clinical outcomes. Where possible, patients should be diverted to early pregnancy units instead of presenting out-of-hours to maternity units. Systems should be in place to inform local general practitioners (GPs) of the early pregnancy service and ensure easy access. All units should provide training to highlight the importance of accurate early pregnancy diagnosis. Evidence that this has taken place should be readily available to outside reviewers.

6.0 Support for Couples

It is recognised that for many couples repeated testing (either ultrasound or blood) and uncertainty may lead to anxiety and occasional depression. In a small percentage, the loss of an early pregnancy can cause similar suffering to that of a late stillbirth. There is a need for consistency of information and language with clear communication in easy-to-understand English. It is also well recognised that in times of stress and when receiving bad news, couples rarely take in all of the information. Written information sheets for the following scenarios should be readily available.

1. What is a threatened miscarriage
2. What is an inconclusive scan result
3. Pregnancy loss – what happens next
4. Conservative management of miscarriage
5. Medical management of miscarriage
6. Surgical management of miscarriage
7. What you need to know after miscarriage

A thorough discussion and provision of written information may suffice. If the general practitioner has received the appropriate communication follow-up appointments may be more appropriately done in a primary care setting. Some hospitals may choose to review couples at a designated Miscarriage Clinic if resources allow. All women should be given contact numbers with the appropriate leaflets, which contain contact telephone numbers should they require further support and advice. In individual circumstances formal counselling may be required.

All women with a history of recurrent miscarriage should be offered a review in the gynaecological outpatients (or the Miscarriage Clinic) following discharge. A recurrent miscarriage is defined as three or more consecutive clinical miscarriages.

7.0 References and Recommended Reading

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8.0 Key Performance Indicators

- No. of attendances in EPAU: new and review
- No. of miscarriages diagnosed
- No. of ectopics diagnosed
- No. of written complaints and CIS forms in first trimester.
- No. of errors in ultrasound diagnosis

9.0 Useful Resources

- Miscarriage Association of Ireland
www.miscarriage.ie
info@miscarriage.ie
- Association of Early Pregnancy Units
<http://www.earlypregnancy.org.uk/default.asp>

10.0 Qualifying Statement

These guidelines have been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. Clinical material offered in this guideline does not replace or remove clinical judgment or the professional care and duty necessary for each pregnant woman. Clinical care carried out in accordance with this guideline should be provided within the context of locally available resources and expertise.

This Guideline does not address all elements of standard practice and assumes that individual clinicians are responsible to:

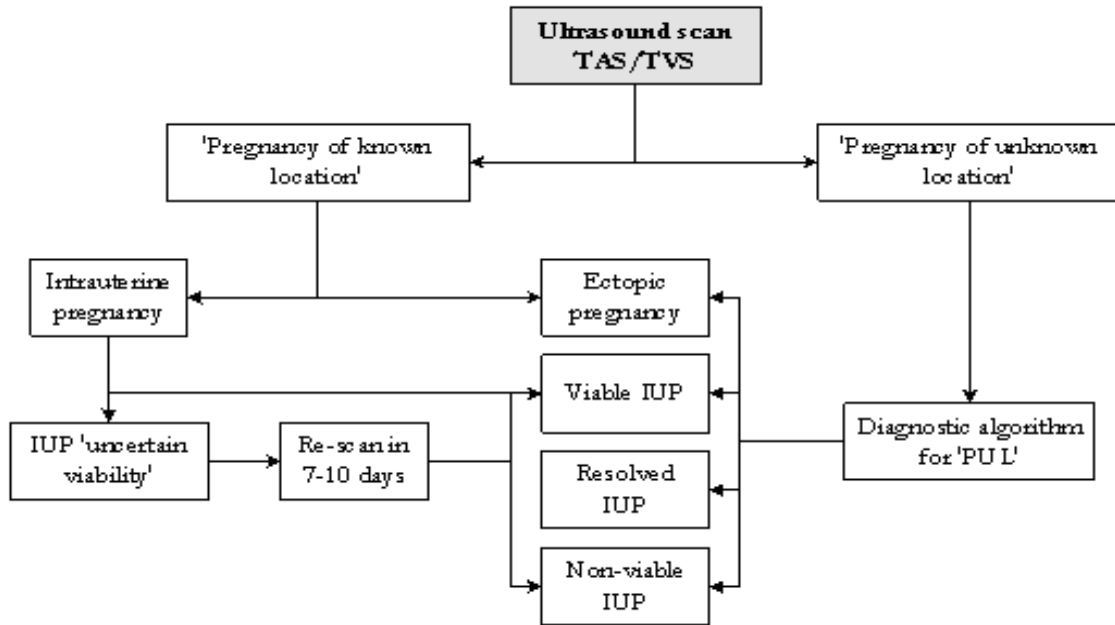
- Discuss care with women in an environment that is appropriate and which enables respectful confidential discussion.
- Advise women of their choices and ensure informed consent is obtained.
- Meet all legislative requirements and maintain standards of professional conduct.
- Apply standard precautions and additional precautions as necessary, when delivering care.
- Document all care in accordance with local and mandatory requirements.

