

Methods of repair for obstetric anal sphincter injury (Review)

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ABSTRACT

Background

Anal sphincter injury during childbirth - obstetric anal sphincter injuries (OASIS) - is associated with significant maternal morbidity including perineal pain, dyspareunia and anal incontinence. Anal incontinence affects women psychologically and physically. Many do not seek medical attention because of embarrassment. The two recognised methods for the repair of damaged external anal sphincter (EAS): are end-to-end (approximation) repair and overlap repair.

Objectives

To compare the effectiveness of overlap repair versus end-to-end repair following OASIS in reducing subsequent anal incontinence, perineal pain, dyspareunia and improving quality of life.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 January 2006), MEDLINE (January 1966 to 31 January 2006), EMBASE (January 1974 to 31 January 2006), SciSearch (January 1974 to 31 January 2006) and conference proceedings of obstetrics and gynaecology, surgery and coloproctology.

Selection criteria

Randomised controlled trials comparing different techniques of immediate primary repair of EAS following OASIS.

Data collection and analysis

Trial quality was assessed independently by all authors.

Main results

Three eligible trials, of grade A quality, involving 279 women, were included. 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 (relative risk (RR) 0.08, 95% confidence interval (CI) 0.00 to 1.45, one trial, 52 women), dyspareunia (RR 0.62, 95% CI 0.11 to 3.39, one trial, 52 women), flatus incontinence (RR 0.93, 95% CI 0.26 to 3.31, one trial, 52 women) and faecal incontinence (RR 0.07, 95% CI 0.00 to 1.21, one trial, 52 women) between the two repair techniques at 12 months but showed a statistically significantly lower incidence in faecal urgency (RR 0.12, 95% CI 0.02 to 0.86, one trial, 52 women) and lower anal incontinence score (weighted mean difference -1.70, 95% CI -3.03 to -0.37) in the overlap group. 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 to 0.79, one trial, 41 women). There was no significant difference in quality of life.

Authors' conclusions

The limited data available show that compared to immediate primary end-to-end repair of OASIS, early primary overlap repair appears to be associated with lower risks for faecal urgency and anal incontinence symptoms. As the experience of the surgeon is not addressed in the three studies reviewed, it would be inappropriate to recommend one type of repair in favour of another.

PLAIN LANGUAGE SUMMARY

Ways of repairing damage to the muscles of the back passage following tearing during a difficult vaginal birth

Most women give birth without any significant damage to their perineums or back passages. However, occasionally, in about 1% to 4% of births, there is tearing and damage which extends to the back passage, and this can cause considerable problems for some of these women in terms of pain, incontinence and painful intercourse. For a few of these women, the incontinence can be very embarrassing and can impact significantly on their daily lives and relationships. The review of trials compared two different stitching techniques, one where the edges were overlapped and the other where they were sewn end-to-end. There was an insufficient number of women (279) in the three trials to be able to report anything with a reasonable degree of confidence. The overlap technique appeared to be better in terms of feelings of urgency and incontinence, though these data were from just one small trial. Further research is needed and this research needs to address women's views and experiences.

BACKGROUND

Perineal trauma sometimes occurs spontaneously during vaginal delivery (Sultan 1994a). However, a cut (episiotomy) may be made to facilitate the birth. Until recently there has been inconsistency in the classification of perineal trauma (Sultan 2002). This caused confusion among the clinicians in identification and management resulting in systematic under-reporting and misclassification (Sultan 1995). A survey amongst consultant obstetricians in the UK in 2000 revealed that 46% were still classifying a complete or partial injury to the external anal sphincter (EAS) as a second-degree tear (Fernando 2000). The current classification of perineal trauma was modified by Sultan in 1999 (Sultan 1999b) and has been adopted by the Royal College of Obstetricians and Gynaecologists (RCOG 2001) and the International Consultation on Incontinence (Norton 2002):

- first-degree perineal tear: injury to the skin only;
- second-degree perineal tear: injury to the perineum involving perineal muscles but not involving the anal sphincter;
- third-degree perineal tear: injury to the perineum involving the anal sphincter complex: 3a: less than 50% of EAS thickness torn; 3b: more than 50% of EAS thickness torn; 3c: internal anal sphincter (IAS) torn;
- fourth-degree perineal tear: injury to the perineum involving the anal sphincter complex (EAS and IAS) and ano-rectal epithelium.

Obstetric anal sphincter injuries (OASIS) include only third- or fourth-degree perineal tears and may cause considerable morbidity when compared to first- or second-degree perineal tears.

One of the most distressing immediate complications of any perineal injury is perineal pain which may interfere with mother's abilities to breastfeed and cope with the daily tasks of motherhood (Sleep 1991). Short-term perineal pain is associated with reactionary oedema, bruising, tight sutures, infection and wound breakdown. Persistent pain and discomfort from perineal trauma may also cause urinary retention and defecation problems. Several

studies reported that following OASIS, perineal pain and dyspareunia (painful sexual intercourse) may last for several years and up to 50% of women complained of perineal pain and dyspareunia following OASIS (Haadem 1987; Haadem 1990; Sultan 1994b). Long-term perineal pain and dyspareunia can have considerable impact on sexual and social wellbeing (Giebel 1993). Wheelless 1998 reported that some women with dyspareunia following OASIS abstained from sexual intercourse for up to 14 years. Sorensen 1988 reported that there is also a significant permanent disfigurement of the perineum following OASIS.

Abscess formation, wound breakdown and recto-vaginal fistulae (abnormal communication between rectum and vagina) have been reported following OASIS (Combs 1990; Corman 1980; Goldberg 1980; Pezim 1987; Rothenberger 1982). Venkatesh 1989 reported a 10% perineal wound disruption rate following primary repair of OASIS. Giebel 1993 reported that most rectovaginal fistulae were caused by failure to recognise the true extent of OASIS at the time of repair resulting in inadequate sphincter reconstruction and subsequent wound breakdown. Recto-vaginal fistulae are difficult to treat and may ultimately result in permanent colostomy (Giebel 1993; Pezim 1987).

In addition to perineal pain, dyspareunia, wound breakdown and recto-vaginal fistulae formation (abnormal communication between rectum and vagina), OASIS has been reported as the most common cause of anal incontinence following childbirth (Sultan 1997). Anal incontinence is defined by the International Continence Society as involuntary loss of flatus or faeces which becomes a social or hygienic problem (Norton 2002). It is estimated that anal incontinence affects one in 20 women up to one year after childbirth, affecting nearly 40,000 mothers each year in the UK (Clarkson 2001; Glazener 1995; Glazener 1997; Glazener 1998; Macarthur 1991). One third of these are considered to be due to clinically undiagnosed (occult) anal sphincter injury (Sultan 1993). The reported incidence of anal incontinence following primary repair of recognised anal sphincter injury has been between 15% and 59% (Norton 2002).

Anal incontinence affects women psychologically as well as phys-

ically. Many of them do not seek medical attention because of embarrassment engendered by these taboo symptoms (Browning 1983; DOH 2000; Gjessing 1998; Haadam 1988; Sultan 1993; Sultan 1994b; Wood 1998). Wood 1998 reported that the majority of women who sustained OASIS were either unaware of the diagnosis or were given a poor explanation for the injury. Indeed, some women were discouraged from discussing this because they felt that the anal incontinence symptoms were a normal consequence of childbirth (Haadam 1988; Walsh 1996). In one study only one third of women with faecal incontinence had ever discussed the problem with a physician (Johanson 1996). One woman, in a letter to the Continence Foundation, described the eternal shame of being with another person when the worst occurs (Contin. Found. 2000). The impact of this complication on the vulnerable postnatal woman and her baby is potentially catastrophic, affecting her physically and psychosocially. Furthermore, anal incontinence caused by OASIS has been reported to be associated with very high cumulative costs for the health services (Mellgren 1999).

Increased awareness of these complications following vaginal birth has led women to request elective caesarean section without any other medical indication. A survey of female obstetricians reported that 31% would choose an elective caesarean section even in an uncomplicated pregnancy. The reason given by the majority was the potential risk of perineal trauma (Al-Mufti 1996). However, caesarean delivery is associated with an increased risk of maternal morbidity compared with vaginal birth (NICE 2004).

The reported incidence of clinically detectable OASIS in the world literature is in the range of 0.5% to 3% with medio-lateral episiotomy (Sultan 1994b; Tetzschner 1996; Ustul Fornell 1996), but there are some reports with an incidence as high as 17% with midline episiotomy (Fenner 2003).

Over the last five years, there has been an increase in litigation related to anal sphincter injury during childbirth and subsequent complications including faecal incontinence (Eddy 1999).

The risk factors for OASIS include midline episiotomy (Fenner 2003) forceps delivery (Sultan 1994b) and occipito-posterior position (Fitzpatrick 2001) at delivery and birthweight more than 4 kg (Sultan 1994b). Like other perineal trauma, it is less likely in subsequent pregnancies (Poeh 1997; Walsh 1996).

There are two recognised methods for the repair of damaged external anal sphincter, that is, end-to-end (approximation) repair and overlap repair. In the end-to-end method, the torn ends of the external anal sphincter are approximated together and sutured without any overlap of the muscle. In the overlap method, the torn ends of the external anal sphincter are brought together and sutured by overlapping one end of the muscle over the other in a double-breasted fashion (Sultan 1999a). At present about half of the consultants in the UK use the end-to-end method and the other half use the overlap method (Fernando 2000). Repair of

OASIS is carried out immediately after detection and is defined as 'primary' repair. This is in contrast to 'secondary' repair which is carried out several months or years after the initial injury which may not be related to childbirth. Secondary repair is carried out by coloproctologists as a treatment for anal incontinence.

The degree of anal incontinence can be measured by incontinence scoring systems (Vaizey 1999) or by quality of life assessment (Rockwood 2000). Both these methods involve using validated questionnaires inquiring about different aspects of incontinence and how this affects the individual's day-to-day life. These scores range from 0 to 24, with 0 indicating complete continence and 24 indicating complete incontinence.

The anatomy of the anal sphincter can be assessed by anal endosonography using an ultrasound probe. With this method, the extent of damage and degree of healing of the external and internal anal sphincter can be clearly seen. Another technique, ano-rectal manometry, measures the pressure in the anal canal at rest and during voluntary squeeze.

There are several important questions related to the management of OASIS. These include the method of repair, suture materials used for the repair, the ideal clinician to perform the repair (obstetrician or colorectal surgeon), effectiveness of immediate versus delayed repair, prevention of OASIS and mode of delivery in subsequent pregnancies. The authors regard each of these questions as being important for future review. However, the aim of the current review is to examine the available studies to determine whether there is any clear scientific evidence that repair technique has any effect on subsequent continence and quality of life. Use of prophylactic antibiotics has been addressed in a separate Cochrane review by Buppasiri et al (Buppasiri 2005).

OBJECTIVES

The objective of this review is to compare the effectiveness of overlap repair versus end-to-end repair following obstetric anal sphincter injuries in terms of preventing subsequent anal incontinence, perineal pain, dyspareunia and general improvement in the quality of life.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomised controlled trials, which compared primary overlap versus end-to-end repair of obstetric anal sphincter injuries (OASIS), were included in this review.

