Royal College of Obstetricians and Gynaecologists

Setting standards to improve women's health

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PLACENTA PRAEVIA AND PLACENTA PRAEVIA ACCRETA: DIAGNOSIS AND MANAGEMENT

This is the second edition of this guideline. The original edition, entitled *Placenta Praevia: Diagnosis and Management,* was published in January 2001.

1. Aim and introduction

Maternal and fetal morbidity and mortality from placenta praevia are considerable[1–9] and are associated with high demands on health resources. With the rising incidence of caesarean section operations combined with increasing maternal age, the numbers of cases of placenta praevia and its complications will continue to increase,[7,8,10–14] so updating the guideline for this condition is timely. The purpose of this guideline is to address the methods of diagnosing placenta praevia and placenta praevia accreta and their clinical management in both the antenatal and peripartum periods.

Placenta praevia exists when the placenta is inserted wholly or in part into the lower segment of the uterus. If it lies over the cervical os, it is considered a major praevia, if not, then minor praevia exists. This diagnosis has evolved from the original clinical I–IV grading system and is determined by ultrasonic imaging techniques relating the leading edge of the placenta to the cervical os. Management decisions for women with placenta praevia are based on clinical and ultrasound findings.

2. Identification and assessment of evidence

To update this guideline, the Cochrane Library 2004, Issue 2, and Embase and Medline were searched for relevant randomised controlled trials (RCT), systematic reviews and meta-analyses relating to placenta praevia from 2000 to 2004 (the search for the previous guidelines was up to April 2000). The last search was performed in May 2004. The searches were performed using the MeSH headings 'placenta praevia' and 'placenta accreta'.

The majority of publications on placenta praevia are retrospective studies, case reports and reviews, with a paucity of prospective studies and randomised trials or meta-analyses. Since the last guideline was written, there have been over 80 case reports featuring over 130 women with varying degrees of morbidly adherent placentas. These represent wide international experience and concern with this condition.

In addition to the above, during the peer review process the Confidential Enquiry into Maternal Deaths in the UK was published and, as it made important points regarding placenta praevia, this information has been included.

3. Screening and diagnosis

While clinical acumen remains vitally important in suspecting and managing placenta praevia, the definitive diagnoses of most low-lying placentas is now achieved with ultrasound imaging. Clinical suspicion should, however, be raised in any woman with vaginal bleeding and a high presenting part or an abnormal lie, irrespective of previous imaging results.

3a. Ultrasound imaging in screening for low-lying placenta and diagnosing placenta praevia

Transvaginal ultrasound is safe in the presence of placenta praevia and is more accurate than transabdominal ultrasound in locating the placenta. **B**

Numerous prospective observational studies have used transvaginal ultrasound scanning (TVS) to diagnose placenta praevia and none has experienced any haemorrhagic complications, thus confirming its safety.[15–19] There is still only one small RCT which exists comparing transabdominal scans (TAS) and TVS for placenta praevia that supports this safety profile.[20]

Evidence level Ib, III

With the lower segment still unformed in the second trimester, screening for future placenta praevia at this time is inevitably associated with false positives, as not all low lying placentas will persist and this is especially so when TAS is employed.[21] TVS can improve on this. In the second trimester, 26–60% of cases of low-lying placenta diagnosed by TAS are reclassified by TVS,[16,18] while in the third trimester TVS changed the TAS diagnosis of placenta praevia in 12.5% of 32 women.[15] Leerentveld *et al.*[17] demonstrated high levels of accuracy of TVS in predicting placenta praevia in 100 women suspected of having a low-lying placenta in the second and third trimester (sensitivity 87.5%, specificity 98.8%, positive predictive value 93.3%, negative predictive value 97.6%, false negative rate 2.33%).

Evidence level IIb

An RCT investigating 38 women demonstrated superior views with TVS compared to TAS, especially in the case of the posteriorly situated placenta and with the additional benefit of reduced scanning time.[20]

Evidence level Ib

Magnetic resonance imaging (MRI) has been reported in the diagnosis of placenta praevia where TAS images have been unsatisfactory.[22] MRI has the advantage of being possible without a full bladder and is an objective test, removing operator error. It is particularly useful in imaging posterior placentas[22] but has not been subject to comparison with TVS and can only be recommended for use in a research context at this stage.

