



Royal College of
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Gynaecologists

The Management of Third- and Fourth-Degree Perineal Tears

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The Management of Third- and Fourth-Degree Perineal Tears

This is the third edition of this guideline, which was previously published in July 2001 and March 2007 under the same title.

Executive summary of recommendations

Classification and terminology

How should obstetric anal sphincter injury be classified?

It is recommended that the classification outlined in this guideline be used when describing any obstetric anal sphincter injury.



If there is any doubt about the degree of third-degree tear, it is advisable to classify it to the higher degree rather than the lower degree.



Prediction and prevention of obstetric anal sphincter injury

Can obstetric anal sphincter injury be predicted?

Clinicians need to be aware of the risk factors for obstetric anal sphincter injuries (OASIS).



Clinicians should be aware, however, that risk factors do not allow the accurate prediction of OASIS.



Can obstetric anal sphincter injury be prevented?

Clinicians should explain to women that the evidence for the protective effect of episiotomy is conflicting. [New 2015]



Mediolateral episiotomy should be considered in instrumental deliveries. [New 2015]



Where episiotomy is indicated, the mediolateral technique is recommended, with careful attention to ensure that the angle is 60 degrees away from the midline when the perineum is distended.



Perineal protection at crowning can be protective. [New 2015]



Warm compression during the second stage of labour reduces the risk of OASIS. [New 2015]



Identification of obstetric anal sphincter injuries

How can the identification of obstetric anal sphincter injuries be improved?

All women having a vaginal delivery are at risk of sustaining OASIS or isolated rectal buttonhole tears. They should therefore be examined systematically, including a digital rectal examination, to assess the severity of damage, particularly prior to suturing.



Repair of OASIS

General principles

Repair of third- and fourth-degree tears should be conducted by an appropriately trained clinician or by a trainee under supervision.



Repair should take place in an operating theatre, under regional or general anaesthesia, with good lighting and with appropriate instruments. If there is excessive bleeding, a vaginal pack should



be inserted and the woman should be taken to the theatre as soon as possible. Repair of OASIS in the delivery room may be performed in certain circumstances after discussion with a senior obstetrician. [New 2015]

Figure of eight sutures should be avoided during the repair of OASIS because they are haemostatic in nature and may cause tissue ischaemia. [New 2015]



A rectal examination should be performed after the repair to ensure that sutures have not been inadvertently inserted through the anorectal mucosa. If a suture is identified it should be removed. [New 2015]



Which techniques should be used to accomplish the repair of the anorectal mucosa?

The torn anorectal mucosa should be repaired with sutures using either the continuous or interrupted technique. [New 2015]



Which techniques should be used to accomplish the repair of the internal anal sphincter?

Where the torn internal anal sphincter (IAS) can be identified, it is advisable to repair this separately with interrupted or mattress sutures without any attempt to overlap the IAS.



Which techniques should be used to repair the external anal sphincter?

For repair of a full thickness external anal sphincter (EAS) tear, either an overlapping or an end-to-end (approximation) method can be used with equivalent outcomes.



For partial thickness (all 3a and some 3b) tears, an end-to-end technique should be used. [New 2015]



Choice of suture materials

Which suture materials should be used to accomplish repair of obstetric anal sphincter injuries?

3-0 polyglactin should be used to repair the anorectal mucosa as it may cause less irritation and discomfort than polydioxanone (PDS) sutures. [New 2015]



When repair of the EAS and/or IAS muscle is being performed, either monofilament sutures such as 3-0 PDS or modern braided sutures such as 2-0 polyglactin can be used with equivalent outcomes.



When obstetric anal sphincter repairs are being performed, the burying of surgical knots beneath the superficial perineal muscles is recommended to minimise the risk of knot and suture migration to the skin.



Surgical competence

Who should repair obstetric anal sphincter injury?

Obstetric anal sphincter repair should be performed by appropriately trained practitioners.



Formal training in anal sphincter repair techniques should be an essential component of obstetric training.



Postoperative management

How should women with obstetric anal sphincter injury be managed postoperatively?

The use of broad-spectrum antibiotics is recommended following repair of OASIS to reduce the risk of postoperative infections and wound dehiscence.



The use of postoperative laxatives is recommended to reduce the risk of wound dehiscence.	C
Bulking agents should not be given routinely with laxatives. [New 2015]	B
Local protocols should be implemented regarding the use of antibiotics, laxatives, examination and follow-up of women with obstetric anal sphincter repair.	<input checked="" type="checkbox"/>
Women should be advised that physiotherapy following repair of OASIS could be beneficial.	<input checked="" type="checkbox"/>
Women who have undergone obstetric anal sphincter repair should be reviewed at a convenient time (usually 6–12 weeks postpartum). Where possible, review should be by clinicians with a special interest in OASIS.	<input checked="" type="checkbox"/>
If a woman is experiencing incontinence or pain at follow-up, referral to a specialist gynaecologist or colorectal surgeon should be considered.	<input checked="" type="checkbox"/>
 <i>Prognosis</i>	
What is the prognosis following surgical repair?	
Women should be advised that 60–80% of women are asymptomatic 12 months following delivery and EAS repair.	B
 <i>Future deliveries</i>	
What advice should women be given following an obstetric anal sphincter injury concerning future pregnancies and mode of delivery?	
All women who sustained OASIS in a previous pregnancy should be counselled about the mode of delivery and this should be clearly documented in the notes.	<input checked="" type="checkbox"/>
The role of prophylactic episiotomy in subsequent pregnancies is not known and therefore an episiotomy should only be performed if clinically indicated.	<input checked="" type="checkbox"/>
All women who have sustained OASIS in a previous pregnancy and who are symptomatic or have abnormal endoanal ultrasonography and/or manometry should be counselled regarding the option of elective caesarean birth.	<input checked="" type="checkbox"/>
 <i>Risk management</i>	
What processes and policies should be in place for women who have sustained obstetric OASIS?	
Units should have a clear protocol for the management of OASIS. [New 2015]	<input checked="" type="checkbox"/>
Documentation of the anatomical structures involved, the method of repair and the suture materials should be made.	<input checked="" type="checkbox"/>
The woman should be fully informed about the nature of her tear and the offer of follow-up should be made, all supported by relevant written information.	<input checked="" type="checkbox"/>

1. Purpose and scope

The purpose of this guideline is to provide evidence-based guidance on the diagnosis, management and treatment of third- and fourth-degree perineal tears (obstetric anal sphincter injuries, referred to as OASIS).