Types of participants

All women who sustained OASIS and in whom the repair was performed in the immediate postpartum period (primary repair).

Types of intervention

All randomised controlled comparisons of overlap versus end-to-end technique following OASIS.

Types of outcome measures

The main focus is on outcome measures relating to short- and long-term postpartum morbidity.

The main outcome measures were:

- (1) anal incontinence symptoms;
- (2) perineal pain;
- (3) dyspareunia;
- (4) quality of life assessment.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (30 January 2006).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

- (1) quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
- (2) monthly searches of MEDLINE;
- (3) handsearches of 30 journals and the proceedings of major conferences;
- (4) weekly current awareness search of a further 37 journals.

Details of the search strategies for CENTRAL and MEDLINE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Search strategies for identification of studies' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are given a code (or codes) depending on the topic. The codes are linked to review topics. The Trials Search Co-ordinator searches the register for each review using these codes rather than keywords.

In addition, we searched:

MEDLINE (January 1966 to 31 January 2006);
EMBASE (January 1974 to 31 January 2006);
SciSearch (January 1974 to 31 January 2006).

The search terms used were:

perin*, anal sphincter AND tear*, rupture*, trauma, damage, injur* AND labor, labour, birth, childbirth, delivery.

Also

obstetric* AND tear*, rupture*, injur*, damage, trauma

In addition, we searched conference proceedings of associations of obstetrics and gynaecology (British Congress of Obstetrics & Gynaecology, Blair-Bell Research Society meetings) surgery and coloproctology (Annual meetings of Coloproctologists of the Great Britain and Ireland) and Urogynaecology (International Urogynaecology Association meetings and International Continence Society meetings) up to March 2005.

We did not apply any language restrictions.

METHODS OF THE REVIEW

The five review authors (Ruwan Fernando, Chris Kettle, Abdul Sultan, Simon Radley and Raneer Thakar) independently assessed and selected trials for inclusion in the review and reasons for exclusion of any trial are clearly stated.

We resolved disagreements by discussion.

The trials were assessed according to the following three main criteria.

- (1) Method of allocation to treatment (for example, by centrally-controlled randomisation such as computer-randomisation, by random number tables or by quasi-randomisation methods such as alternation or medical record numbers).
- (2) Adequate documentation of how exclusions were handled after treatment allocation to facilitate intention-to-treat analysis and methods sought to minimise loss for follow up.
- (3) Adequate blinding of outcome assessment.

Letters were used to indicate the quality of the included trials; for example, A was used to indicate a trial which has a high level of quality in which all the criteria were met, B was used to indicate that one or more criteria were partially met or if it is unclear if all the criteria were met, and C was used if one or more criteria were not met (Higgins 2005).

The methodological quality of each trial was independently assessed by the same five authors. Details of randomisation, blinding of outcome assessment and handling of exclusions were documented. Data on all randomised women irrespective of compliance to treatment allocation or if the participant was excluded from follow up were sought to allow an intention-to-treat analysis. If any of the above data were not available in the publication or if it was unclear if the criteria were met, we sought additional information from the trialists.

Data were entered directly from the published reports into the Review Manager software (RevMan 2003) and a second coder checked the accuracy of the entered data. Where data were not presented in a suitable format for data entry, or if data were missing, we sought additional information from the trialists by personal

communication in the form of a letter. We planned to perform sensitivity analyses by removing data from methodologically weak studies and comparing results.

Statistical analyses were undertaken using the Review Manager software (RevMan 2003) for calculations of the treatment effects as represented by the relative risks. Heterogeneity between trials was assessed using the I-squared statistic. No trials were identified as having high levels of heterogeneity (exceeding 50%). A fixed-effect meta-analysis was used as an overall summary.

DESCRIPTION OF STUDIES

Included studies

Three trials (Fernando 2005; Fitzpatrick 2000; Williams 2006) involving 279 women were included in this review. See 'Characteristics of included studies' for details.

There were considerable variations in outcome measures amongst the three included studies. Main outcome measures of the Fitzpatrick 2000 study were symptoms of faecal incontinence, abnormal findings relating to anal manometry investigations and abnormal findings on endoanal ultrasonography at three months post-partum. The primary outcome measure of the Fernando 2005 study was symptoms of faecal incontinence at 12 months. Secondary outcome measures included faecal urgency, perineal pain, dyspareunia and quality of life at three, six and 12 months, faecal incontinence at six weeks, three and six months, anal manometry, endoanal scan findings and improvement of anal incontinence symptoms at 12 months. Main outcome measures of the Williams 2006 study were suture related morbidity at six weeks, bowel symptoms at three, six and 12 months assessed by a validated questionnaire, anorectal physiology at three months and quality of life scores assessed by a validated questionnaire at three and 12 months.

All three studies compared primary overlap and primary end-to-end repair techniques of external anal sphincter (EAS) performed immediately after obstetric anal sphincter injuries (OASIS). Fitzpatrick 2000 performed a three month follow up while Williams 2006 and Fernando 2005 performed a 12 month follow up.

In addition to repair techniques, Williams 2006 compared two suture materials (polydioxanone and polyglactin) for the repair of EAS. But details of repair of perineal muscles, vaginal epithelium and perineal skin were not available for the authors. Fitzpatrick 2000 used long-acting monofilament absorbable sutures (2-0 Maxon) for the repair of EAS and 2-0 Dexon sutures were used to reconstruct the perineal body and suture the vaginal and perineal skin. Fernando 2005 used 3-0 polydioxanone for the repair of internal anal sphincter (IAS) and EAS and continuous non-locking method of repair with fast absorbing 2-0 polyglactin sutures were used to repair the perineal muscles, vaginal epithelium and perineal skin.

There is a considerable variation in inclusion criteria in two these studies. Fitzpatrick 2000 and Williams 2006 included all women with partial or complete disruption of EAS whereas Fernando 2005 included only women with disruption of more than 50% thickness of EAS (grade 3b and 3c tears). In five of these women with grade 3b tears, the remaining fibres were divided in order to perform an overlap repair. Fitzpatrick and Williams performed the overlap in women with partial EAS tears.

In the Fitzpatrick 2000 and Williams 2006 studies, no attempt was made to identify and repair IAS separately. In contrast, Fernando 2005 repaired the IAS if it was torn and recognised at the time of repair.

Fitzpatrick 2000, Fernando 2005 and Williams 2006 performed the repairs under regional or general anaesthesia, in the operating theatre under aseptic conditions with antibiotic cover. In all studies repairs were carried out by trained clinicians. Following repair, Fitzpatrick 2000 prescribed a codeine based constipating agent for three days followed by a laxative regimen for five days or until defecation occurred whereas Fernando 2005 and Williams 2006 prescribed a bulking agent (Fybogel) and a stool softener (Lactulose) for 10 days after the repair.

Two studies (Fernando 2005; Fitzpatrick 2000) used questionnaires and modified Wexner scoring system for anal incontinence (Jorge 1993; Vaizey 1999) for subjective assessment of symptoms during follow up. In addition, Fernando 2005 used Minneapolis Quality of life scoring system (Rockwood 2000). These scores range from 0 to 24 where 0 indicates complete continence and 24 indicates complete incontinence. Fitzpatrick 2000 used the questionnaire and scoring system at three months after the repair whereas Fernando 2005 used the questionnaires and scoring systems at 6 weeks, three, six and 12 months after the repair. In addition to modified Wexner scoring system, Williams 2006 used the Manchester Health Questionnaire (Bugg 2001) to assess quality of life.

In addition, all three studies objectively assessed anal sphincter function using endoanal ultrasonography and manometry. Fitzpatrick 2000 and Williams 2006 assessed at three months and Fernando 2005 assessed at six and 12 months.

Excluded study

One trial was excluded because the repair of EAS was not performed immediately after OASIS but was regarded as secondary repair (Goh 2004). In addition, this study included some women who had previous anal sphincter repair for anal incontinence and included postmenopausal women.

METHODOLOGICAL QUALITY

All three included studies have clearly described the method used to calculate the power of study (number of participants necessary

to achieve statistical significance). Fitzpatrick 2000 calculated that 110 women were required based on the assumption of a 30% difference in symptoms between the two techniques with 90% probability. Fernando 2005 calculated the power based on two previous observational studies (Sultan 1994b; Sultan 1999a) and required 64 women to demonstrate a reduction in anal incontinence from 46% to 8% with 90% probability. Williams 2006 calculated the power based on the assumption that absorbable sutures would reduce suture-related morbidity from 30% to less than 1% compared with non-absorbable sutures and that the overlapping technique would reduce suture-related morbidity (defined as above) from 30% to less than 1% compared with end-to-end anastomoses.

Methodological quality of two of the included studies (Fernando 2005; Williams 2006) was rated as 'A' which indicates adequate allocation concealment. Fitzpatrick 2000 and Williams 2006 both used sealed-envelope randomisation, Williams 2006 stating the envelopes were opaque. Fernando 2005 used a computer-randomisation package. Only two clinicians who carried out the repairs had access to this password-protected computer-randomisation package. Once the details of the participants were entered, the computer programme generated the treatment allocation randomly. Twelve women out of 64 (19%) women in the Fernando study (Fernando 2005) and 43/103 (42%) women in the Williams study (Williams 2006) were lost to follow up. All three studies clearly documented the steps taken to minimise the loss to follow up.

The authors accept that it is impossible to blind the surgeon to the method of repair in these types of studies. However, the authors assessed the blinding of objective assessments such as endoanal ultrasonography and anal manometry at the time of performing the investigation and analysing the data. The blinding of the assessments carried out in the Fitzpatrick 2000 study was not clear. In the study carried out by Fernando 2005, the individuals who performed and reported the endoanal ultrasonography and the person who performed the anal manometry were blinded to the technique of repair.

RESULTS

Three trials involving 279 women were included in this review.

Perineal pain

It was somewhat difficult to compare the degree of perineal pain in the three included studies because of different definitions and different time intervals. Fitzpatrick 2000 sub-divided perineal pain into perineal discomfort and need for perineal injection with local anaesthetic at three months. Fernando 2005 reported rates of perineal pain at six weeks, three, six and 12 months. Williams 2006 reported perineal pain and dyspareunia together at six weeks, three, six, and 12 months.

Meta-analysis of perineal pain at six weeks (relative risk (RR) 0.97, 95% confidence interval (CI) 0.42 to 2.26, one trial, 63 women),

three months (RR 0.85, 95% CI 0.54 to 1.34, two trials, 172 women), six months (RR 0.25, 95% CI 0.03 to 2.10, one trial, 56 women) and 12 months (RR 0.08, 95% CI 0.00 to 1.45, one trial, 52 women) showed no statistically significant difference between overlap and end-to-end techniques. There was also no statistically significant difference in the need for perineal injection with a local anaesthetic between the two repair techniques (RR 0.96, 95% CI 0.48 to 1.91, one trial, 112 women). Combined perineal pain and dyspareunia at six weeks (RR 0.71, 95% CI 0.27 to 1.84, one trial, 103 women), three months (RR 1.79, 95% CI 0.83 to 3.84, one trial, 89 women), six months (RR 0.38, 95% CI 0.11 to 1.36, one trial, 79 women) and 12 months (RR 0.35, 95% CI 0.07 to 1.66, one trial, 60 women) also did not show a statistically significant difference between the two repair techniques.