A reasonable antenatal imaging policy is to perform a transvaginal ultrasound scan on all women in whom a low-lying placenta is suspected from their transabdominal anomaly scan (at approximately 20–24 weeks) to reduce the numbers of those for whom follow-up will be needed. **C**

A further transvaginal scan is required for all women whose placenta reaches or overlaps the cervical os at their anomaly scan as follows:

- **Women who bleed should be managed individually according to their needs.**
- **In cases of asymptomatic suspected minor praevia, follow-up imaging can be left until 36 weeks.**
- **In cases with asymptomatic suspected major placenta praevia, a transvaginal ultrasound scan should be performed at 32 weeks, to clarify the diagnosis and allow planning for third-trimester management and delivery.** **C**

Placental migration occurs during the second and third trimesters,[23–25] owing to the development of the lower uterine segment, but it is less likely if the placenta is posterior[26] or if there has been a previous caesarean section.[24] A retrospective review of 714 women with placenta praevia found that, even with a marginal 'praevia' at 20–23 weeks (i.e. the edge of the placenta reached the

Evidence level III

internal cervical os), the chance of persistence of the placenta praevia requiring abdominal delivery was 11% with no uterine scar and 50% with a previous caesarean section.[24] In another study of 55 women with a placenta reaching or overlapping the cervical os at 18–23 weeks diagnosed by transvaginal sonography, only five had placenta praevia at birth and in all these cases the edge of the placenta had overlapped 15 mm over the os.[27] Conversely, although significant migration to allow vaginal delivery is unlikely if the placenta substantially overlaps the internal os (by over 23 mm at 11–14 weeks in one study,[25] by over 25 mm at 20–23 weeks[23] in another and by over 20 mm at 26 weeks in a third study[28]) such migration is still possible, with a 50% chance of resolution if the placenta covers the os at 20 weeks.[24]

Evidence level III

For these reasons, a third-trimester follow-up scan is needed to confirm the diagnosis and plan further care. In the case of asymptomatic women in whom the placental edge has only reached or just overlapped the cervical os at the second trimester scan, with anticipated minor placenta praevia, a scan should be performed at 36 weeks.[29] Those suspected of major placenta praevia require clarification of the diagnosis earlier to enable counselling and careful planning. This should be taken into account in the timing of the follow-up scan, which should be conducted at around 32 weeks. Placentas still diagnosed as complete praevia at this gestation remain so in 90% of cases[24] (see also section 4).

Evidence level IIb

3b. Diagnosis of a morbidly adherent placenta

Antenatal imaging by colour flow Doppler ultrasonography should be performed in women with placenta praevia who are at increased risk of placenta accreta. Where this is not possible locally, such women should be managed as if they have placenta accreta until proven otherwise.

C

Women with placenta praevia are at increased risk of having a morbidly adherent placenta if they have an anterior placenta praevia and have previously been delivered by caesarean section,[7,30–32] especially when there has been a short caesarean to conception interval.[33] Antenatal imaging can help to establish a diagnosis in such cases and techniques used include ultrasound imaging,[34,35] power amplitude ultrasonic angiography,[35] MRI[36] and colour flow Doppler.

Since the previous edition of this guideline, there have been numerous case reports detailing diagnosis of placenta accreta, from as early as the first trimester, using TVS[37] or colour Doppler sonography.[38–40]

Chou *et al.*[41] prospectively followed 80 women with persistent placenta praevia using trans-abdominal B-mode and colour Doppler ultrasonography, with 17 cases of accreta identified at delivery. Doppler imaging identified 16 cases of suspected accreta, of which 14 were correct with two false positives, and it failed to diagnose the three other cases of accreta, giving a sensitivity of 82.4% and a specificity of 96.8%. The positive and negative predictive values were 87.5% and 95.3%, respectively.

Preliminary work suggests that the application of three-dimensional colour power Doppler ultrasound may be complementary to other techniques for antenatal imaging.[42,43] MRI has been compared to TAS in a small retrospective study of 13 women with histologically confirmed placenta accreta.[44] Of the nine who had had an MRI, only four were correctly diagnosed and of the 13 who had ultrasound only four were correctly diagnosed. These sensitivities, of 38% and 33%, respectively, are too poor to be useful clinically at present and colour flow Doppler is the investigation of choice until further experience and/or refinements occur with MRI.