2. Introduction and background epidemiology

The reported rate of OASIS (in singleton, term, cephalic, vaginal first births) in England has tripled from 1.8% to 5.9% from 2000 to 2012.¹ The overall incidence in the UK is 2.9% (range 0–8%), with an incidence of 6.1% in primiparae compared with 1.7% in multiparae.²

With increased awareness and training, there appears to be an increase in the detection of anal sphincter injuries.¹ A trend towards an increasing incidence of third- or fourth-degree perineal tears does not necessarily indicate poor quality care. It may indicate, at least in the short term, an improved quality of care through better detection and reporting.³

Obstetricians who are appropriately trained are more likely to provide a consistent, high standard of anal sphincter repair and contribute to reducing the extent of morbidity and litigation associated with anal sphincter injury.⁴

3. Identification and assessment of evidence

The Cochrane Library was searched for relevant randomised controlled trials, systematic reviews and meta-analyses. MEDLINE and EMBASE were also searched from 2006–2014 and the date of the last search was November 2014. NICE Evidence Search, Trip and the National Guideline Clearinghouse were also searched for relevant guidelines and reviews.

The databases were searched using the relevant Medical Subject Headings (MeSH), including all subheadings, and this was combined with a keyword search that included the terms: 'human', 'female', 'childbirth', 'obstetric', 'perineum', 'third degree', 'fourth degree', 'anal sphincter', 'tear', 'injury', 'rupture', 'damage', 'incontinence', 'faecal', 'anal', 'repair', 'surgery' and 'sutures'.

The definitions of the types of evidence used in this guideline originate from the Scottish Intercollegiate Guidelines Network. Where possible, recommendations are based on and explicitly linked to the evidence that supports them. Areas lacking evidence are highlighted and annotated as 'good practice points'.

4. Classification and terminology

4.1 How should obstetric anal sphincter injury be classified?

It is recommended that the classification outlined in this guideline be used when describing any obstetric anal sphincter injury.



If there is any doubt about the degree of third-degree tear, it is advisable to classify it to the higher degree rather than the lower degree.



The following classification described by Sultan⁵ has been adopted by the International Consultation on Incontinence⁶ and the RCOG:

First-degree tear: Injury to perineal skin and/or vaginal mucosa.

Second-degree tear: Injury to perineum involving perineal muscles but not involving the anal sphincter.

Evidence level 4

Third-degree tear: Injury to perineum involving the anal sphincter complex:

Grade 3a tear: Less than 50% of external anal sphincter (EAS) thickness torn.

Grade 3b tear: More than 50% of EAS thickness torn.

Grade 3c tear: Both EAS and internal anal sphincter (IAS) torn.

Fourth-degree tear: Injury to perineum involving the anal sphincter complex (EAS and IAS) and anorectal mucosa.

Evidence
level 4

The lining of the anal canal varies along its length due to its embryological derivation. The proximal anal canal is lined with rectal mucosa (columnar epithelium) whereas the distal 1–1.5 cm of the anal canal is lined with modified squamous epithelium.⁷ To avoid confusion, the term ‘anorectal mucosa’ has been used instead of anal epithelium throughout this guideline.

Obstetric anal sphincter injuries (OASIS) encompass both third- and fourth-degree perineal tears.

Anal incontinence is defined as the complaint of involuntary loss of flatus and/or faeces affecting quality of life.⁸

The IAS plays a role in the maintenance of continence. In a prospective study involving follow-up of 531 women after OASIS, those with a grade 3c/4 tear had a significantly poorer outcome ($P < 0.05$) compared with women with a grade 3a/3b tear with respect to the development of defaecatory symptoms, anal manometry results and the associated quality of life.⁹ Another prospective follow-up study of 125 women who had OASIS reported a significantly increased incidence of anal incontinence ($P < 0.001$) in women who had 3b and fourth-degree compared with 3a tears.¹⁰ A third prospective study of 500 women followed up at 3 months showed that IAS defect thickness (partial thickness defect greater than one quadrant or full thickness IAS defect) was predictive of severe incontinence (OR 5.1, 95% CI 1.5–22.9).¹¹ A retrospective, descriptive cross-sectional study of 66 women who were followed up for a mean of 5 years showed that women with combined IAS and EAS injury ($n = 6$) had worse faecal incontinence ($P < 0.05$) and lower anal pressures ($P = 0.04$) than women with isolated EAS injury ($n = 10$).¹²

Evidence
level 2+

Inclusion of the IAS in the classification above would allow differentiation between future incontinence related to IAS injury and that related to EAS injury alone. It is recognised that identification of the IAS may be difficult in acute obstetric trauma, but every attempt should nonetheless be made to exclude and document injury to the IAS. Recording the degree of EAS damage (more or less than 50%) should be possible in all cases. If one is unsure whether it is more than 50% then it should be classified as 3b to avoid underestimation.

Rectal buttonhole tear

If the tear involves the rectal mucosa with an intact anal sphincter complex, it is by definition not a fourth-degree tear. This has to be documented as a rectal buttonhole tear. If not recognised and repaired, this type of tear may lead to a rectovaginal fistula.¹³

Evidence
level 4

5. Prediction and prevention of obstetric anal sphincter injury

5.1 Can obstetric anal sphincter injury be predicted?

Clinicians need to be aware of the risk factors for OASIS.



Clinicians should be aware, however, that risk factors do not allow the accurate prediction of OASIS.



The following risk factors have been identified. There is, however, considerable difference in the reported risks for the same risk factor.^{1,14–16}

Evidence
level 3

- Asian ethnicity¹ (OR 2.27, 95% CI 2.14–2.41)
- nulliparity¹⁵ (relative risk [RR] 6.97, 95% CI 5.40–8.99)
- birthweight greater than 4 kg¹ (OR 2.27, 95% CI 2.18–2.36)
- shoulder dystocia¹ (OR 1.90, 95% CI 1.72–2.08)
- occipito-posterior position¹⁵ (RR 2.44, 95% CI 2.07–2.89)
- prolonged second stage of labour:¹⁵
 - duration of second stage between 2 and 3 hours (RR 1.47, 95% CI 1.20–1.79)
 - duration of second stage between 3 and 4 hours (RR 1.79, 95% CI 1.43–2.22)
 - duration of second stage more than 4 hours (RR 2.02, 95% CI 1.62–2.51)
- instrumental delivery:¹
 - ventouse delivery without episiotomy (OR 1.89, 95% CI 1.74–2.05)
 - ventouse delivery with episiotomy (OR 0.57, 95% CI 0.51–0.63)
 - forceps delivery without episiotomy (OR 6.53, 95% CI 5.57–7.64)
 - forceps delivery with episiotomy (OR 1.34, 95% CI 1.21–1.49).