Dyspareunia

There was no statistically significant difference in dyspareunia at three months (RR 0.82, 95% CI 0.48 to 1.41, two trials, 172 women), six months (RR 0.86, 95% CI 0.33 to 2.23, one trial, 56 women) and 12 months (RR 0.62, 95% CI 0.11 to 3.39, one trial, 52 women) between the overlap and end-to-end groups.

Faecal urgency

Only Fernando 2005 reported incidence of faecal urgency at six weeks, three and 12 months. Fitzpatrick (Fitzpatrick 2000) reported faecal urgency at three months. Williams 2006 did not report incidence of faecal urgency. At six weeks (RR 1.09, 95% CI 0.48 to 2.46, one trial, 63 women) and three months (RR 0.68, 95% CI 0.42 to 1.09, two trials, 172 women) there was no statistically significant difference in faecal urgency between the two repair techniques (Fernando 2005; Fitzpatrick 2000). However, at six months (RR 0.22, 95% CI 0.05 to 0.94, one trial, 56 women) and 12 months (RR 0.12, 95% CI 0.02 to 0.86, one trial, 52 women) the overlap group reported a statistically significant reduction in the incidence of faecal urgency compared to end-to-end group.

Flatus incontinence

Fitzpatrick 2000 and Williams Williams 2006 did not report the incidence of flatus incontinence, whereas Fernando 2005 reported the incidence of flatus incontinence at six weeks (RR 0.48, 95% CI 0.13 to 1.77, one trial, 63 women), three months (RR 1.50, 95% CI 0.53 to 4.19, one trial, 60 women), six months (RR 1.75, 95% CI 0.58 to 5.32, one trial, 56 women) and 12 months (RR 0.93, 95% CI 0.26 to 3.31, one trial, 52 women). There was no statistically significant difference in flatus incontinence between the two intervention groups.

Faecal incontinence, alteration in faecal continence and anal incontinence score

Only Fernando 2005 reported the incidence of faecal incontinence separately at six weeks, three, six and 12 months whereas Fitzpatrick 2000 reported "alteration in faecal continence" at three months. Hence we analysed incidence of faecal incontinence from Fernando 2005 separately and incidence of "alteration in faecal continence" from the Fitzpatrick 2000 and Fernando 2005 stud-

ies separately. Williams 2006 did not report incidences of faecal incontinence or alteration of faecal continence.

Analysis of incidence of faecal incontinence at six weeks (RR 0.65, 95% CI 0.20 to 2.07, one trial, 63 women), three months (RR 0.24, 95% CI 0.06 to 1.01, one trial, 60 women), six months (RR 0.08, 95% CI 0.00 to 1.30, one trial, 56 women), and 12 months (RR 0.07, 95% CI 0.00 to 1.21, one trial, 52 women) did not show a statistically significant difference between the two repair techniques (Fernando 2005).

Analysis of alteration in faecal continence, which included Fitzpatrick 2000 and Fernando 2005, also revealed similar results. There was no difference in incidence of alteration in faecal continence at six weeks (RR 0.73, 95% CI 0.41 to 1.27, one trial, 63 women), three months (RR 0.85, 95% CI 0.64 to 1.14, two trials, 172 women) six months (RR 0.82, 95% CI 0.40 to 1.66, one trial, 56 women) and at 12 months (RR 0.46, 95% CI 0.18 to 1.17, one trial, 52 women).

All three studies reported mean anal incontinence scores. Fernando 2005 reported mean anal incontinence score at six weeks, three, six and 12 months whereas Fitzpatrick 2000 reported median anal incontinence score at three months. There was no statistically significant difference in mean anal incontinence score at six weeks, three and six months between the two repair techniques. However, meta-analysis at 12 months showed a statistically significant low anal incontinence score in the overlap group suggestive of better continence (weighted mean difference (WMD) -1.70, 95% CI -3.03 to -0.37 and -1.26, 95% CI -2.00 to -0.51 respectively). This result was based on the Fernando 2005 study where the confidence intervals were wide suggesting a skewness. Hence this data should be treated with caution. When analysing the overall number of participants with an anal incontinence score more than 10 (that is, clinically significant anal incontinence) at 12 months, there was no difference in anal incontinence score more than 10 between the two groups (RR 0.29, 95% CI 0.01 to 6.91, two trials 112 women).

Deterioration of anal incontinence symptoms

Out of the three included studies only Fernando 2005 analysed any improvement or deterioration of anal incontinence symptoms over 12 months. The meta-analysis showed a statistically significant fewer number of participants in the overlap group who reported deterioration of anal incontinence symptoms over the 12 months (RR 0.26, 95% CI 0.09 to 0.79, one trial, 41 women).

Quality of life assessment

Only Fernando 2005 reported quality of life assessment following two repair techniques from six weeks to 12 months based on scales described by Rockwood (Rockwood 2000). There are four subscales, addressing lifestyle (effect of incontinence on day-to-day activity), coping and behaviour (effect of incontinence on ability to cope with the situation and resulting behaviour), depression and self-perception (effect of incontinence on feelings and

self confidence), and embarrassment (incontinence causing embarrassment). Each scale ranges from one to five, one indicating lower functional status of quality of life. Analysis of quality of life at 12 months based on four scales showed no statistically significant difference between overlap and end-to-end in mean lifestyle scale (WMD 0.06, 95% CI -0.23 to 0.35, one trial, 52 women), mean coping and behaviour scale (WMD 0.13, 95% CI -0.24 to 0.50, one trial, 52 women) mean depression scale (WMD 0.00, 95% CI -0.26 to 0.26, one trial, 52 women) and mean embarrassment scale (WMD 0.20, 95% CI -0.14 to 0.54, one trial, 52 women).

DISCUSSION

There are three randomised controlled studies comparing immediate primary overlap and end-to-end techniques for obstetric anal sphincter injuries (OASIS). However, there was considerable heterogeneity in the outcome measures, time points and reported results amongst these studies which made it difficult to group them into similar outcome groups.

Meta-analysis showed that there was no statistically significant difference in perineal pain, dyspareunia, flatus incontinence and faecal incontinence between the two repair techniques at six weeks, three, six and 12 months after the repair. Only the study carried out by Fernando 2005 separately analysed faecal urgency symptoms and analysis showed a statistically significant lower incidence in faecal urgency in the overlap group at 12 months. When addressing the outcome of faecal incontinence by mean anal incontinence score and deterioration of anal incontinence symptoms over 12 months, the overlap group showed significantly lower relative risks compared to the end-to-end group.

The authors noted that the majority of weight in the meta-analysis was based only on one study where repairs were carried out by only two experienced clinicians (Fernando 2005) and the effect of the surgeon's experience in the outcome of repair technique is not addressed in any of these studies.

None of the studies reported incidence of re-repair and women's view with regards to the type of repair and subsequent outcome.

AUTHORS' CONCLUSIONS

Implications for practice

The limited data available show that, compared to immediate primary end-to-end repair of obstetric anal sphincter injuries (OASIS), immediate primary overlap repair appears to be associated with reduced risk for faecal urgency, anal incontinence score and deterioration of anal incontinence symptoms. As the majority of the results were based on one small randomised controlled trial

carried out by two experienced surgeons and the surgeon's experience is not addressed in any of the other two studies reviewed, it would be inappropriate to recommend one type of repair in favour of another.

Implications for research

This review clearly shows the limited research relating to the repair of OASIS and the need for future pragmatic studies with larger numbers. It also highlights the difficulty in analysing data from different studies because of heterogeneity. We recommend that future studies, addressing the repair techniques of OASIS, follow up women with predefined time periods such as six weeks, three, six and 12 months with validated questionnaires with predefined outcome measures such as faecal urgency, faecal incontinence and anal incontinence score. Outcome measures of future trials need to address quality of life issues that are important and meaningful to women, including the degree of disability caused by anal incontinence during day-to-day activities. However, at present there are no validated questionnaires to assess the quality of life affected by anal incontinence during day-to-day activity.

POTENTIAL CONFLICT OF INTEREST

Ruwan Fernando, Abdul Sultan, Chris Kettle and Simon Radley conducted a randomised controlled trial for overlap and end-to-end repair for obstetric anal sphincter injury (Fernando 2005).

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Consumer views as to what outcomes they would expect from this review were sought from women's local focus groups and the National Childbirth Trust's research and information group.

As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team), one or more members of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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* Indicates the major publication for the study

TABLES**Characteristics of included studies**

Study	Fernando 2005
Methods	Computer randomisation using minimisation.
Participants	64 women with 3b, 3c and 4th degree perineal tears following vaginal delivery at a hospital in Stoke-on-Trent, England. Parity: primiparae and multiparae. Mean age: 39.8. Operators: 2 trained clinicians.
Interventions	Method of repair: participants divided in to two groups: 1. overlap repair of EAS using 3-0 Polydioxanone sutures (n = 32); 2. end-to-end repair of EAS using 3-0 Polydioxanone sutures (n = 32).
Outcomes	1. Faecal incontinence at 12 months (primary outcome). 2. Faecal incontinence at 6 weeks, 3, 6 and 12 months. 3. Faecal urgency at 6 weeks, 3, 6 and 12 months. 4. Dyspareunia at 3, 6 and 12 months. 5. Perineal pain at 6 weeks, 3, 6 and 12 months. 6. Improvement of anal incontinence from 6 weeks to 12 months. 7. Mean anal incontinence score (based on Vaizey 1999). 8. Quality of life scales based on Rockwood 2000. 9. Anal manometry at 6 and 12 months. 10. Anal sphincter defects detected by endoanal ultrasonography at 6 and 12 months.
Notes	Method of repair: described. Exclusion criteria: described. Inclusion criteria described.
Allocation concealment	A – Adequate

Study Fitzpatrick 2000

Methods	Sealed-envelope randomisation.
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Characteristics of included studies (Continued)

Participants	112 women with 3rd and 4th degree perineal tears following vaginal delivery at a hospital in Dublin, Ireland. Parity: primigravidae. Mean age: not reported. Operators: experienced clinicians.
Interventions	Method of repair: participants divided into two groups: 1. overlap repair of EAS using 2-0 Maxon sutures (n = 55); 2. end-to-end repair of EAS using 2-0 Maxon sutures (n = 57).
Outcomes	Included in analysis: 1. faecal incontinence symptoms at 3 months. 2. fecal urgency at 3 months. 3. median continence score at 3 months (based on Jorge 1993). 4. perineal pain (sub-divided in to discomfort, apareunia and need for perineal injection of hyaluronidase and methylprednisolone) at 3 months. 5. anal manometry (median resting pressure, median squeeze pressure, median squeeze increment, vector symmetry index) at 3 months. 6. anal sphincter defects detected by endoanal ultrasonography at 3 months.
Notes	Method of repair: described. Exclusion criteria: described. Inclusion criteria described. Grades of 3rd degree tears were not described. Grade 3a tears can not be repaired by overlap technique unless the sphincter is completely divided. This aspect is not clarified in this study. Internal anal sphincter was not separately repaired.
Allocation concealment	B – Unclear

Study	Williams 2006
Methods	Sealed-envelope randomisation.
Participants	103 women with complete or partial 3rd degree tears and 4th degree tears following vaginal delivery in a hospital in Liverpool, England. Parity: primiparae and multiparae. Mean age: 29.
Interventions	Participants were divided into 4 groups: 1. overlap repair with Vicryl (n = 28); 2. overlap repair with PDS (n = 28); 3. end-to-end repair with Vicryl (n = 28); 4. end-to-end repair with PDS (n = 28).
Outcomes	1. Suture related morbidity at 6 weeks. 2. Bowel symptoms at 3, 6, and 12 months assessed by validated questionnaire. 3. Anorectal physiology at 3 months. 4. Quality of life scores assessed by validated questionnaire at 3 and 12 months.
Notes	Setting: Liverpool, United Kingdom. Method of repair: overlap and end-to-end.