Evidence level III

Imaging antenatally allows for preparation for surgery but false positives do occur and the diagnosis should be confirmed intraoperatively to avoid inappropriate treatment.[45]

4. Antenatal management

Women with major placenta praevia who have previously bled should be admitted and managed as inpatients from 34 weeks of gestation. Those with major placenta praevia who remain asymptomatic, having never bled, require careful counselling before contemplating outpatient care. Any home-based care requires close proximity with the hospital, the constant presence of a companion and full informed consent from the woman.

C

The concern in caring for asymptomatic women with placenta praevia major are that they will bleed suddenly and heavily, requiring urgent delivery. For this reason, traditional care has involved hospital admission during the latter part of the third trimester (commencing from 32–34 weeks) in women who have not previously bled who have placenta praevia major. There have been a number of observational studies to clarify which women are most likely to bleed. Raised serum alphafetoprotein levels at 15–20 weeks[46] and placentas which encroach on the os,[47, 48] are thick inferiorly[49] or show turbulent flow at their lower margin[50] by ultrasound imaging are most associated with antepartum haemorrhage.

Evidence level III

The Cochrane systematic review (last updated November 2002)[51] includes no new trials since the previous edition of this guideline. The three RCTs of interventions for placenta praevia included involve a total of 114 women: one trial compared hospital versus home care[52] and two investigated the use of cervical cerclage.[53,54] The trial by Wing *et al.*[52] compared 26 women allowed home with 27 women kept in hospital and the only significant difference was a reduction in hospital stay. With such a small study, underpowered to answer any questions on safety, the current standard of conservative inpatient management of women with major placenta praevia in the late third trimester remains the cautious option. International opinion is more liberal, with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists recommending that all women at risk of major antepartum haemorrhage should be encouraged to remain close to the hospital of confinement for the duration of the third trimester of pregnancy.[55]

Evidence level Ib

Retrospective reviews have been performed demonstrating that the outcomes of women with placenta praevia are very variable and not always predicted by antenatal events,[56,57] although women with placenta praevia who have bled tend to deliver earlier.[56,58] Two other retrospective casenote reviews have assessed the outcome of a total of 86 women managed expectantly at home compared with 90 managed as inpatients.[59,60] In both studies, decisions for care in the community were made on clinical grounds (unspecified) and neither study showed a significant difference in clinical outcomes, although outpatient care was associated with reduced hospitalisation and cost.

Evidence level III

The most recent Confidential Enquiry into Maternal Deaths in the UK acknowledges the continuing dilemma of whether a woman who has never bled needs hospitalisation based on a scan diagnosis of placenta praevia. The report also illustrates and reiterates the importance of hospitalisation if bleeding has occurred.[1]

Women managed at home should be encouraged to ensure that they have safety precautions in place, including having someone available to help them should the need arise and, particularly, having ready access to the hospital.

✓

It should be made clear to any woman being managed at home that she should attend hospital immediately if she experiences any bleeding, any contractions or any pain (including vague suprapubic period-like aches).

✓

Prior to delivery, all women with placenta praevia and their partners should have had antenatal discussions regarding delivery, haemorrhage, possible blood transfusion and major surgical interventions, such as hysterectomy, and any objections or queries dealt with effectively.[3]

✓

Decisions regarding blood availability during inpatient antenatal care should be based on clinical factors relating to individual cases, as well as local blood bank services. Women with atypical antibodies form a particular high-risk group and discussions in these cases should involve the local haematologist and blood bank.

✓

The use of cervical cerclage to reduce bleeding and prolong pregnancy is not backed up by sufficient evidence to recommend this practice outside of a clinical trial.

✓

Two studies on cervical cerclage[53,54] included in the Cochrane review[51] randomised 64 women between them (but three were lost to follow-up) and only one of these showed any possible benefit.[53] Arias *et al.*[53] demonstrated a reduction in the number of babies born before 34 weeks or less than 2 kg although randomisation was by birth date, and analysis was by treatment received, not intention to treat.

Evidence level Ib

Tocolysis for treatment of bleeding due to placenta praevia can be useful in selected cases. However betamimetics were used in the studies to date and, as these are known to be associated with significant side effects, the agent and optimum regime are still to be determined: further research is needed in this area.