Risk factors for OASIS were assessed in a retrospective study of 123 women who sustained third- or fourth-degree tears and 123 controls without OASIS. The authors concluded that a scoring system based on the reported risks from meta-analyses to identify women at risk is unlikely to be of practical use.¹⁶

Evidence level 2-

There is limited evidence in relation to the risk of sustaining recurrent OASIS. A large retrospective cohort study showed an odds ratio of 5.51 (95% CI 5.18–5.86) of sustaining recurrent OASIS in the subsequent pregnancy.¹⁷ Risk factors for sustaining recurrent OASIS in the subsequent pregnancy include Asian ethnicity (OR 1.59, 95% CI 1.48–1.71), forceps delivery (OR 4.02, 95% CI 3.51–4.60) and birthweight more than 4 kg (OR 2.29, 95% CI 2.16–2.43).

Evidence level 2++

5.2 Can obstetric anal sphincter injury be prevented?

Clinicians should explain to women that the evidence for the protective effect of episiotomy is conflicting.

C

Mediolateral episiotomy should be considered in instrumental deliveries.

D

Where episiotomy is indicated, the mediolateral technique is recommended, with careful attention to ensure that the angle is 60 degrees away from the midline when the perineum is distended.

D

Perineal protection at crowning can be protective.

C

Warm compression during the second stage of labour reduces the risk of OASIS.

A

Episiotomy

The evidence that episiotomy prevents OASIS and/or anal incontinence is conflicting. Hospital Episode Statistics data have shown that episiotomy is associated with the lowest risk of OASIS.¹ Some studies have shown a protective effect while others have not.^{18–20}

Evidence level 2-

However, there is evidence that a mediolateral episiotomy should be performed with instrumental deliveries as it appears to have a protective effect on OASIS.^{1,10}

The angle of the episiotomy away from the midline has been shown to be important in reducing the incidence of OASIS,^{21,22} with the National Institute for Health and Care Excellence (NICE) recommending an angle of 45–60 degrees from the midline.²³ Nonetheless, a prospective study by Kalis et al. suggests that a resultant suture angle of 40–60 degrees is more important than the incision angle of 45–60 degrees.²⁴

Evidence level 3

However, this can be difficult to achieve at ‘crowning’ when the perineum is fully stretched. An episiotomy performed at 40 degrees results in a post-delivery angle of 22 degrees, which is too close to the midline to be maximally protective. A 60-degree episiotomy from the centre of the introitus results in a post-delivery angle of 45 degrees.²⁴ A study has demonstrated that doctors and midwives were unable to correctly estimate angles and lengths required to perform safe mediolateral episiotomies.²⁵ None of the midwives and only 22% of doctors were able to perform a truly mediolateral episiotomy. Only 13% of episiotomies were at a post-delivery angle of 40 degrees or more.²⁶ Special scissors designed to ensure an incision angle of 60 degrees have been shown to be effective in achieving the correct angle.^{27,28}

Evidence level 3

Perineal protection

The NICE *Intrapartum care* guideline²³ found no difference between ‘hands poised’ and ‘hands on’ the perineum as prevention for OASIS. However, more recently there have been interventional studies using programmes which have successfully reduced OASIS rates, all of which have described manual perineal protection/‘hands on’ techniques.^{29,30}

These include:

1. Left hand slowing down the delivery of the head.
2. Right hand protecting the perineum.
3. Mother NOT pushing when head is crowning (communicate).
4. Think about episiotomy (risk groups and correct angle).

Evidence level 2+

The best method of perineal support/protection is unclear, with the Ritgen manoeuvre (delivering the fetal head, using one hand to pull the fetal chin from between the maternal anus and the coccyx and the other on the fetal occiput to control speed of delivery) no better than ‘standard care’ (not specifically defined but it included perineal protection/‘hands on’).³¹

Evidence level 1+

However, the positive effects of perineal support^{29,30} suggest that this should be promoted, as opposed to ‘hands off’ or ‘poised’, in order to protect the perineum and reduce the incidence of OASIS.

Evidence level 2+

Warm compress

A Cochrane review has found the application of warm compresses during the second stage of labour to have a significant effect on reducing OASIS.³² The analysis, comprising two studies (1525 women), found that warm compresses significantly reduced the risk of third- and fourth-degree tears (RR 0.48, 95% CI 0.28–0.84). The intervention involves holding the compress on the perineum continuously during and between contractions.

Evidence level 1++

Perineal massage during antenatal period and in second stage of labour

Perineal massage during the last month of pregnancy has been suggested as a possible way of enabling perineal tissue to expand more easily during birth. The Cochrane review³³ of four trials (2497 women) showed that perineal massage undertaken by the woman or her partner was associated with an overall reduction in the incidence of trauma requiring suturing (four trials, 2480 women, RR 0.91, 95% CI 0.86–0.96, number needed to treat to benefit [NNTB] 15 [10–36]). Women practising perineal massage were less likely to have an episiotomy (four trials, 2480 women, RR 0.84, 95% CI 0.74–0.95, NNTB 21 [12–75]). These findings were significant for women without previous vaginal birth only. No differences were seen in the incidence of first- or second-degree perineal tears or third-/fourth-degree perineal trauma (four trials, 2480 women, RR 0.81, 95% CI 0.56–1.18).

Evidence level 1–

The data regarding the protective effect of perineal massage in the second stage of labour are inconclusive; a small randomised trial found that the rates of intact perineums, first- and second-degree tears and episiotomies were similar in the massage and control groups. There were fewer third-degree tears in the massage group (12 [1.7%] versus 23 [3.6%]; absolute risk 2.11, RR 0.45, 95% CI 0.23–0.93), although the trial was underpowered to measure this outcome.^{32,34}

Evidence level 1–

6. Identification of obstetric anal sphincter injuries

6.1 How can the identification of obstetric anal sphincter injuries be improved?

All women having a vaginal delivery are at risk of sustaining OASIS or isolated rectal buttonhole tears. They should therefore be examined systematically, including a digital rectal examination, to assess the severity of damage, particularly prior to suturing.



According to NICE perineal care guidance,²³ before assessing for genital trauma, healthcare professionals should:

- explain to the woman what they plan to do and why
- offer inhalational analgesia
- ensure good lighting
- position the woman so that she is comfortable and so that the genital structures can be seen clearly.