Exclusion criteria: not available at the time of review.

Inclusion criteria: not available at the time of review.

Details of repair technique were not available at the time of review.

Allocation concealment	A – Adequate
EAS: external anal sphincter	
IAS: internal anal sphincter	
PDS: polydioxanone	

Characteristics of excluded studies

Study	Reason for exclusion
Goh 2004	The repair of EAS was not performed immediately after OASIS but was regarded as a secondary repair. In addition, these studies included some participants who had previous anal sphincter repair for anal incontinence and included postmenopausal women. It appears that participants from the Goh 2004 study were included in the Tjandra 2003 study.
EAS: external anal sphincter	
OASIS: obstetric anal sphincter injuries	

Characteristics of ongoing studies

Study	Johanson 2001
Trial name or title	The REPAIR study: recognition and expertise of in the prevention of anal incontinence from ruptured sphincter.
Participants	Any woman postpartum with complete obstetric anal sphincter rupture (3rd or 4th degree perineal tear), where an experienced clinician is available to perform the repair. Exclusions: women who have had previous surgery for obstetric repair or anal fistula.
Interventions	Repair of rupture.
Outcomes	Primary: anal incontinence one year after repair. Secondary: perineal pain, anal incontinence and faecal evacuation problems at 10 days breastfeeding.
Starting date	October 2001
Contact information	Linda Lucking; linda@kogs.freeseerve.co.uk
Notes	Details of this study are not known.

ANALYSES

Comparison 01. Overlap versus end-to-end

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Perineal pain			Relative Risk (Fixed) 95% CI	Subtotals only
02 Need for perineal injection at 3 months	1	112	Relative Risk (Fixed) 95% CI	0.96 [0.48, 1.91]
03 Dyspareunia			Relative Risk (Fixed) 95% CI	Subtotals only
04 Perineal pain/dyspareunia			Relative Risk (Fixed) 95% CI	Subtotals only
05 Faecal urgency			Relative Risk (Fixed) 95% CI	Subtotals only
06 Flatus incontinence			Relative Risk (Fixed) 95% CI	Subtotals only
07 Faecal incontinence			Relative Risk (Fixed) 95% CI	Subtotals only

Methods of repair for obstetric anal sphincter injury (Review)

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08 Alteration in faecal continence			Relative Risk (Fixed) 95% CI	Subtotals only
09 Anal incontinence score			Weighted Mean Difference (Fixed) 95% CI	Subtotals only
10 Anal incontinence score > 10			Relative Risk (Fixed) 95% CI	Subtotals only
11 Deterioration of anal incontinence symptoms	1	41	Relative Risk (Fixed) 95% CI	0.26 [0.09, 0.79]
12 Quality of life scale 1: lifestyle			Weighted Mean Difference (Fixed) 95% CI	Subtotals only
13 Quality of life scale 2: coping and behaviour			Weighted Mean Difference (Fixed) 95% CI	Subtotals only
14 Quality of life scale 3: depression and self-perception			Weighted Mean Difference (Fixed) 95% CI	Subtotals only
15 Quality of life scale 4: embarrassment			Weighted Mean Difference (Fixed) 95% CI	Subtotals only

INDEX TERMS

Medical Subject Headings (MeSH)

Anal Canal [*injuries; *surgery]; Dyspareunia [prevention & control]; Episiotomy [adverse effects]; Fecal Incontinence [surgery]; Obstetric Labor Complications [*surgery]; Perineum [injuries; surgery]; Quality of Life; Randomized Controlled Trials; *Suture Techniques

MeSH check words

Female; Humans; Pregnancy

COVER SHEET

Title	Methods of repair for obstetric anal sphincter injury
Authors	Fernando R, Sultan AH, Kettle C, Thakar R, Radley S
Contribution of author(s)	<p>(1) Ruwan Fernando: conceiving the review, designing the review, co-ordinating the review, data collection for the review, developing the search strategy, undertaking searches, screening search results, organising retrieval of papers, screening retrieved papers against inclusion criteria, appraising quality of papers, abstracting data from papers, obtaining and screening data on unpublished studies, data management for the review, entering data into Review Manager, analysis of data, interpretation of data, providing a methodological perspective, providing a clinical perspective, writing the review, guarantor for the review.</p> <p>(2) Abdul Sultan: conceiving the review, developing the search strategy, screening retrieved papers against inclusion criteria, appraising quality of papers, providing a clinical perspective, writing the review, providing general advice on the review.</p> <p>(3) Christine Kettle: conceiving the review, developing the search strategy, screening retrieved papers against inclusion criteria, appraising quality of papers, providing a clinical perspective, writing the review, providing general advice on the review.</p> <p>(4) Simon Radley: conceiving the review, providing a clinical perspective, providing general advice on the review.</p> <p>(5) Rane Thakar: conceiving the review, developing the search strategy, screening retrieved papers against inclusion criteria, appraising quality of papers, providing a clinical perspective, writing the review, providing general advice on the review.</p>

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What's New	Information not supplied by author
Date new studies sought but none found	Information not supplied by author
Date new studies found but not yet included/excluded	Information not supplied by author
Date new studies found and included/excluded	30 January 2006
Date authors' conclusions section amended	Information not supplied by author
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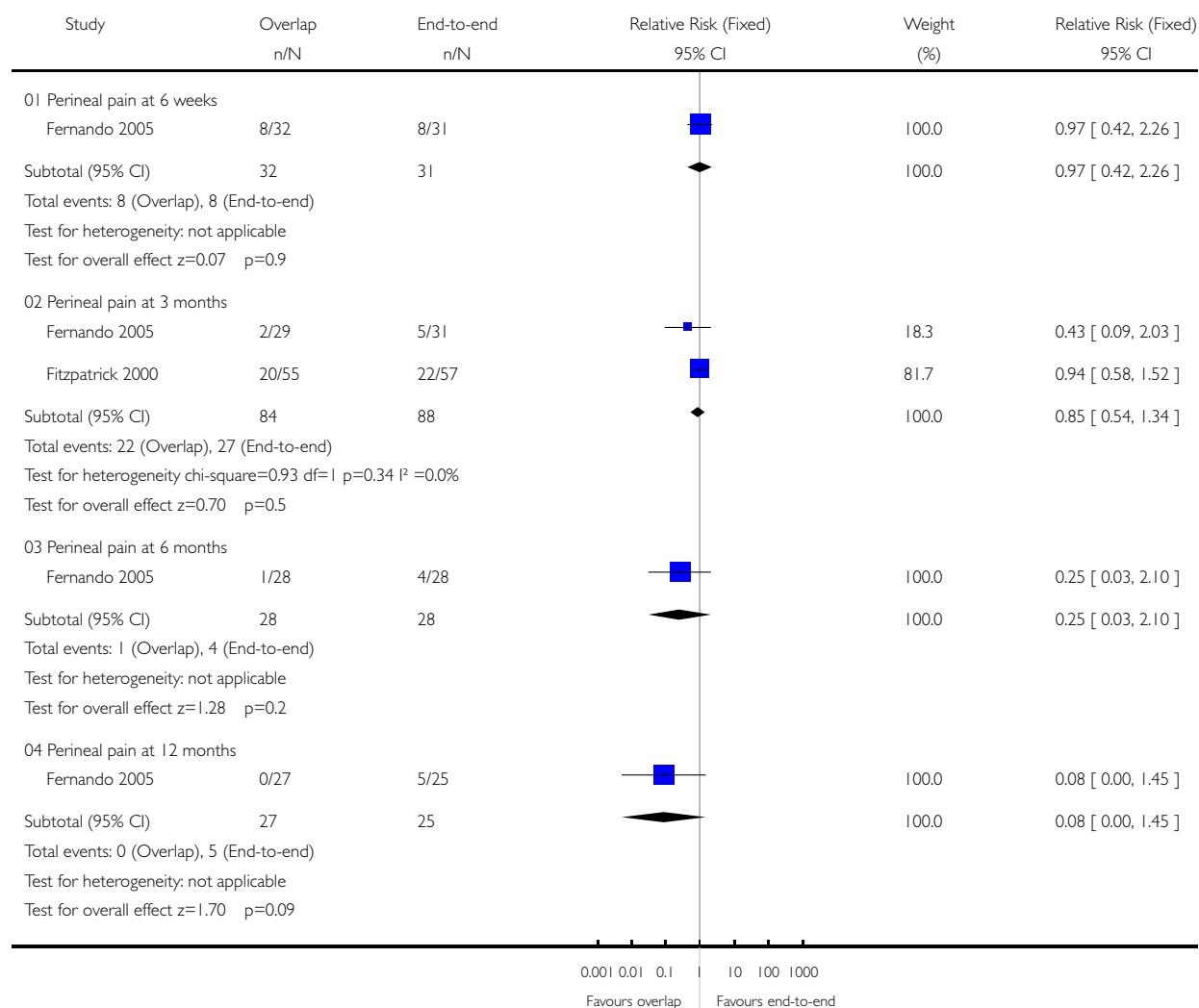
GRAPHS AND OTHER TABLES

Analysis 01.01. Comparison 01 Overlap versus end-to-end, Outcome 01 Perineal pain