11.0 Implementation Strategy

- Distribution of guideline to all members of the Institute and to all maternity units.
- Implementation through HSE Obstetric and Gynaecological programme local implementation boards.
- Distribution to other interested parties, including general practitioners, regulatory and educational training bodies

Appendix One

Basic Diagnostic Algorithm for Early Pregnancy Loss



IUP: Intrauterine pregnancy
 PUL: Pregnancy of unknown location
 TAS: Transabdominal scan

Appendix Two

A 2.1 Patient Information Leaflet

What is a Threatened Miscarriage?

A threatened miscarriage is a pregnancy where vaginal bleeding has taken place but an ultrasound has shown a healthy fetus and fetal heartbeat. The bleeding can be very varied and can occur at any time after a missed period. It can range from being a smear of pink, brown or red loss on the toilet paper to heavy vaginal bleeding similar or even heavier than a period. The diagnosis of a threatened miscarriage is made when you attend for an ultrasound scan and as long as you are at least 6 weeks pregnant the ultrasound should be able to visualise your tiny baby and show a healthy heartbeat. It may be necessary to demonstrate by performing an internal vaginal scan.

Sometimes the scan may show up a small haematoma (blood clot) around the pregnancy sac but very often nothing abnormal is seen and it is difficult to explain why the bleeding has occurred. The bleeding may have come from the implantation site which is when the placenta of your baby burrows itself into the lining of the womb. This process may cause some bleeding. If we can see a baby's heartbeat on ultrasound it is very likely that your pregnancy will continue with success rates exceeding 95%.

Follow-Up

If there is a collection of blood around the pregnancy sac or the bleeding continues, it may be appropriate to repeat an ultrasound scan in 1-2 weeks. In any case the heartbeat will be checked at your first booking visit in the hospital. If the bleeding settles down there is probably no need for a further scan unless you have further anxieties. Traditionally bed rest has been advised for mothers with threatened miscarriage but all the evidence would suggest that this does not prevent miscarriage. It may help some patients psychologically to rest in bed but it is not necessary. Unfortunately there is no specific treatment to stop the bleeding and if you do adopt bed rest there is the possibility that on standing up bleeding may become heavier due to pooling of blood in the vagina that results from lying down.

With regard to work, our advice will depend on the nature of work, your history and the nature of bleeding, but it is probably prudent to stop work if you are having significant bleeding. If you have further heavy bright red bleeding, particularly if this is associated with crampy abdominal pains, it is appropriate to get in touch with the early pregnancy assessment unit (EPAU) again for advice. There is no evidence that having intercourse at any stage in pregnancy causes miscarriage or pregnancy loss though again it seems sensible to avoid intercourse until the bleeding has completely stopped. If you are Rhesus Negative you probably do not need Anti-D immunoglobulin if you are less than 12 weeks pregnant unless you have experienced very heavy bleeding.

We hope you have found this information leaflet of some benefit. We are constantly modifying information leaflets and if you have any feedback on the above please do not hesitate to contact us.

A 2.2 Patient Information Leaflet

What Does an Inconclusive Scan Result Mean?

Following your visit today, unfortunately it has not been possible to confirm whether your pregnancy is going to continue or not. We fully appreciate that it can be difficult to take in all the facts when you are anxious especially in the hospital environment. There are three main reasons for uncertainty:

- 1) It is possible that we have not seen a fetus and fetal heartbeat because you are too early in the pregnancy. A repeat scan in 7 to 10 days should clarify whether the pregnancy is healthy or not.
- 2) It is also possible that the pregnancy is not growing as it should and the bleeding may be a sign of an impending miscarriage. Similarly a repeat scan will clarify the situation.
- 3) There is also the outside possibility that the pregnancy is outside the womb. This is unlikely but we cannot exclude it at this stage as it is too early to diagnose. If we suspect that this may be the case we may suggest doing a blood test called β eta HCG (human chorionic gonadatrophin). It is a hormone produced by the placental tissue and its levels roughly double every two days in a normally growing early pregnancy. We may also repeat the scan in a few days.

It is quite possible that you will have further bleeding if you have bled already and as long as it is not too heavy you may stay at home and wait for the follow-up scan in 7 – 10 days which should clarify the situation for you. However, if you develop sharp pain or are aware of increasing crampy abdominal pains, it is reasonable to take paracetamol tablets. If the pain becomes too severe or the bleeding becomes too heavy, or indeed if you are anxious about your situation, please do not hesitate to get in touch. *The contact numbers are as follows:*

A 2.3 Patient Information Leaflet

Miscarriage – What Happens Next?

The loss of a pregnancy can be a sad and distressing experience but it is not uncommon. It is estimated that up to 20% of pregnancies ends in a miscarriage. This information leaflet is designed to help you cope with the loss of your pregnancy at this difficult time. We have provided answers to some of the questions you are likely to have.

What happens next?