The examination should be performed gently and may be done in the immediate period following birth. If genital trauma is identified following birth, further systematic assessment should be carried out, including a rectal examination.

Systematic assessment of genital trauma should include:¹³

- further explanation of what the healthcare professional plans to do and why
- confirmation by the woman that effective local or regional analgesia is in place
- visual assessment of the extent of perineal trauma to include the structures involved, the apex of the injury and assessment of bleeding
- a rectal examination to assess whether there has been any damage to the external or internal anal sphincter if there is any suspicion that the perineal muscles are damaged.

The woman should usually be in the lithotomy position to allow adequate visual assessment of the degree of the trauma and for the repair itself. This position should only be maintained for as long as is necessary for the systematic assessment and repair. The systematic assessment and its results should be fully documented, preferably pictorially.

The woman should be referred to a more experienced healthcare professional if uncertainty exists as to the nature or extent of the trauma sustained. All relevant healthcare professionals should attend hands-on training in perineal/genital assessment and repair and ensure that they maintain these skills.

Following vaginal delivery, anal sphincter and anorectal mucosal injury cannot be excluded without performing a rectal examination. With increased awareness and training in examination and diagnosis, there appears to be an increase in the detection of OASIS;⁴ one observational study showed that increased vigilance can double the detection rate.³⁵

Evidence level 2+

Since the introduction of endoanal ultrasound, sonographic abnormalities of the anal sphincter ('occult' injuries) have been identified in 33% of women following vaginal delivery.³⁶ However, when endoanal ultrasound was performed immediately following delivery, the detection rate of OASIS was not significantly increased compared with clinical examination alone.³⁷ As there are current limitations in availability, image quality, interpretation skills and patient acceptability, the use of endoanal ultrasound in detecting anal sphincter injuries immediately after delivery should be viewed as a research tool.

Evidence level 3

7. Repair of OASIS

7.1 General principles

Repair of third- and fourth-degree tears should be conducted by an appropriately trained clinician or by a trainee under supervision.



Repair should take place in an operating theatre, under regional or general anaesthesia, with good lighting and with appropriate instruments. If there is excessive bleeding, a vaginal pack should be inserted and the woman should be taken to the theatre as soon as possible. Repair of OASIS in the delivery room may be performed in certain circumstances after discussion with a senior obstetrician.



Figure of eight sutures should be avoided during the repair of OASIS because they are haemostatic in nature and may cause tissue ischaemia.



A rectal examination should be performed after the repair to ensure that sutures have not been inadvertently inserted through the anorectal mucosa. If a suture is identified it should be removed.



Involvement of a colorectal surgeon will be dependent on local protocols, expertise and availability as the majority of colorectal surgeons are not familiar with acute OASIS.³⁸ Repair in an operating theatre will allow the repair to be performed under optimal conditions with appropriate instruments, adequate light and an assistant. Regional or general anaesthesia will facilitate identification of the full extent of the injury and enable retrieval of the retracted ends of the torn anal sphincter.¹³

Evidence level 4

7.2 Which techniques should be used to accomplish the repair of the anorectal mucosa?

The torn anorectal mucosa should be repaired with sutures using either the continuous or interrupted technique.



Traditionally, the technique described to repair the torn anal mucosa was to insert interrupted sutures with the knot tied within the anal canal. However, this was recommended when catgut was in use to minimise tissue reaction and infection.³⁹ With the availability of polyglactin suture material this is no longer necessary as it dissolves by hydrolysis. Whichever technique is used, figure of eight sutures should be avoided during repair of the anal mucosa as they can cause ischaemia.

Evidence level 4

7.3 Which techniques should be used to accomplish the repair of the internal anal sphincter?

Where the torn IAS can be identified, it is advisable to repair this separately with interrupted or mattress sutures without any attempt to overlap the IAS.



In 1999, Sultan first described separate repair of the IAS during primary repair using the end-to-end technique.⁴⁰ Since then, a number of studies have demonstrated that a separate repair of the IAS improves the likelihood of subsequent anal continence.⁹⁻¹²

Evidence level 2+

7.4 Which techniques should be used to repair the external anal sphincter?

For repair of a full thickness EAS tear, either an overlapping or an end-to-end (approximation) method can be used with equivalent outcomes.



For partial thickness (all 3a and some 3b) tears, an end-to-end technique should be used.



A Cochrane review demonstrated no difference in outcomes between an end-to-end and an overlap repair and therefore the end-to-end technique can be used for all external sphincter tears.⁴¹

Evidence level 1++

This Cochrane review on the method of repair for third- and fourth-degree tears examined six trials involving 588 women.⁴¹ There was considerable heterogeneity in the outcome measures, time points and reported results. Meta-analyses showed that there was no statistically significant difference in perineal pain (RR 0.08, 95% CI 0.00–1.45, one trial, 52 women), dyspareunia (average RR 0.77, 95% CI 0.48–1.24, two trials, 151 women) or flatus incontinence (RR 1.14, 95% CI 0.58–2.23, three trials, 256 women) between the two repair techniques at 12 months. However, it showed a statistically significant lower incidence of faecal urgency (RR 0.12, 95% CI 0.02–0.86, one trial, 52 women) and lower anal incontinence score (standardised mean difference [SMD] -0.70, 95% CI -1.26 to -0.14, one trial, 52 women) in the overlap group. The overlap technique was also associated with a statistically significant lower risk of deterioration of anal incontinence symptoms over 12 months (RR 0.26, 95% CI 0.09–0.79, one trial, 41 women). There was no significant difference in quality of life. At 36 months' follow-up, there was no difference in flatus incontinence (average RR 1.12, 95% CI 0.63–1.99, one trial, 68 women) or faecal incontinence (average RR 1.01, 95% CI 0.34–2.98, one trial, 68 women). The overlap technique can only be used for full thickness external sphincter tears to allow the torn ends to be overlapped without tension and this technique has only been described to repair full thickness EAS tears. As two free ends of the muscle are needed for a proper overlap repair, overlapping of partial thickness EAS tears would exert undue tension on the repair. Therefore an end-to-end repair should be performed in a partial thickness EAS tear (3a and some 3b).⁴⁰

Evidence level 4

8. Choice of suture materials

8.1 Which suture materials should be used to accomplish repair of obstetric anal sphincter injuries?

3-0 polyglactin should be used to repair the anorectal mucosa as it may cause less irritation and discomfort than polydioxanone (PDS) sutures.