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 01 Perineal pain

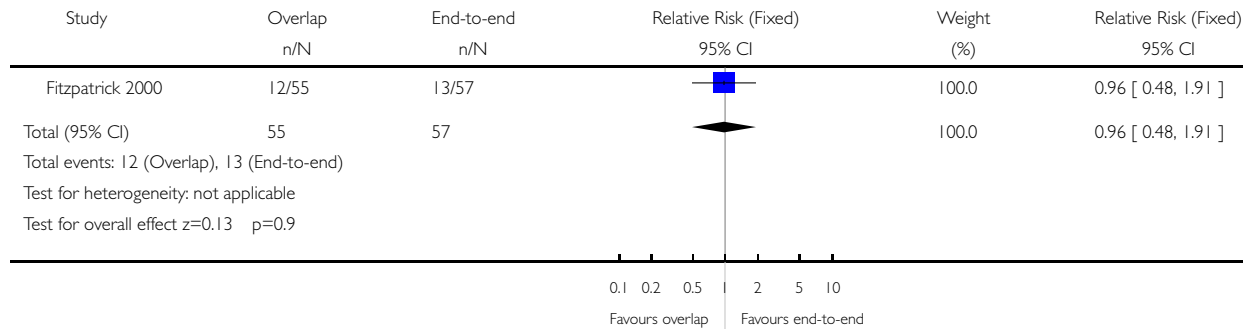


Analysis 01.02. Comparison 01 Overlap versus end-to-end, Outcome 02 Need for perineal injection at 3 months

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 02 Need for perineal injection at 3 months

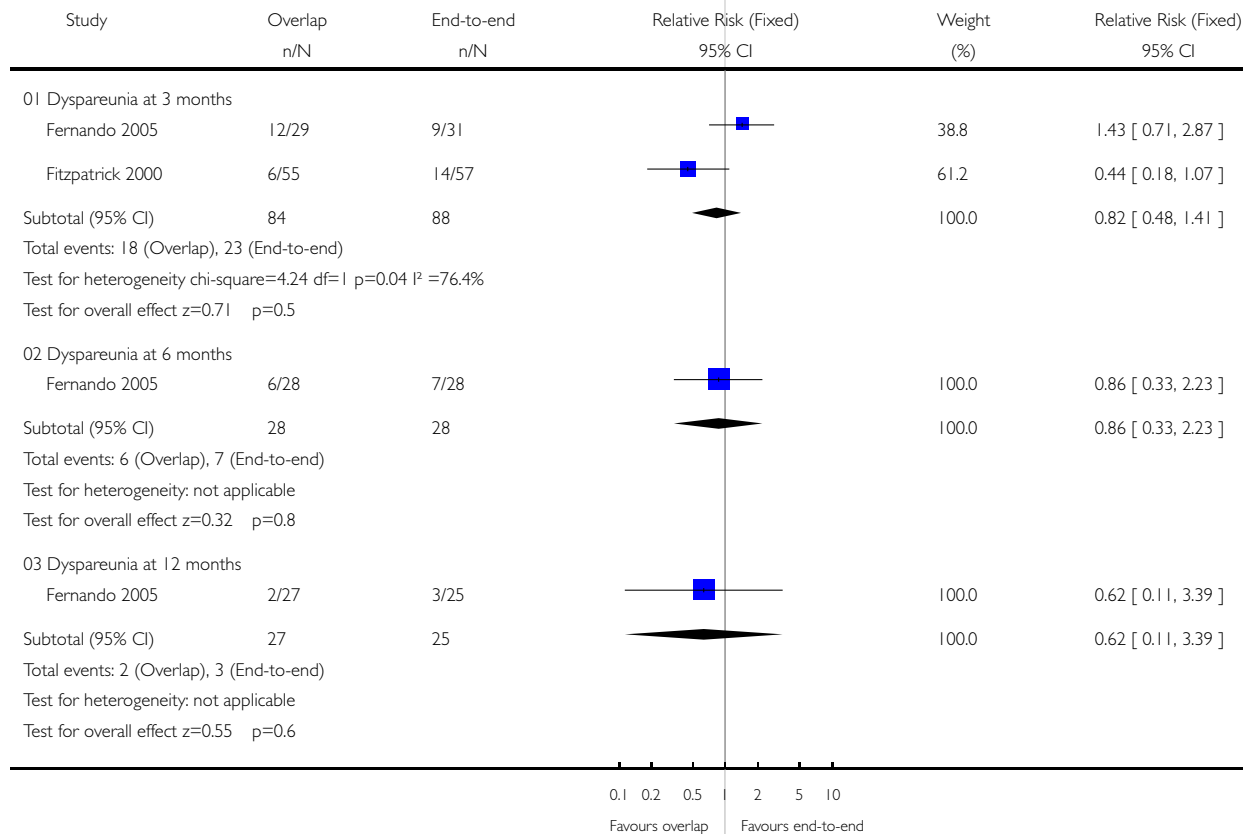


Analysis 01.03. Comparison 01 Overlap versus end-to-end, Outcome 03 Dyspareunia

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 03 Dyspareunia

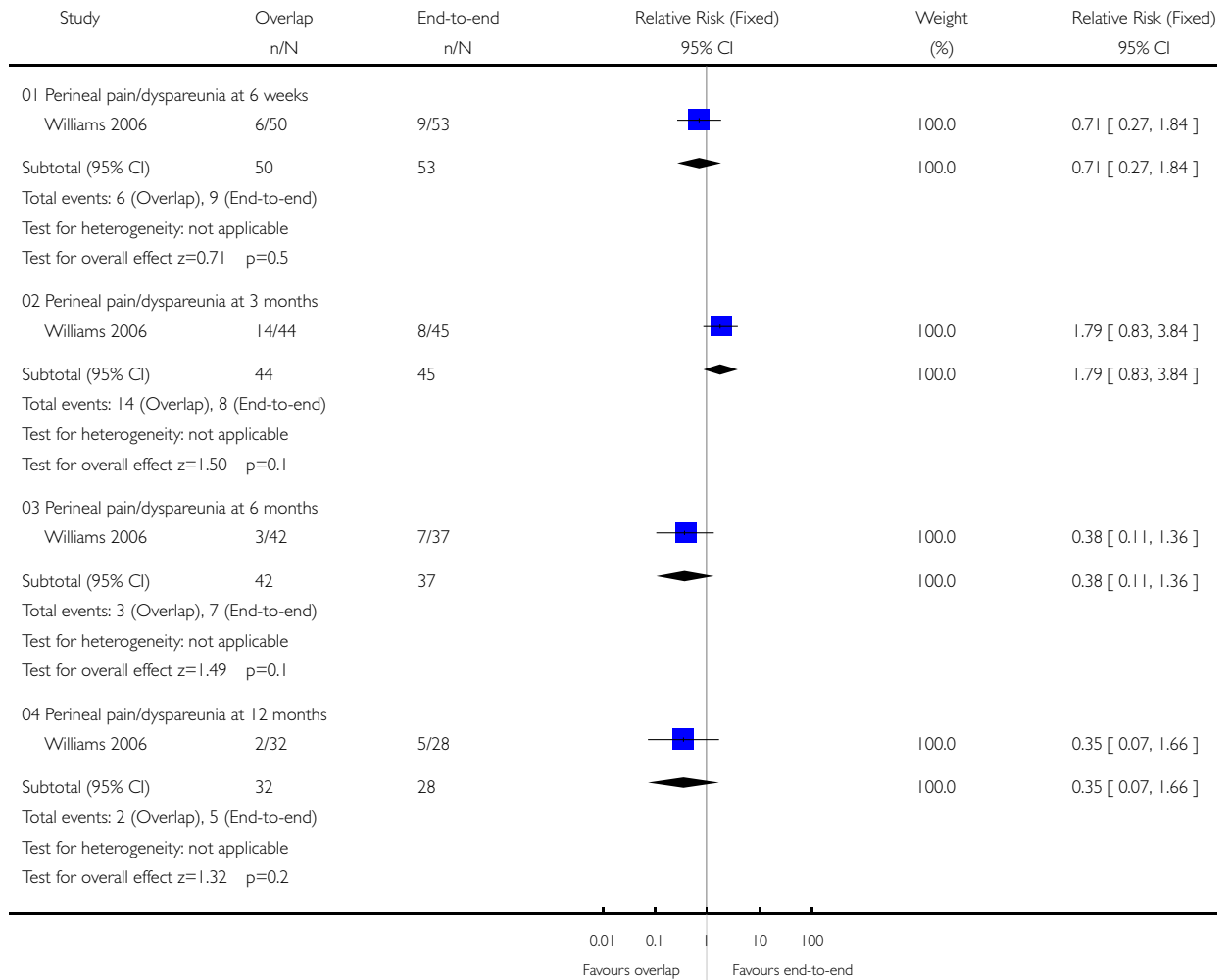


Analysis 01.04. Comparison 01 Overlap versus end-to-end, Outcome 04 Perineal pain/dyspareunia

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 04 Perineal pain/dyspareunia

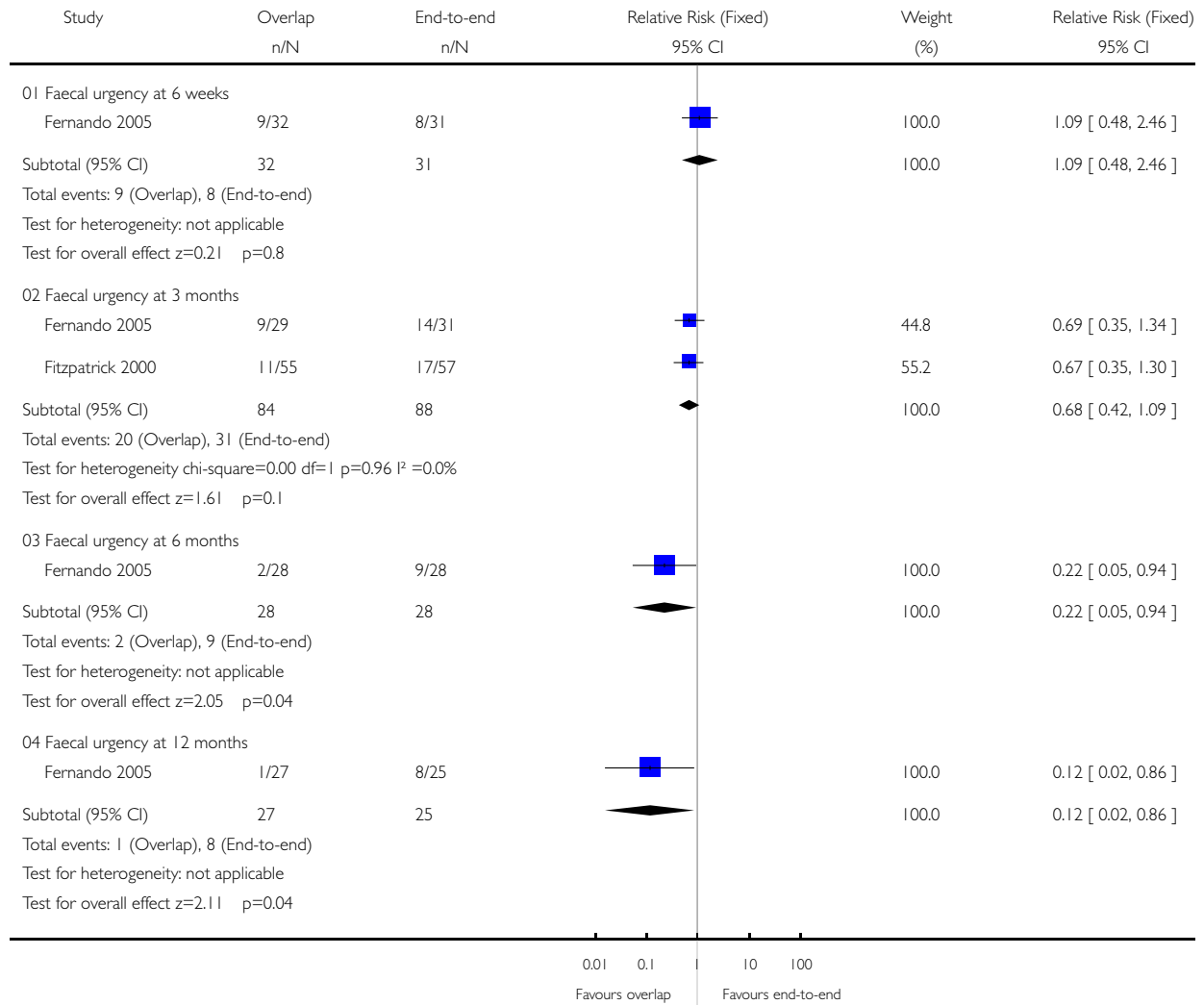


Analysis 01.05. Comparison 01 Overlap versus end-to-end, Outcome 05 Faecal urgency