This depends on what type of miscarriage you have had. It is quite possible that the doctor/sonographer has diagnosed that your miscarriage is complete which means that most of the pregnancy has passed and that there is no need for further treatment. You may still experience blood loss which can go on for up to two weeks.

If your miscarriage has been diagnosed as being a missed or incomplete that means that there is some pregnancy tissue retained within the womb. Depending on your own individual circumstances there are some incomplete miscarriages which are best treated surgically with a D&C and others that may be treated either with no treatment or occasionally using tablets to expel the remaining pregnancy tissue. You may be advised as to which approach is best for your situation. Often it is appropriate to discuss the different approaches. The three ways of dealing with a pregnancy that is not progressing are as follows:

- 1. Wait and see approach (leaving things to nature).** In the past an operation was nearly always performed in cases of miscarriage, however, with the use of ultrasound we can reasonably confidently predict those miscarriages that do not require any treatment. If you have had no bleeding it may take up to 3 weeks for you to start miscarrying. The bleeding may be heavier than a normal period and you may experience strong period like pains in your lower tummy as the womb contracts in an attempt to expel the pregnancy tissue. If the bleeding is very heavy, the pain very severe or you feel unwell you should attend the hospital for review. In a small number of cases an operation may still be necessary should there be some tissue left within the womb or if the bleeding becomes too heavy.
- 2. Medical approach.** Medicines may be used to start a miscarriage if you prefer not to wait. Misoprostol is a medicine that you can take by mouth (or occasionally by placing the tablets in the vagina). You may need to take a few doses before bleeding commences (as described above). The advantages of this approach is that you avoid a hospital admission, an anaesthetic and a surgical procedure all of which carry a small risk. In about 10% of cases an operation may still be necessary should there be some tissue left within the womb or if the bleeding becomes too heavy.
- 3. Surgery (D and C).** D and C means dilation and curettage. We dilate the cervix (neck of the womb) and by using either plastic or metal instruments we remove the pregnancy tissue from the womb. It is correctly called an ERPC (evacuation of retained products of pregnancy). This is done under general anaesthesia through the vagina and you will not have any cuts/stitches. Like with all operations there are small risks such as infection or injury to the womb and cervix. The advantage of this approach is that it clears out the womb quicker than the above approaches.

Generally your chances of having a successful pregnancy in the future are just as good with whichever approach you choose. Following any of the above approaches you may have a period like loss for up to 14 days which is quite normal and should gradually diminish with time.

A 2.4 Miscarriage

Frequently Asked Questions

Why did I miscarry?

Approximately 1 in 5 pregnancies ends in a miscarriage. It is often very difficult to give a definitive answer as to why you had a miscarriage. Many studies have shown that approximately 2 out of every 3 miscarriages are explained by a chromosome problem. This means that when the egg was fertilised by the sperm the process of fusing together was somewhat faulty and in many cases gave rise to one extra chromosome, though in some cases a baby with one less chromosome. It is normal to have 46 chromosomes, 23 from the mother and 23 from the father. Where there is a problem at conception this may give rise to a total of 45 or 47 chromosomes. Very often these chromosome problems are not compatible with life and nature will determine that these pregnancies do not progress and they will then become a miscarriage. Occasionally you may have a miscarriage because of an infection associated with a high temperature / fever, though this is unusual. Occasionally there may be a problem with the cervix, the back of the neck of the womb, and/or uterus (womb). An irregularly shaped womb or the presence of fibroids encroaching into the cavity of the womb are associated with a higher chance of miscarriage. Unfortunately in many cases we are unable to give a definitive cause.

Will this happen again?

If you have had one miscarriage it is extremely likely you will be able to go on and have a normal pregnancy. It is important to say, as mentioned above, that there is up to a 1 in 4 chance of a miscarriage occurring in another pregnancy.

Even after several miscarriages there is a good chance of a successful pregnancy.

Is there anything I can do to prevent a miscarriage?

In truth the answer to this question is almost certainly no. If we assume that 2 out of every 3 miscarriages occur because of a chromosome problem then no amount of rest or medication will make any difference to a pregnancy that might already be a little faulty. There is very little evidence that bed rest reduces the chance of a miscarriage. It does seem sensible to be careful and avoid heavy physical exercise.

How long should I wait before trying again?

There is no perfect time to aim for another pregnancy. This may depend on many different circumstances such as your age, co-existing health problems etc. It is certainly wise to wait until you

have had at least one normal period, which usually occurs about 3-6 weeks after a miscarriage. Some people would advise waiting until you have had a few periods to allow your cycle to go back to being regular, if indeed they were regular before.

Do I need a follow-up appointment in the hospital?

In general most hospitals do not have specific clinics for early miscarriage follow-up. It is probably more appropriate for you to see your family doctor who you will probably know better and who can help you through this difficult time. It may help to talk things over with your partner, friends and other members of the family. It is quite normal to be tearful and feel low from time to time but, if you feel that you are getting depressed and unable to cope it is important to alert your family doctor, or indeed the bereavement counselling service at your local hospital.