D

When repair of the EAS and/or IAS muscle is being performed, either monofilament sutures such as 3-0 PDS or modern braided sutures such as 2-0 polyglactin can be used with equivalent outcomes.

B

When obstetric anal sphincter repairs are being performed, the burying of surgical knots beneath the superficial perineal muscles is recommended to minimise the risk of knot and suture migration to the skin.

B

The use of PDS sutures for repair of the anorectal mucosa should be avoided as they take longer to dissolve and may cause discomfort in the anal canal.³⁹

Evidence level 4

There are no systematic reviews available to evaluate the best suture material for the repair of the EAS. The only randomised controlled trial comparing Vicryl® (3-0 polyglactin; Ethicon, Somerville, New Jersey, USA) and PDS reported no significant difference in suture-related morbidity at 6 weeks and bowel symptoms at 6 and 12 months.⁴² There are no systematic reviews or randomised studies available to evaluate the type of suture materials used in the repair of the IAS. Similar to EAS repair, the use of fine suture sizes such as 3-0 PDS and 2-0 polyglactin (Vicryl®) may cause less irritation and discomfort.

Evidence level 1–

Suture migration is recognised when a woman complains of irritation/pain around the perineum after repair of OASIS. This may also be detected at the time of examination where the exposed ends of suture material are seen or felt on digital examination. Exposed suture ends can be trimmed in the outpatient setting under local anaesthesia. The reported incidence of suture migration is about 7% and this can be reduced by trimming the suture ends and burying the knots in the deep and superficial perineal muscles.⁴²

9. Surgical competence

9.1 Who should repair obstetric anal sphincter injury?

Obstetric anal sphincter repair should be performed by appropriately trained practitioners.

D

Formal training in anal sphincter repair techniques should be an essential component of obstetric training.

✓

Inexperienced attempts at anal sphincter repair may contribute to maternal morbidity, especially subsequent anal incontinence. Published randomised controlled trials have reported residual EAS defects in 19–36% overall following repair.^{43–45} The clinical relevance of asymptomatic defects demonstrated by ultrasound is currently unclear, but it has been suggested that this may be due to inadequate primary repair.^{9,46}

Evidence level 1-

In 2002, a survey of UK consultant obstetricians and trainee obstetricians in two regions highlighted the deficiency in and their dissatisfaction with their training in the management of third-degree tears.^{38,47}

Evidence level 3

Repair of third- and fourth-degree perineal tears has now been incorporated in the module on postpartum problems in the RCOG core training log book.⁴⁸ Many regions now conduct training workshops involving the use of simulation models.²

Evidence level 4

10. Postoperative management

10.1 How should women with obstetric anal sphincter injury be managed postoperatively?

The use of broad-spectrum antibiotics is recommended following repair of OASIS to reduce the risk of postoperative infections and wound dehiscence.

B

The use of postoperative laxatives is recommended to reduce the risk of wound dehiscence.

C

Bulking agents should not be given routinely with laxatives.

B

Local protocols should be implemented regarding the use of antibiotics, laxatives, examination and follow-up of women with obstetric anal sphincter repair.

✓

Women should be advised that physiotherapy following repair of OASIS could be beneficial.

✓

Women who have undergone obstetric anal sphincter repair should be reviewed at a convenient time (usually 6–12 weeks postpartum). Where possible, review should be by clinicians with a special interest in OASIS.

✓

If a woman is experiencing incontinence or pain at follow-up, referral to a specialist gynaecologist or colorectal surgeon should be considered.

✓

A Cochrane review addressing antibiotic prophylaxis for third- and fourth-degree perineal tears, comparing prophylactic antibiotics against placebo or no antibiotics, included only one randomised controlled trial of 147 participants.⁴⁹ Although the data suggested that prophylactic antibiotics help to prevent perineal wound complications following third- or fourth-degree perineal tears, loss to follow-up was very high. The authors concluded that results should be interpreted with caution as they are based on one small trial.

Evidence level 1-

No systematic reviews were identified which evaluated the use of postoperative laxatives and stool softeners. Laxatives are recommended during the postoperative period as passage of a hard stool may disrupt the repair.⁴⁰ Use of stool softeners such as lactulose is recommended for about 10 days after the repair.

Evidence level 2+

One randomised controlled study compared laxatives and bulking agents in the postoperative period following primary OASIS repair.⁵⁰ In this study, women in the laxative group had a significantly earlier and less painful bowel motion and earlier postnatal discharge. There was no difference in the symptomatic or functional outcome of repair between the two regimens. The dose of lactulose should be titrated to keep the stool soft but not loose. A randomised controlled trial of lactulose alone versus lactulose with ispaghula husk (Fybogel®, Reckitt Benckiser, Hull, UK) demonstrated that incontinence in the immediate postpartum period was more frequent (32.86% versus 18.18%; $P = 0.03$) with the latter regime and therefore routine prescription of bulking agents and lactulose together is not recommended.⁵¹

Evidence level 1-

There was one randomised controlled trial comparing early home biofeedback therapy and pelvic floor exercises for women who sustained OASIS and this study showed that there was no added value in using early home biofeedback therapy.⁵²

As there are considerable variations in the use of antibiotics, laxatives and physiotherapy and in available facilities for follow-up in different hospitals, the follow-up regimen is best designed according to local facilities.

There were no systematic reviews or randomised controlled trials to indicate the optimal method of follow-up after OASIS. It is appropriate to review women in the postnatal period to discuss injury sustained during childbirth, assess symptoms and offer advice on how to seek help if symptoms develop, offer treatment and/or referral if indicated and offer advice on future mode of delivery. Use of a validated health-related quality of life questionnaire may be useful for assessment of women who develop anal incontinence after sustaining OASIS.⁵³ The RCOG has produced a patient information leaflet on third- and fourth-degree perineal care and this, or a suitable alternative, should be given to all women who have had OASIS.⁵⁴

Evidence level 4

If facilities are available and resources allow, follow-up of women with OASIS should be in a dedicated perineal clinic with access to endoanal ultrasonography and anal manometry as this can aid decision making regarding future delivery.^{55,56}

11. Prognosis

11.1 What is the prognosis following surgical repair?

Women should be advised that 60–80% of women are asymptomatic 12 months following delivery and EAS repair.