✓

The aetiology of bleeding in placenta praevia is due to the dynamics of the development of the lower uterine segment but may also be triggered by uterine activity.This has prompted obstetricians to try 'conservative aggressive management' of placenta praevia using tocolysis in this situation.[61,62] Since the previous edition of this guideline, this has been explored in a prospective RCT of 60 women who presented with bleeding due to placenta praevia between 28 and 34 weeks.[63] Tocolysis using 10 mg ritodrine every 6 hours by intramuscular injections for 7 days was compared with no treatment. Treatment was associated with prolongation of pregnancy (25.33 ± 17.7 days compared with 14.47 ± 20.33 days; $P < 0.05$) and an increased birth weight (2.27 ± 0.59 kg compared with 1.95 ± 0.55 kg). No adverse effects to mother or baby were shown and no increased risk of bleeding was found.

Evidence level Ib

Previous observational studies have reported similarly encouraging results: Besinger *et al.*[64] conducted a prospective study on 112 women with acute vaginal bleeding and known placenta praevia and gave tocolysis to 72 who had significant uterine activity (85%).This group of patients had a prolongation from admission to delivery interval (39.2 days versus 26.9 days; $P < 0.02$) and an increase in birth weight (2.520 kg versus 2.124 kg, $P < 0.03$) compared with the 40 women who were not given tocolysis.

The largest series of cases where tocolysis has been used for bleeding in the third trimester, including 76 of 105 women with placenta praevia, is reported in a retrospective review by Towers *et al.*[65] and has suggested no increased morbidity or mortality associated with such use in a tertiary setting. Conversely, prophylactic terbutaline to prevent bleeding has not been found to benefit women with placenta praevia.[66]

Evidence level IIb

Prolonged inpatient care can be associated with an increased risk of thromboembolism. Thus, gentle mobility should be encouraged together with the use of prophylactic thromboembolic stockings. Prophylactic anticoagulation should be reserved for those at high risk of thromboembolism and, in these cases, unfractionated heparin is to be preferred over the longer-acting low-molecular-weight preparations.

✓

5. Delivery

The mode of delivery should be based on clinical judgement supplemented by sonographic information. A placental edge less than 2 cm from the internal os is likely to need delivery by caesarean section, especially if it is posterior or thick.

B

Recommendation of mode of delivery based on ultrasound findings is difficult as studies have been observational, often retrospective, and with knowledge of ultrasound scan findings and the clinical impressions and bias that understandably exist. Oppenheimer *et al.*[19] performed TVS in the third trimester on 127 women and 52 had placenta praevia. In 31 cases there was complete or major placenta praevia and, of the 21 partial praevias, the mean distance of the leading placental edge to the cervical os was significantly different in those delivered by caesarean section than those aiming for and achieving vaginal delivery with a cut-off distance of 2 cm ($P = 0.0004$).

Evidence level III

More recently, a prospective observational study of 63 women with placenta praevia has demonstrated that, in all those who delivered vaginally, the distance to the internal os was 2 cm in cases of anterior placenta praevia and 3 cm in cases of posterior praevia.[26]

Evidence level IIb

In another retrospective study of 121 cases, two of 40 women with a placenta within 0.1–2.0 cm delivered vaginally, while 22 of 39 with a placenta further than 2 cm from the internal os achieved vaginal delivery.[47] No mention is made in this paper of whether the placentas were anterior or posterior.

Evidence level III

Decisions regarding mode of delivery will take into account clinical factors as well as ultrasound findings, especially if the fetal head has entered the pelvis. Ultrasound can add to this information, in terms of where the fetal head is relative to the leading edge of the placenta. The thickness of the encroaching tongue of placenta has been shown to influence outcome: the thicker the placenta (over 1 cm), the more likely abdominal delivery ($P = 0.02$).[49]

Evidence level IIb

Blood should be readily available for the peripartum period. Requirements for crossmatched blood and what amount will depend on the clinical features of each individual case and the local blood bank services available. When women have atypical antibodies, direct communication with the local blood bank should enable specific plans to be made to match the individual circumstance.

✓

There is no evidence to support the use of autologous blood transfusion for placenta praevia.

B

Dinsmoor *et al.*[67] retrospectively reviewed 88 women who had placenta praevia and only 12 (14%) would have been eligible for autologous blood donation/transfusion. Of the 12, only two were transfused at delivery but they required a total of 12 and 18 units, respectively.

Evidence level III

Cell salvage may be considered in cases at high risk of massive haemorrhage.