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 05 Faecal urgency

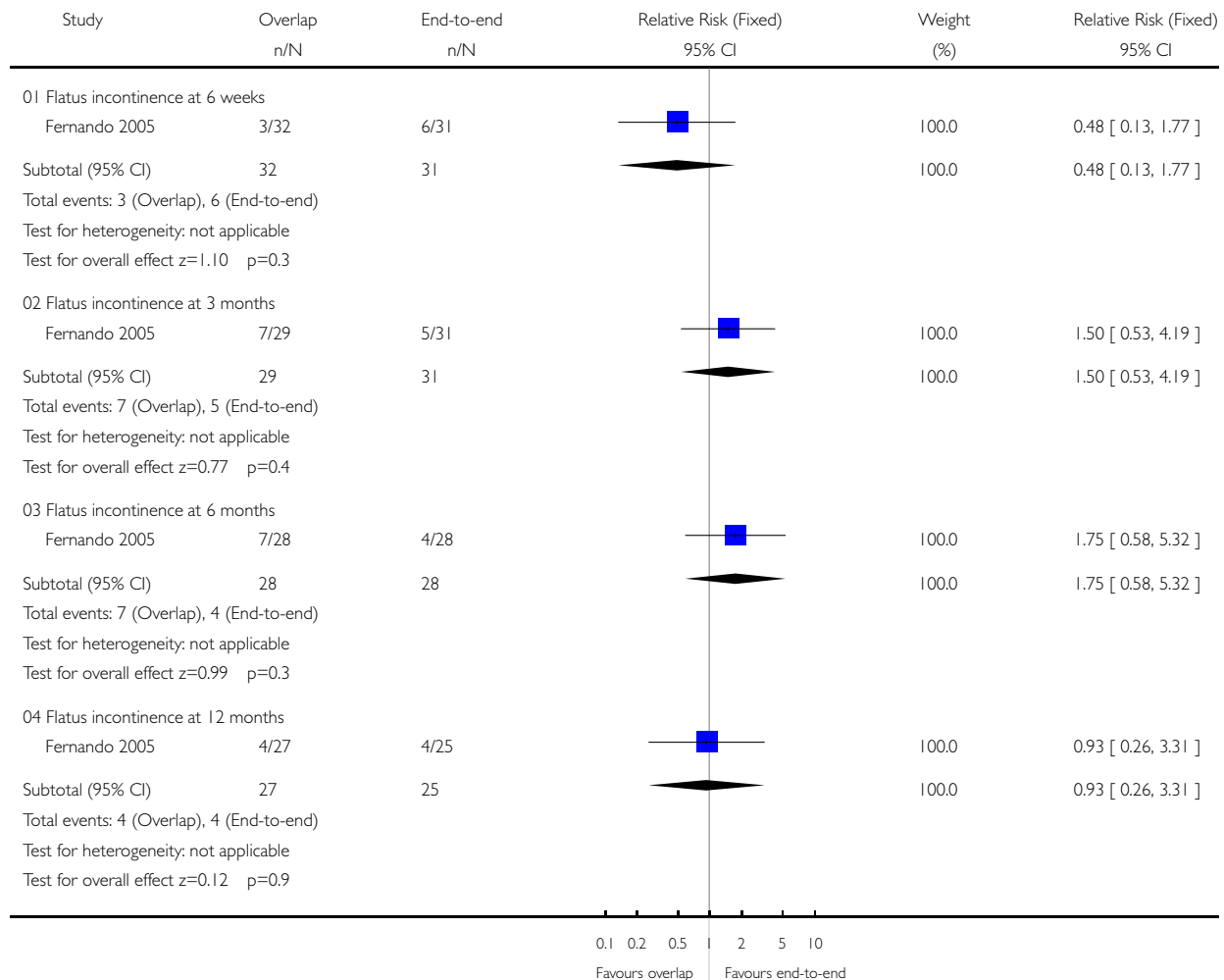


Analysis 01.06. Comparison 01 Overlap versus end-to-end, Outcome 06 Flatus incontinence

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 06 Flatus incontinence

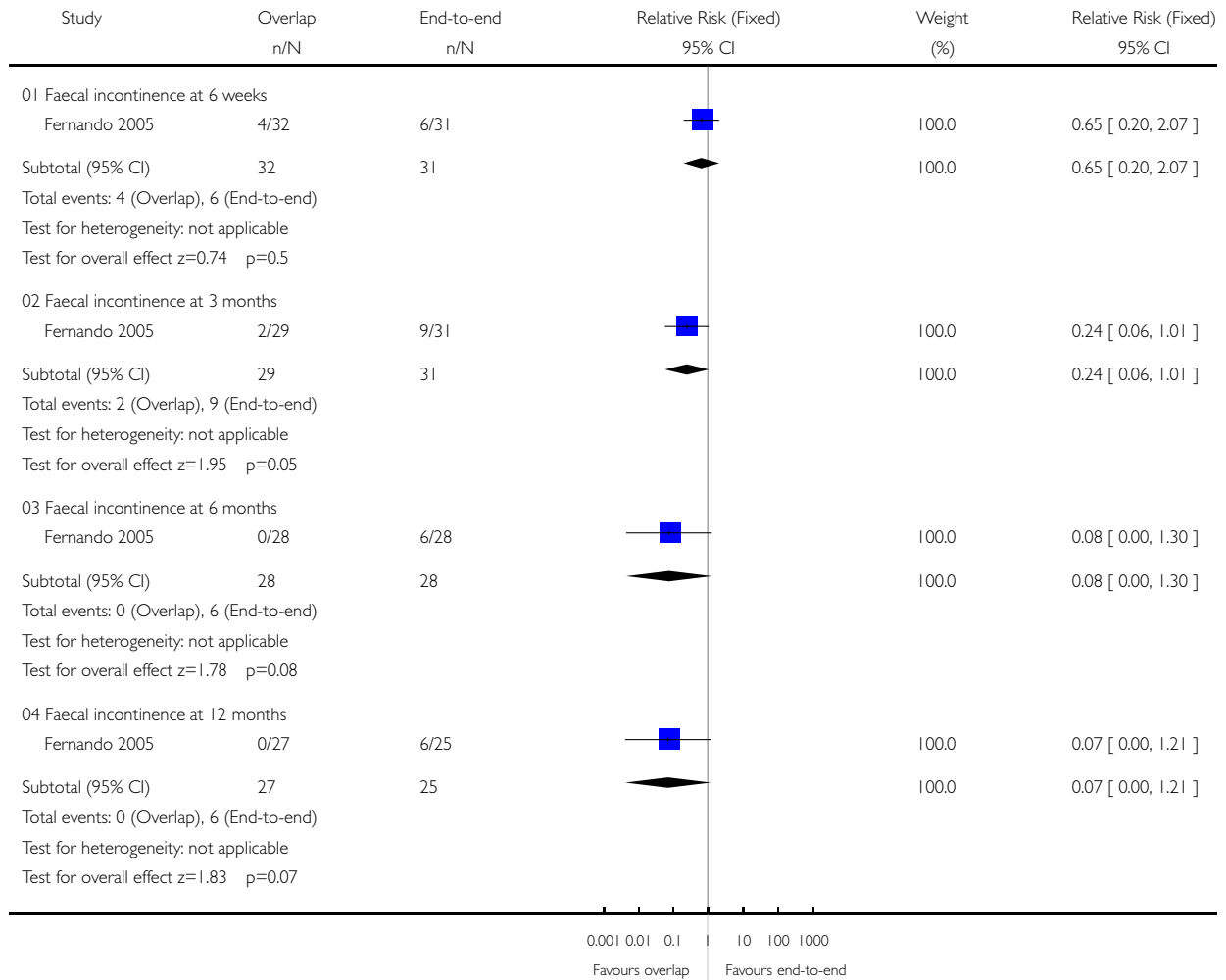


Analysis 01.07. Comparison 01 Overlap versus end-to-end, Outcome 07 Faecal incontinence