B

Several randomised controlled studies carried out since 2000 comparing overlap and end-to-end techniques of EAS repair have reported low incidences of anal incontinence symptoms in both arms,^{42–45} with 60–80% of women described as asymptomatic at 12 months.^{4,42,44,45}

Evidence level 1-

12. Future deliveries

12.1 What advice should women be given following an obstetric anal sphincter injury concerning future pregnancies and mode of delivery?

All women who sustained OASIS in a previous pregnancy should be counselled about the mode of delivery and this should be clearly documented in the notes.

✓

The role of prophylactic episiotomy in subsequent pregnancies is not known and therefore an episiotomy should only be performed if clinically indicated.

✓

All women who have sustained OASIS in a previous pregnancy and who are symptomatic or have abnormal endoanal ultrasonography and/or manometry should be counselled regarding the option of elective caesarean birth.



There were no systematic reviews or randomised controlled trials to suggest the best method of delivery following OASIS. The risk of sustaining a further third- or fourth-degree tear after a subsequent delivery is 5-7%.^{56,57} The risks of a subsequent vaginal delivery after a third-degree tear have been assessed, with 17% of women developing worsening faecal symptoms after a second vaginal delivery.⁵⁸⁻⁶¹ This seemed to occur if there had been faecal incontinence beyond 3 months but resolution by 6 months after the index delivery.⁶⁰

Evidence level 4

There are no studies to suggest that prophylactic episiotomy in the subsequent delivery would prevent OASIS. Hence the decision to perform an episiotomy during the subsequent delivery after previous OASIS needs to be a clinical decision independent of the previous OASIS.

All women who have suffered OASIS should be counselled regarding the mode of delivery and this should be clearly documented in the notes. If the woman is symptomatic or shows abnormally low anorectal manometric pressures and/or endoanal ultrasonographic defects, an elective caesarean section may be considered.³⁹ One prospective study of pregnant women who previously sustained OASIS evaluated a protocol in which women who had a sonographic defect of the external sphincter of more than 30 degrees accompanied by an incremental squeeze pressure of less than 20 mmHg were offered a caesarean section. All other women were advised to have a vaginal delivery. Short-term follow-up of this cohort of 73 women showed that the women who underwent vaginal delivery suffered no significant deterioration in anal sphincter function or quality of life.⁵⁶

Evidence level 4

13. Risk management

13.1 *What processes and policies should be in place for women who have sustained obstetric OASIS?*

Units should have a clear protocol for the management of OASIS.



Documentation of the anatomical structures involved, the method of repair and the suture materials should be made.



The woman should be fully informed about the nature of her tear and the offer of follow-up should be made, all supported by relevant written information.



There has been a rise in litigation related to OASIS. The majority of cases are related to failure to identify the injury after delivery, leading to subsequent anal incontinence and rectovaginal and anovaginal fistulae.⁶² From 1 April 2000 to 31 March 2010, there were 441 claims in England in which allegations of negligence were made arising out of obstetric perineal trauma (the fourth highest number of claims in obstetrics). The total value of those claims, including both damages and legal costs, was estimated to be £31.2 million and 85% of these claims were related to misdiagnosis of perineal trauma.⁶²

At present, the occurrence of OASIS is not considered substandard care because it is a known complication of vaginal delivery. However, failure to recognise anal sphincter damage or carry out an adequate repair may be considered substandard care. A poor technique, poor selection of materials or poor healing may cause a repair to fail.⁶³

Clear documentation, preferably using a drawing, together with providing the woman with an explanation and patient information leaflet, is important.⁵⁴

14. Recommendations for future research

There is a lack of evidence to inform decision making regarding the optimal mode of delivery following OASIS. This needs to be addressed by encouraging participation in multicentre randomised controlled trials.

Further research is required into patient acceptability of endoanal ultrasound and the interpretation of endoanal ultrasound in detecting residual anal sphincter defects immediately after primary surgical repair.

The need for secondary surgery in women who have had OASIS should be investigated.

15. Auditable topics

Organisations should audit the recognition of OASIS and institute a protocol for repair and follow-up. Collected data should be audited against recommended/locally agreed standards.

- Incidence of OASIS compared with reported incidence of less than 3% in the UK.
- 100% evidence of adequate documentation of systematic examination of the vagina, perineum and rectum prior to suturing of OASIS.
- 100% of OASIS repaired with documented evidence of type of analgesia, suture material, method of repair and grade of operator.
- 100% of women with OASIS receiving postoperative advice as per local protocol and follow-up appointment.
- 100% of doctors and midwives undertaking repair of OASIS have attended recognised training courses.

16. Useful links and support groups

- Bladder and Bowel Foundation [<http://www.bladderandbowelfoundation.org/bowel/>].
- Royal College of Obstetricians and Gynaecologists. *A third- or fourth-degree tear during birth: Information for you*. London: RCOG; 2015.

References

1. Gurol-Urganci I, Cromwell DA, Edozien LC, Mahmood TA, Adams EJ, Richmond DH, et al. Third- and fourth-degree perineal tears among primiparous women in England between 2000 and 2012: time trends and risk factors. *BJOG* 2013;120:1516–25.
2. Thiagamorthy G, Johnson A, Thakar R, Sultan AH. National survey of perineal trauma and its subsequent management in the United Kingdom. *Int Urogynecol J* 2014;25:1621–7.
3. Baghurst PA. The case for retaining severe perineal tears as an indicator of the quality of obstetric care. *Aust N Z J Obstet Gynaecol* 2013;53:3–8.
4. Andrews V, Shelmerdine S, Sultan AH, Thakar R. Anal and urinary incontinence 4 years after a vaginal delivery. *Int Urogynecol J* 2013;24:55–60.
5. Sultan AH. Obstetric perineal injury and anal incontinence. *Clin Risk* 1999;5:193–6.
6. Koelbl H, Igawa T, Salvatore S, Laterza RM, Lowry A, Sievert KD, et al. Pathophysiology of urinary incontinence, faecal incontinence and pelvic organ prolapse. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. *Incontinence*. 5th ed. [place unknown]: ICUD-EAU; 2013. p. 261–359.
7. Thakar R, Fenner DE. Anatomy of the Perineum and the Anal Sphincter. In: Sultan AH, Thakar R, Fenner DE, editors. *Perineal and anal sphincter trauma*. London: Springer; 2007. p. 1–12.
8. Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al.; International Urogynecological Association; International Continence Society. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Neurourol Urodyn* 2010;29:4–20.
9. Roos AM, Thakar R, Sultan AH. Outcome of primary repair of obstetric anal sphincter injuries (OASIS): does the grade of tear matter? *Ultrasound Obstet Gynecol* 2010;36:368–74.
10. De Leeuw JW, Vierhout ME, Struijk PC, Hop WC, Wallenburg HC. Anal sphincter damage after vaginal delivery: functional outcome and risk factors for fecal incontinence. *Acta Obstet Gynecol Scand* 2001;80:830–4.
11. Mahony R, Behan M, Daly L, Kirwan C, O’Herlihy C, O’Connell PR. Internal anal sphincter defect influences continence outcome following obstetric anal sphincter injury. *Am J Obstet Gynecol* 2007;196:217.e1–5.
12. Visscher AP, Lam TJ, Hart N, Felt-Bersma RJ. Fecal incontinence, sexual complaints, and anorectal function after third-degree obstetric anal sphincter injury (OASIS): 5-year follow-up. *Int Urogynecol J* 2014;25:607–13.
13. Sultan AH, Kettle C. Diagnosis of Perineal Trauma. In: Sultan AH, Thakar R, Fenner DE, editors. *Perineal and anal sphincter trauma*. London: Springer; 2007. p. 13–9.