C

Since the last edition of this guideline, the use of cell salvage in obstetrics has been increasingly studied[68–70] and National Institute for Health and Clinical Excellence and RCOG guidelines on its role in massive haemorrhage are currently in development. It has been used with success in placenta praevia[71] and in the USA anticipated difficulties with surgery for placenta praevia/accreta are an indication for considering the use of cell salvage technology, where it is available.[72]

Evidence level III

The choice of anaesthetic technique for caesarean section for placenta praevia must be made by the anaesthetist, in consultation with the obstetrician and mother, but there is increasing evidence to support the safety of regional blockade.

B

The data available on choice of anaesthetic technique for these cases has previously demonstrated differing opinions from UK obstetric anaesthetists,[73] while evidence from the USA has supported regional anaesthesia.[11] Since the previous edition of this guideline, there have been two trials adding to the evidence in support of regional anaesthesia. The first is a large retrospective study of 350 cases of placenta praevia, where 210 who received regional blockade were compared with 140

Evidence level IIb

who received general anaesthesia.[74] There was more blood loss and more transfusion requirements in those having a general anaesthesia and the two cases of major morbidity (one pulmonary embolus and one cerebral embolus) both received general anaesthesia. Of the five cases with placenta accreta, four had regional anaesthesia initially but two required conversion to general anaesthesia. In this trial, general anaesthesia was more commonly used in the emergency situations and consultants were more likely to have given regional anaesthesia than their junior colleagues, especially in emergencies.

Evidence level IIb

The second trial is a small RCT of regional versus general anaesthesia for placenta praevia, where 12 women received general anaesthesia and 13 women received regional blockade.[75] The numbers are small and more women in the general anaesthesia group had placenta praevia accreta (two versus one) or anterior praevia (four versus one) but outcomes were similar for the baby and blood transfusion requirements (although not estimated blood loss) were more in the general anaesthesia group.

Evidence level Ib

Any woman going to theatre with known placenta praevia should be delivered by the most experienced obstetrician and anaesthetist on duty. As a minimum requirement during a planned procedure, a consultant obstetrician and anaesthetist should be present within the delivery suite. A junior doctor should not be left unsupervised when caring for these women. When an emergency arises, consultant staff should be alerted and should attend as soon as possible.

✓

The timing of emergency surgery will be influenced by individual circumstances but, where possible, elective caesarean section should be deferred to 38 weeks to minimise neonatal morbidity.[1]

✓

6. Surgery in the presence of placenta accreta, increta and percreta

Women with placenta praevia who have had a previous caesarean section are at high risk of having a morbidly adherent placenta and should have been imaged antenatally. When placenta accreta is thought to be likely, consultant anaesthetic and obstetric input are vital in planning and conducting the delivery. Crossedmatched blood should be available and colleagues from other specialties/ subspecialties may be alerted to be on standby to attend as needed.

C

In the case of placenta accreta, increta and percreta, the risk of haemorrhage, transfusion and hysterectomy should be discussed with the patient as part of the consent procedure.

✓

The American College of Obstetricians and Gynecologists and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists have issued a committee opinion[72] and statement,[55] respectively, that, when hysterectomy is anticipated, consent should include that for hysterectomy. In addition, delivery should involve specialised multidisciplinary personnel and should occur where there are facilities for high-volume blood transfusion and availability of other blood products.

Evidence level IV

The most recent Confidential Enquiry into Maternal Deaths in the UK stresses that all caesarean sections performed in women with placenta praevia who have had a previous caesarean section should be conducted by a consultant obstetrician, because of the high risk of major morbidity.[1]

✓

Conservative management of placenta praevia accreta can be successful and can preserve fertility. This can involve a number of different management strategies, which are outlined below, but precise recommendations are outside the scope of this guideline.

B

Since the previous edition of this guideline, there have been numerous case reports of placenta praevia accreta and its management, which include a number of series where the placenta has been left in place at the end of the caesarean section. Management in these cases has varied, with some having prophylactic or

therapeutic uterine artery embolisation,[76–78] or internal iliac artery ligation at the same time as initial surgery,[77] and some being treated following delivery with methotrexate.[77] Successful pregnancies have been reported after this approach[76,77] but there have been cases of delayed haemorrhage necessitating hysterectomy.[79,80] In contrast, some cases have had no additional treatment after leaving the placenta in place and still had successful outcomes.[81,82]