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 07 Faecal incontinence

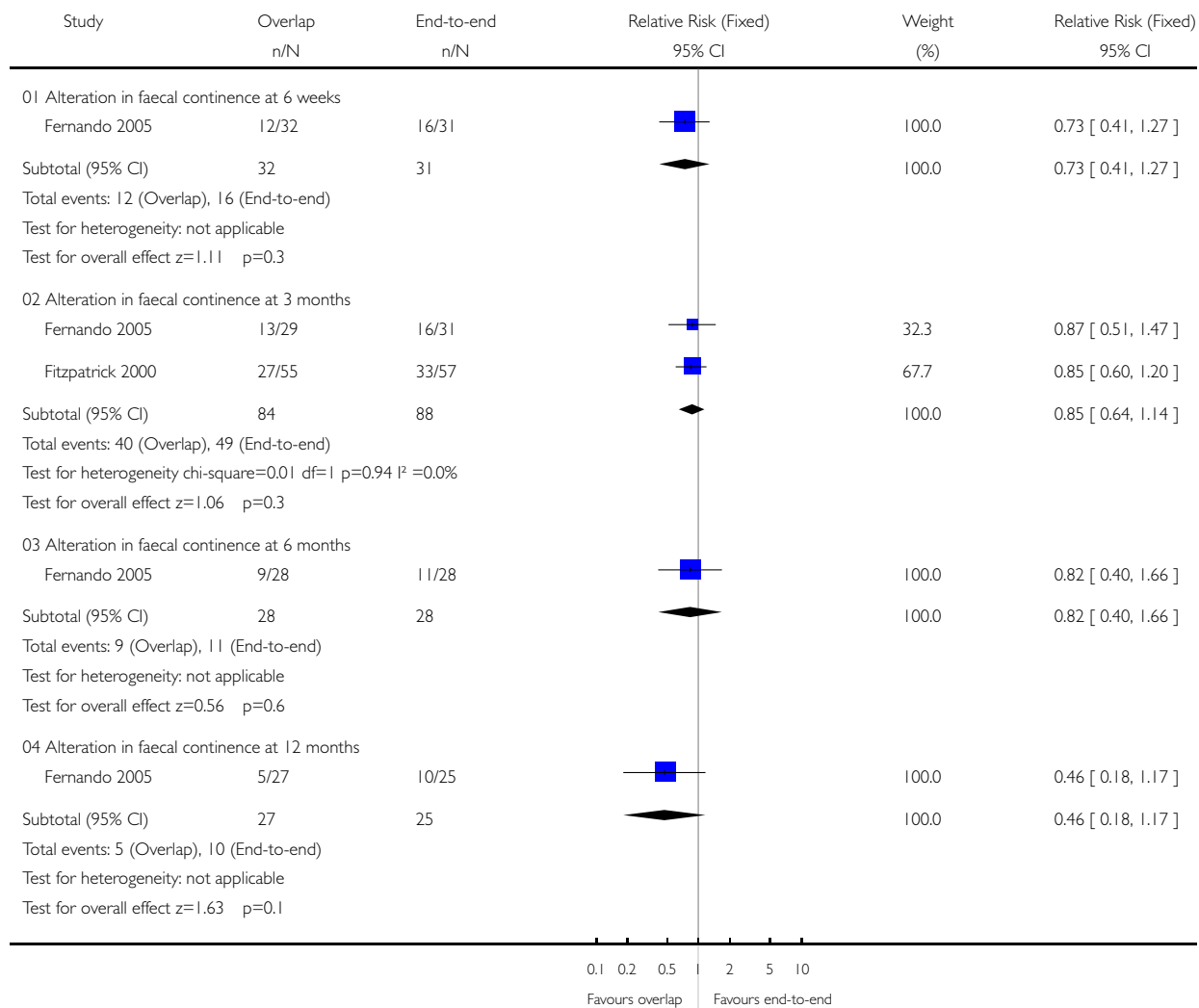


Analysis 01.08. Comparison 01 Overlap versus end-to-end, Outcome 08 Alteration in faecal continence

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 08 Alteration in faecal continence

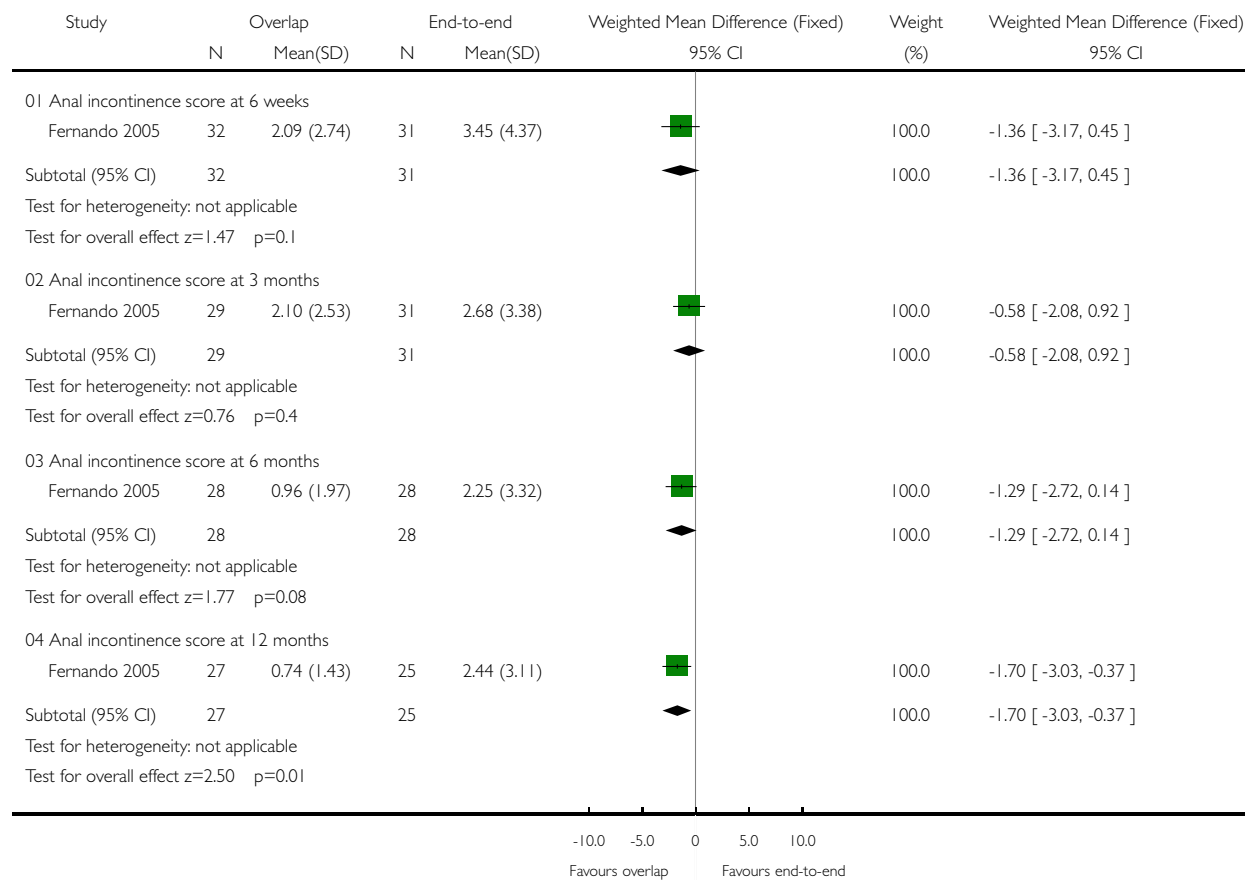


Analysis 01.09. Comparison 01 Overlap versus end-to-end, Outcome 09 Anal incontinence score

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 09 Anal incontinence score

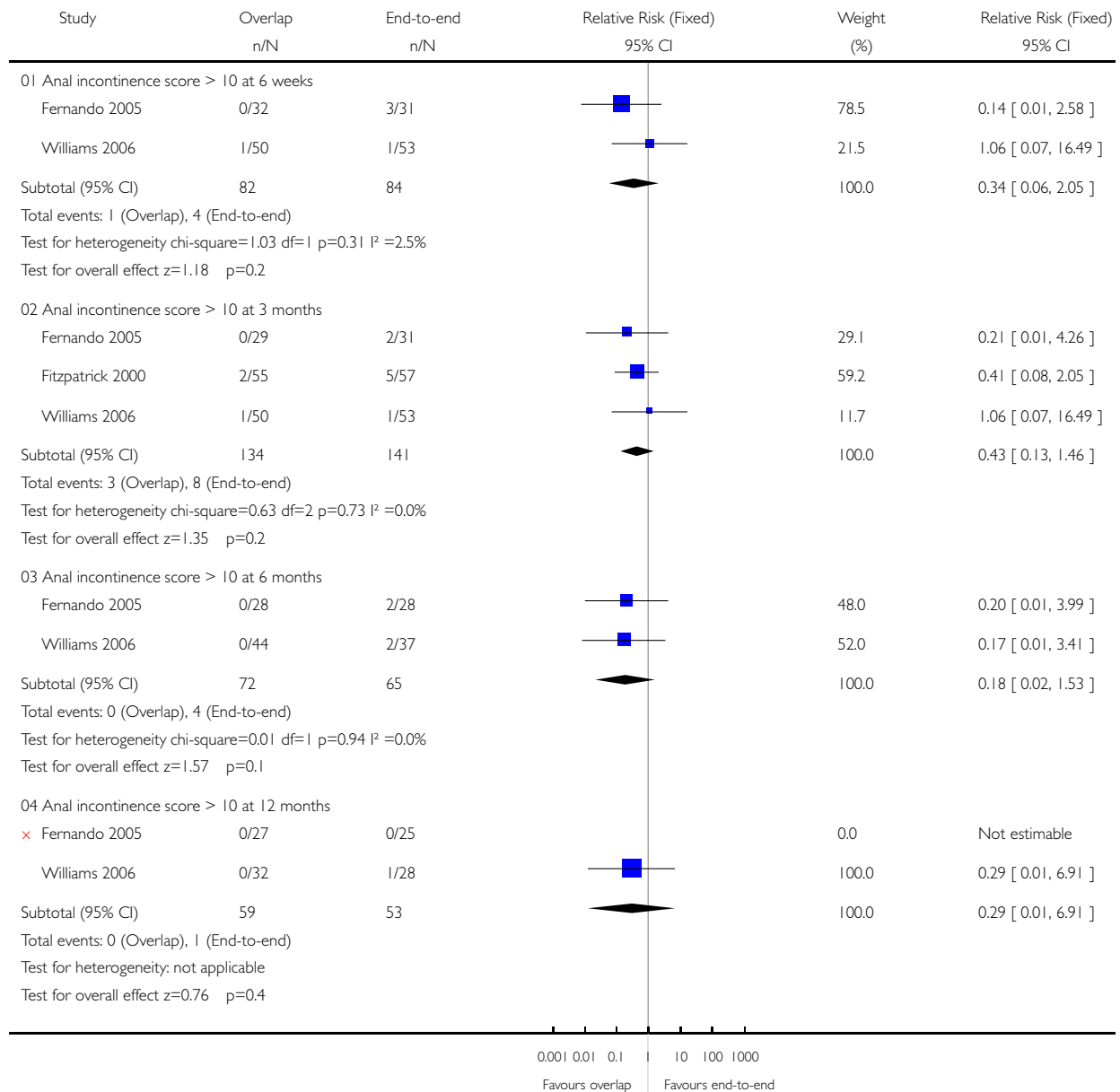


Analysis 01.10. Comparison 01 Overlap versus end-to-end, Outcome 10 Anal incontinence score > 10

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 10 Anal incontinence score > 10