14. Richter HE, Brumfield CG, Cliver SP, Burgio KL, Neely CL, Varner RE. Risk factors associated with anal sphincter tear: a comparison of primiparous patients, vaginal births after cesarean deliveries, and patients with previous vaginal delivery. *Am J Obstet Gynecol* 2002;187:1194-8.
15. McLeod NL, Gilmour DT, Joseph KS, Farrell SA, Luther ER. Trends in major risk factors for anal sphincter lacerations: a 10-year study. *J Obstet Gynaecol Can* 2003;25:586-93.
16. Williams A, Tincello DG, White S, Adams EJ, Alfirevic Z, Richmond DH. Risk scoring system for prediction of obstetric anal sphincter injury. *BJOG* 2005;112:1066-9.
17. Edozien LC, Gurol-Urganci I, Cromwell DA, Adams EJ, Richmond DH, Mahmood TA, et al. Impact of third- and fourth-degree perineal tears at first birth on subsequent pregnancy outcomes: a cohort study. *BJOG* 2014;121:1695-704.
18. Fritel X, Schaal JP, Fauconnier A, Bertrand V, Levet C, Pigné A. Pelvic floor disorders 4 years after first delivery: a comparative study of restrictive versus systematic episiotomy. *BJOG* 2008;115:247-52.
19. de Vogel J, van der Leeuw-van Beek A, Gietelink D, Vujkovic M, de Leeuw JW, van Bavel J, et al. The effect of a mediolateral episiotomy during operative vaginal delivery on the risk of developing obstetrical anal sphincter injuries. *Am J Obstet Gynecol* 2012;206:404.e1-5.
20. Räisänen S, Vehviläinen-Julkunen K, Heinonen S. Need for and consequences of episiotomy in vaginal birth: a critical approach. *Midwifery* 2010;26:348-56.
21. Eogan M, Daly L, O'Connell PR, O'Herlihy C. Does the angle of episiotomy affect the incidence of anal sphincter injury? *BJOG* 2006;113:190-4.
22. Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, Vonon B, Øian P. Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study. *BJOG* 2012;119:724-30.
23. National Institute for Health and Clinical Excellence. *Intrapartum care: Care of healthy women and their babies during childbirth*. NICE clinical guideline 55. Manchester: NICE; 2007.
24. Kalis V, Landsmanova J, Bednarova B, Karbanova J, Laine K, Rokyta Z. Evaluation of the incision angle of mediolateral episiotomy at 60 degrees. *Int J Gynaecol Obstet* 2011;112:220-4.
25. Tincello DG, Williams A, Fowler GE, Adams EJ, Richmond DH, Alfirevic Z. Differences in episiotomy technique between midwives and doctors. *BJOG* 2003;110:1041-4.
26. Andrews V, Thakar R, Sultan AH, Jones PW. Are mediolateral episiotomies actually mediolateral? *BJOG* 2005;112:1156-8.
27. Freeman RM, Hollands HJ, Barron LF, Kapoor DS. Cutting a mediolateral episiotomy at the correct angle: evaluation of a new device, the Episcissors-60. *Med Devices (Auckl)* 2014;7:23-8.
28. Patel RP, Ubale SM. Evaluation of the angled Episcissors-60® episiotomy scissors in spontaneous vaginal deliveries. *Med Devices (Auckl)* 2014;7:253-6.
29. Hals E, Øian P, Pirhonen T, Gissler M, Hjelle S, Nilsen EB, et al. A multicenter interventional program to reduce the incidence of anal sphincter tears. *Obstet Gynecol* 2010;116:901-8.
30. Laine K, Skjeldestad FE, Sandvik L, Staff AC. Incidence of obstetric anal sphincter injuries after training to protect the perineum: cohort study. *BMJ Open* 2012;2:e001649.
31. Jönsson ER, Elfaghi I, Rydhström H, Herbst A. Modified Ritgen's maneuver for anal sphincter injury at delivery: a randomized controlled trial. *Obstet Gynecol* 2008;112:212-7.
32. Aasheim V, Nilsen AB, Lukasse M, Reinar LM. Perineal techniques during the second stage of labour for reducing perineal trauma. *Cochrane Database Syst Rev* 2011;(12):CD006672.
33. Beckmann MM, Stock OM. Antenatal perineal massage for reducing perineal trauma. *Cochrane Database Syst Rev* 2013;(4):CD005123.
34. Stamp G, Kruzins G, Crowther C. Perineal massage in labour and prevention of perineal trauma: randomised controlled trial. *BMJ* 2001;322:1277-80.
35. Groom KM, Paterson-Brown S. Can we improve on the diagnosis of third degree tears? *Eur J Obstet Gynecol Reprod Biol* 2002;101:19-21.
36. Sultan AH, Kamm MA, Hudson CN, Thomas JM, Bartram CI. Anal-sphincter disruption during vaginal delivery. *N Engl J Med* 1993;329:1905-11.
37. Andrews V, Sultan AH, Thakar R, Jones PW. Occult anal sphincter injuries—myth or reality? *BJOG* 2006;113:195-200.
38. Fernando RJ, Sultan AH, Radley S, Jones PW, Johanson RB. Management of obstetric anal sphincter injury: a systematic review & national practice survey. *BMC Health Serv Res* 2002;2:9.
39. Sultan AH, Thakar R. Lower genital tract and anal sphincter trauma. *Best Pract Res Clin Obstet Gynaecol* 2002;16:99-115.
40. Sultan AH, Monga AK, Kumar D, Stanton SL. Primary repair of obstetric anal sphincter rupture using the overlap technique. *Br J Obstet Gynaecol* 1999;106:318-23.
41. Fernando RJ, Sultan AH, Kettle C, Thakar R. Methods of repair for obstetric anal sphincter injury. *Cochrane Database Syst Rev* 2013;(12):CD002866.
42. Williams A, Adams EJ, Tincello DG, Alfirevic Z, Walkinshaw SA, Richmond DH. How to repair an anal sphincter injury after vaginal delivery: results of a randomised controlled trial. *BJOG* 2006;113:201-7.
43. Fitzpatrick M, Behan M, O'Connell PR, O'Herlihy C. A randomized clinical trial comparing primary overlap with approximation repair of third-degree obstetric tears. *Am J Obstet Gynecol* 2000;183:1220-4.
44. Garcia V, Rogers RG, Kim SS, Hall RJ, Kammerer-Doak DN. Primary repair of obstetric anal sphincter laceration: a randomized trial of two surgical techniques. *Am J Obstet Gynecol* 2005;192:1697-701.
45. Fernando RJ, Sultan AH, Kettle C, Radley S, Jones P, O'Brien PM. Repair techniques for obstetric anal sphincter injuries: a randomized controlled trial. *Obstet Gynecol* 2006;107:1261-8.
46. Pronk P, Van Leeuwen E, Albicher C, Dermout SM, Doornbos JP, Engel AF. Temporal endosonographic evaluation of anal sphincter integrity after primary repair for obstetric ruptures: a case for specific training of obstetricians. *Colorectal Dis* 2010;12:e140-4.
47. Andrews V, Thakar R, Sultan AH. Structured hands-on training in repair of obstetric anal sphincter injuries (OASIS): an audit of clinical practice. *Int Urogynecol J Pelvic Floor Dysfunct* 2009;20:193-9.
48. Royal College of Obstetricians and Gynaecologists. Core Module 12: Postpartum Problems (the Puerperium) [https://www.rcog.org.uk/globalassets/documents/careers-and-training/core-curriculum/2013-05-16_core_module_12.pdf]. Accessed 2014 Oct 2.
49. Buppasiri P, Lumbiganon P, Thinkhamrop J, Thinkhamrop B. Antibiotic prophylaxis for third- and fourth-degree perineal tear during vaginal birth. *Cochrane Database Syst Rev* 2010;(11):CD005125.
50. Mahony R, Behan M, O'Herlihy C, O'Connell PR. Randomized, clinical trial of bowel confinement vs. laxative use after primary repair of a third-degree obstetric anal sphincter tear. *Dis Colon Rectum* 2004;47:12-7.
51. Eogan M, Daly L, Behan M, O'Connell PR, O'Herlihy C. Randomised clinical trial of a laxative alone versus a laxative and a bulking agent after primary repair of obstetric anal sphincter injury. *BJOG* 2007;114:736-40.
52. Peirce C, Murphy C, Fitzpatrick M, Cassidy M, Daly L, O'Connell PR, et al. Randomised controlled trial comparing early home biofeedback physiotherapy with pelvic floor exercises for the treatment of third-degree tears (EBAPT Trial). *BJOG* 2013;120:1240-7.