The natural history of five women with retained adherent placenta and no additional therapy was followed by Matsumura *et al.*,[81] who found that serum human chorionic gonadotrophin levels decreased spontaneously with a half-life of 5.2 days ± 0.26 days. The uterine artery pulsatility index remained unchanged (at term pregnancy levels) until the placenta was successfully removed surgically, vaginally, within 6 weeks. This differed from a smaller series of three cases where the placental resolution occurred spontaneously between 10 weeks and 24 weeks following delivery.[82] In all these cases, the uterine artery Doppler resistance increased and showed notching prior to the placental resolution. There are two women from France whose cases were reported, who had also had uterine artery embolisation, where the placentas were left alone and disappeared 5–6 months after delivery.[78]

Evidence level III

7. Massive haemorrhage

The Confidential Enquiries into Maternal Deaths have, over many years, highlighted the dangers associated with massive haemorrhage in general and placenta praevia in particular.[1,83–86] Many points are made concerning what constitutes both substandard care and good practice.

Massive haemorrhage should be dealt with in accordance with the recommendations of the reports of the Confidential Enquiries into Maternal Deaths.[1, 83–86] C

The surgical manoeuvres required in the face of massive haemorrhage associated with placenta praevia caesarean section should be performed by appropriately experienced surgeons. Calling for extra help early should be encouraged and not seen as 'losing face'. ✓

Uterotonic agents may help in reducing the blood loss associated with bleeding from the relatively atonic lower uterine segment,[87] while bimanual compression, hydrostatic balloon catheterisation or uterine packing,[88] or even aortic compression, can buy time while senior help arrives. Additional surgical manoeuvres which may be considered include the B-Lynch suture,[89] uterine[90] or internal iliac artery ligation[91] or hysterectomy. Arterial embolisation has been reported[92] and is useful in selected cases as long as the iliac vessels have not been tied off.

Every unit should have a protocol for the management of massive obstetric haemorrhage which includes:

- **liaison with haematology**
- **giving warm blood rapidly**
- **criteria for invasive monitoring**
- **management of women who refuse blood products.** ✓

Emergency clinical scenarios and fire drills surrounding issues of massive obstetric haemorrhage and obtaining blood products urgently should be run locally. ✓

8. Related issues

Risk factors for placenta praevia include previous uterine infection and/or surgery. This opportunity is taken to reiterate previous recommendations:

- screening for infection before termination of pregnancy and antibiotic prophylaxis to minimise the risk of post-abortion infective morbidity[93]
- prophylactic antibiotics should be used for caesarean section[94] and for manual removal of the placenta.

In addition:

- the use of antenatal corticosteroids in threatened preterm delivery[95]
- anti-D immunoglobulin for who are women rhesus negative who bleed[96]
- thromboprophylaxis for any woman at increased risk of thromboembolism.[97]

9. Auditable standards

Surgical support at caesarean section on women with placenta praevia has been addressed in the reports of the Confidential Enquiries into Maternal Deaths.[83,84] The substandard care associated with these reports focuses on areas which may be suitable for audit in everyday working practice, with care given being compared with those standards identified in these reports.

Women with placenta praevia could be subjected to clinical audit of the following:

- Was TVS used in confirming the diagnosis of placenta praevia?
- Was the diagnosis of a morbidly adherent placenta considered and managed appropriately in high-risk cases?
- Was the antenatal management and counselling appropriate for women with persisting placenta praevia in the third trimester?
- Mode of delivery; appropriate counselling and consent.
- Choice of anaesthesia; appropriate counselling and consent.
- Potential for complications; appropriate counselling and consent.
- Grade of operator and anaesthetist at delivery by caesarean section.
- Management of major obstetric haemorrhage according to hospital protocol.
- Standard of documentation.

10. Risk management

As in all high-risk cases, particular attention should be paid to careful documentation of all issues surrounding clinical discussion and decisions. Names of all clinical staff involved should be recorded legibly and signed in the notes, together with the content of any discussions, advanced directives and decisions.

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APPENDIX

Clinical guidelines are: 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: *Guidance for the Development of RCOG Green-top Guidelines* (available on the RCOG website at www.rcog.org.uk/clingov1). These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels

Ia	Evidence obtained from meta-analysis of randomised controlled trials.
Ib	Evidence obtained from at least one randomised controlled trial.
IIa	Evidence obtained from at least one well-designed controlled study without randomisation.
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study.
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

Grades of recommendations

A	Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)
B	Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)
C	Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

Good practice point

✓	Recommended best practice based on the clinical experience of the guideline development group.

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