Comparison: 01 Overlap versus end-to-end

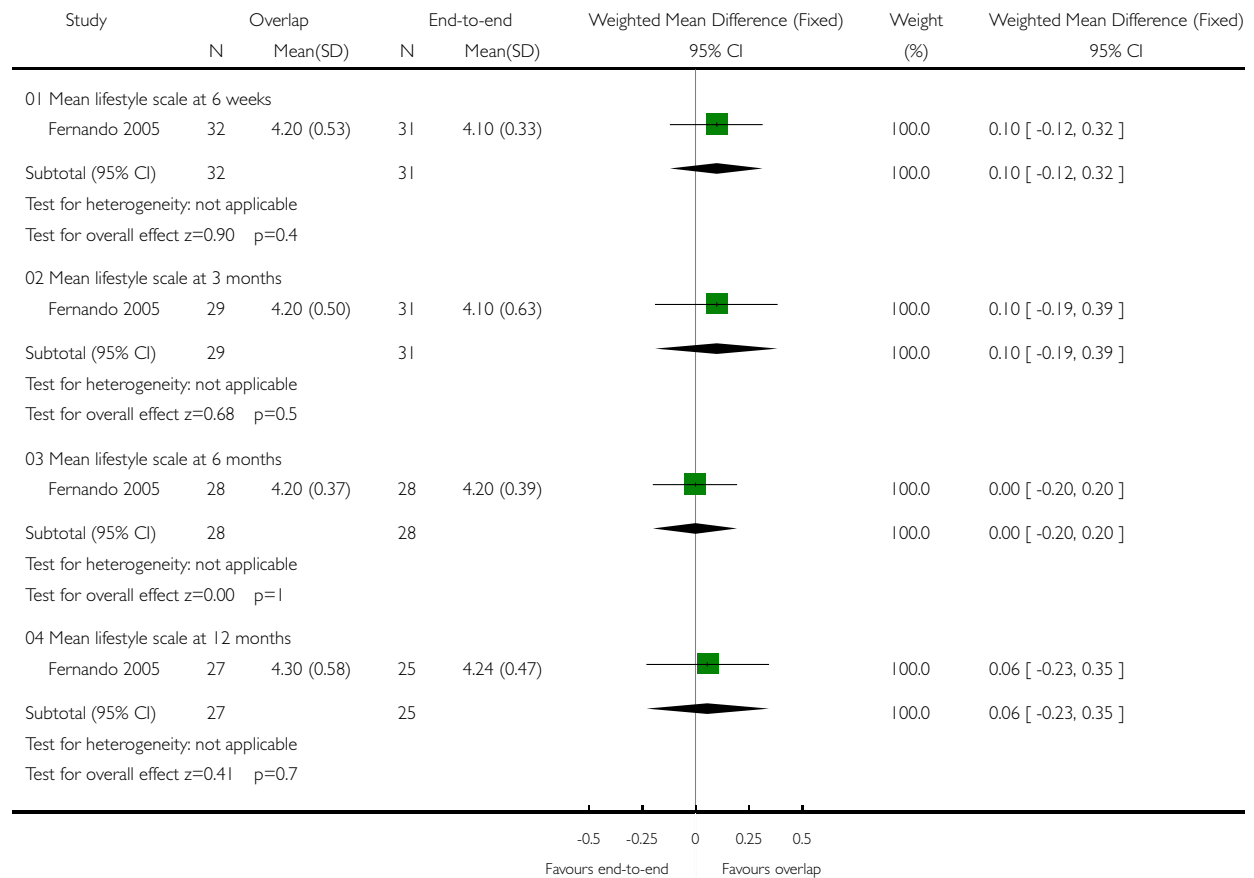
Study	Overlap n/N	End-to-end n/N	Relative Risk (Fixed) 95% CI	Weight (%)	Relative Risk (Fixed) 95% CI
Fernando 2005	3/20	12/21		100.0	0.26 [0.09, 0.79]
Total (95% CI)	20	21		100.0	0.26 [0.09, 0.79]
Total events: 3 (Overlap), 12 (End-to-end)					
Test for heterogeneity: not applicable					
Test for overall effect z=2.37 p=0.02					
			0.01 0.1 10 100		
			Favours overlap Favours end-to-end		

Analysis 01.12. Comparison 01 Overlap versus end-to-end, Outcome 12 Quality of life scale 1: lifestyle

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 12 Quality of life scale 1: lifestyle

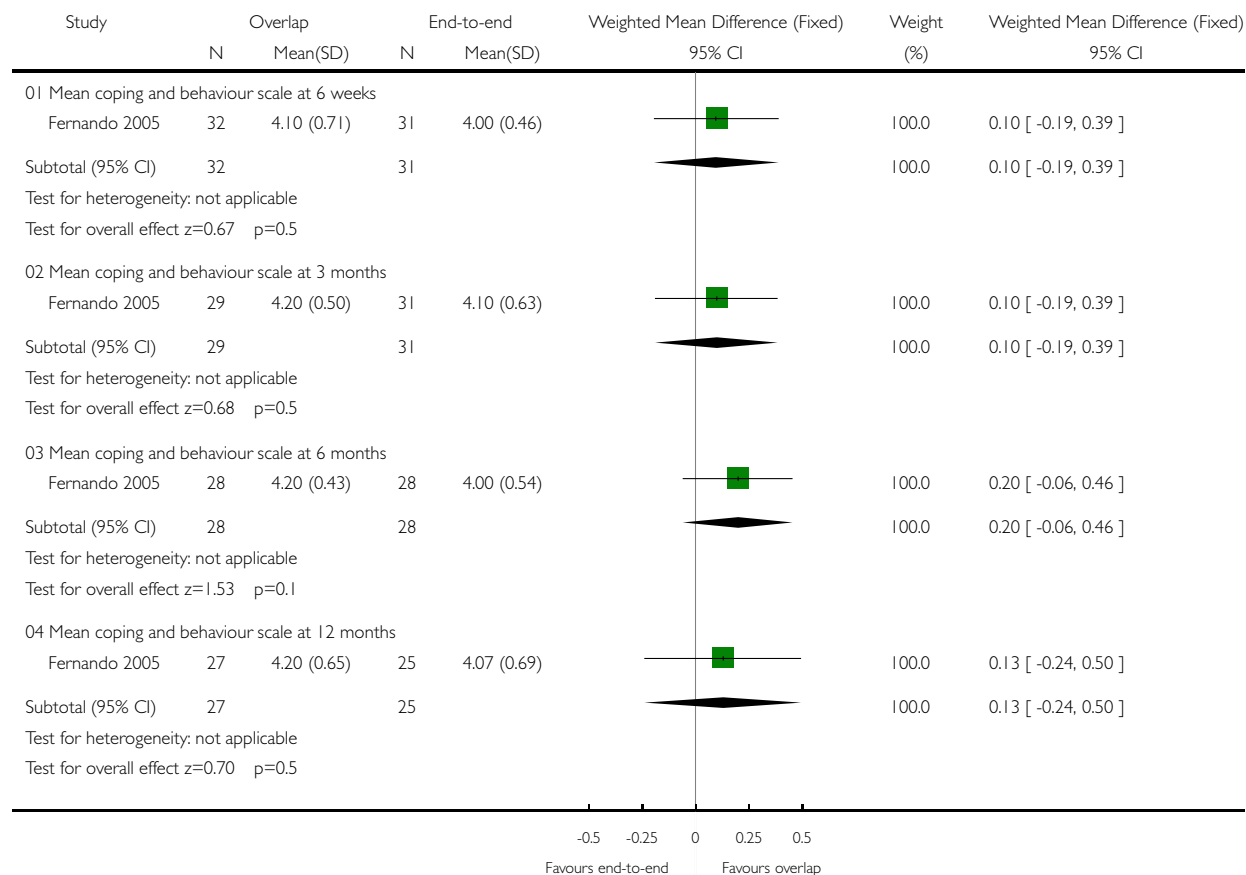


Analysis 01.13. Comparison 01 Overlap versus end-to-end, Outcome 13 Quality of life scale 2: coping and behaviour

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 13 Quality of life scale 2: coping and behaviour

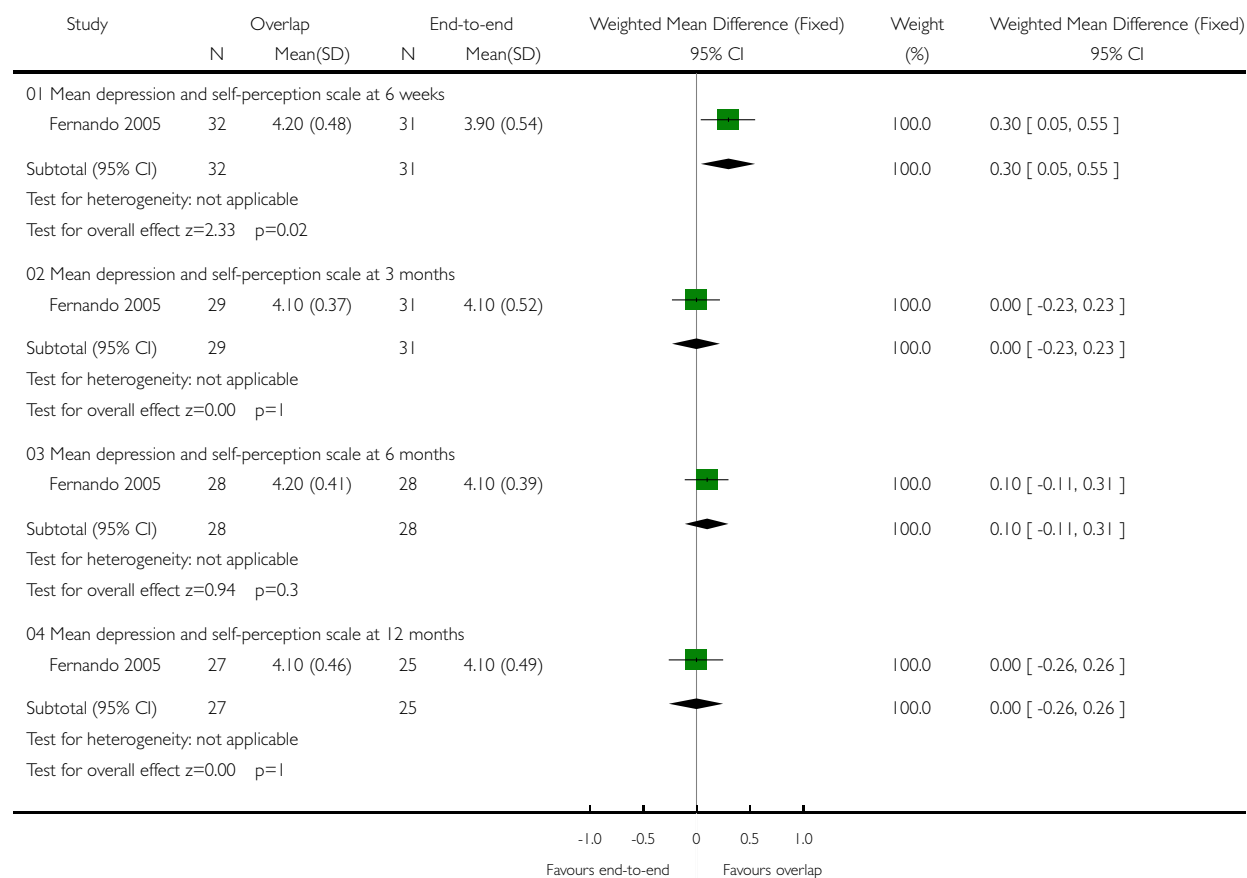


Analysis 01.14. Comparison 01 Overlap versus end-to-end, Outcome 14 Quality of life scale 3: depression and self-perception

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 14 Quality of life scale 3: depression and self-perception



Analysis 01.15. Comparison 01 Overlap versus end-to-end, Outcome 15 Quality of life scale 4: embarrassment

Review: Methods of repair for obstetric anal sphincter injury

Comparison: 01 Overlap versus end-to-end

Outcome: 15 Quality of life scale 4: embarrassment