53. Bugg GJ, Kiff ES, Hosker G. A new condition-specific health-related quality of life questionnaire for the assessment of women with anal incontinence. *BJOG* 2001;108:1057-67.
54. Royal College of Obstetricians and Gynaecologists. *A third- or fourth-degree tear during birth: Information for you*. London: RCOG; 2015.
55. Fowler G, Williams A, Murphy G, Taylor K, Wood C, Adams E. How to set up a perineal clinic. *The Obstetrician & Gynaecologist* 2009;11:129-32.
56. Scheer I, Thakar R, Sultan AH. Mode of delivery after previous obstetric anal sphincter injuries (OASIS)—a reappraisal? *Int Urogynecol J Pelvic Floor Dysfunct* 2009;20:1095-101.
57. Harkin R, Fitzpatrick M, O'Connell PR, O'Herlihy C. Anal sphincter disruption at vaginal delivery: is recurrence predictable? *Eur J Obstet Gynecol Reprod Biol* 2003;109:149-52.
58. Poen AC, Felt-Bersma RJ, Strijers RL, Dekker GA, Cuesta MA, Meuwissen SG. Third-degree obstetric perineal tear: long-term clinical and functional results after primary repair. *Br J Surg* 1998;85:1433-8.
59. Goffeng AR, Andersch B, Andersson M, Berndtsson I, Hulten L, Öresland T. Objective methods cannot predict anal incontinence after primary repair of extensive anal tears. *Acta Obstet Gynecol Scand* 1998;77:439-43.
60. Bek KM, Laurberg S. Risks of anal incontinence from subsequent vaginal delivery after a complete obstetric anal sphincter tear. *Br J Obstet Gynaecol* 1992;99:724-6.
61. Fynes M, Donnelly VS, O'Connell PR, O'Herlihy C. Cesarean delivery and anal sphincter injury. *Obstet Gynecol* 1998;92:496-500.
62. NHS Litigation Authority. *Ten Years of Maternity Claims. An Analysis of NHS Litigation Authority Data*. London: NHSLA; 2012.
63. Eddy A. Litigating and quantifying maternal damage following childbirth. *Clin Risk* 1999;5:178-80.

Appendix I: Explanation of guidelines and evidence levels

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 *Development of RCOG Green-top Guidelines* (available on the RCOG website at <http://www.rcog.org.uk/green-top-development>). 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	Grades of recommendations
1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias	A At least one meta-analysis, systematic review or randomised controlled trial rated as 1++, and directly applicable to the target population; or A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results
1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias	B A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
1- Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias	C A body of evidence including studies rated as 2+ directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
2++ High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal	D Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+
2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal	Good practice point
2- Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal	 Recommended best practice based on the clinical experience of the guideline development group
3 Non-analytical studies, e.g. case reports, case series	
4 Expert opinion	

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All RCOG guidance developers are asked to declare any conflicts of interest. A statement summarising any conflicts of interest for this guideline is available from: <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg29/>.

The final version is the responsibility of the Guidelines Committee of the RCOG.

The review process will commence in 2018, unless otherwise indicated.

DISCLAIMER

The Royal College of Obstetricians and Gynaecologists produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available.

This means that RCOG Guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.