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ROUTINE VERSUS RESTRICTIVE EPISIOTOMY FOR OBSTETRIC ANAL SPHINCTER INJURY: METAREGRESSION OF RANDOMISED CONTROLLED TRIALS

Hypothesis / aims of study

Obstetric anal sphincter injury (OASIS) occurs during vaginal delivery when perineal tears extend into the anal sphincter complex, involving the internal and external anal sphincter muscles, or the rectal mucosa itself. These tears are clinically significant because for many women the outcome of primary repair is poor. Women who sustain these injuries are more likely to suffer long term anal incontinence, with a devastating impact on quality of life.

Previous systematic reviews of randomised controlled trials (RCTs) of routine or restrictive use of episiotomy have indicated benefit from reducing the episiotomy rate, regardless of episiotomy technique [1], but with low numbers of events in included RCTs, and substantial clinical heterogeneity. In contrast, high quality population based observational studies have demonstrated protective benefit from lateral and medio-lateral episiotomy, particularly among nulliparous women or women undergoing operative / instrumental vaginal delivery [2,3].

This systematic review aimed to reassess the association between OASIS and episiotomy in RCTs of routine versus restrictive episiotomy, and test the strength, consistency, and potential for bias among published associations. Secondly we wished to test which factors modify these estimates of association, with prespecified subgroup analyses stratified by parity, mode of delivery, and episiotomy technique, and metaregression of included studies by episiotomy rate.

Study design, materials and methods

The review protocol was prospectively registered with PROSPERO. We searched Medline, EMBASE, and Ovid Nursing through to May 2012 without language restrictions, using the search terms: (perineum OR perineal OR sphincter OR "3rd degree" OR "4th degree" OR "third degree" OR "fourth degree" OR perineum(MeSH)) AND (episiotomies OR episiotomy OR episiotomy(MeSH)). We included a wide selection of grey literature where captured by these databases, including ICS, IUGA, and AJOG abstracts. We contacted primary study authors where necessary for clarifications or additional data. All screening and data extraction were performed in duplicate by trained reviewers. Risk of bias assessments were recorded using GRADE. Fixed and random effect meta-analyses were conducted using the metan command, and metaregression was conducted using the metareg command for Stata 12.

Results

We screened 1389 abstracts and retrieved 519 full texts. 11 trials enrolling 7,411 women provided data. All included studies used either medio-lateral or midline episiotomy. The pooled estimate for all studies irrespective of episiotomy technique favoured restrictive episiotomy with RR 0.73 (95%CI 0.56-0.96, p=0.02, I² 31.8%, p=0.16). There was no evidence of funnel plot asymmetry or small study bias (Harbord test p=0.54). Subgroup analysis by episiotomy type demonstrated non-significant pooled effects for midline episiotomy (studies n=2, RR 0.71 95%CI 0.33-1.53, p=0.38, I² 75.6%, p=0.04), and for mediolateral episiotomy (studies n=9, RR 0.74 95%CI 0.44-1.26, p=0.27, I² 21.5%, p=0.26). Subgroup analysis among medio-lateral episiotomy trials enrolling only nulliparous women, or reporting stratified results for nulliparous women again showed a non-significant pooled effect (studies n=8, RR 0.80 95%CI 0.48-1.33, p=0.39, I² 15.8%, p=0.31). A single trial provided extractable data for women undergoing operative vaginal delivery, and non-significantly favours routine use of medio-lateral episiotomy (RR 1.35 95%CI 0.57-3.21). None of these results were materially changed by exclusion of studies with high risk of bias (n=1), or by inclusion of zero event trials (n=2). We found no evidence in metaregression that the individual study effect sizes were dependent on episiotomy type (p=0.69), absolute episiotomy rate (p=0.68), or the difference in episiotomy rates achieved in routine and restrictive groups (p=0.30).

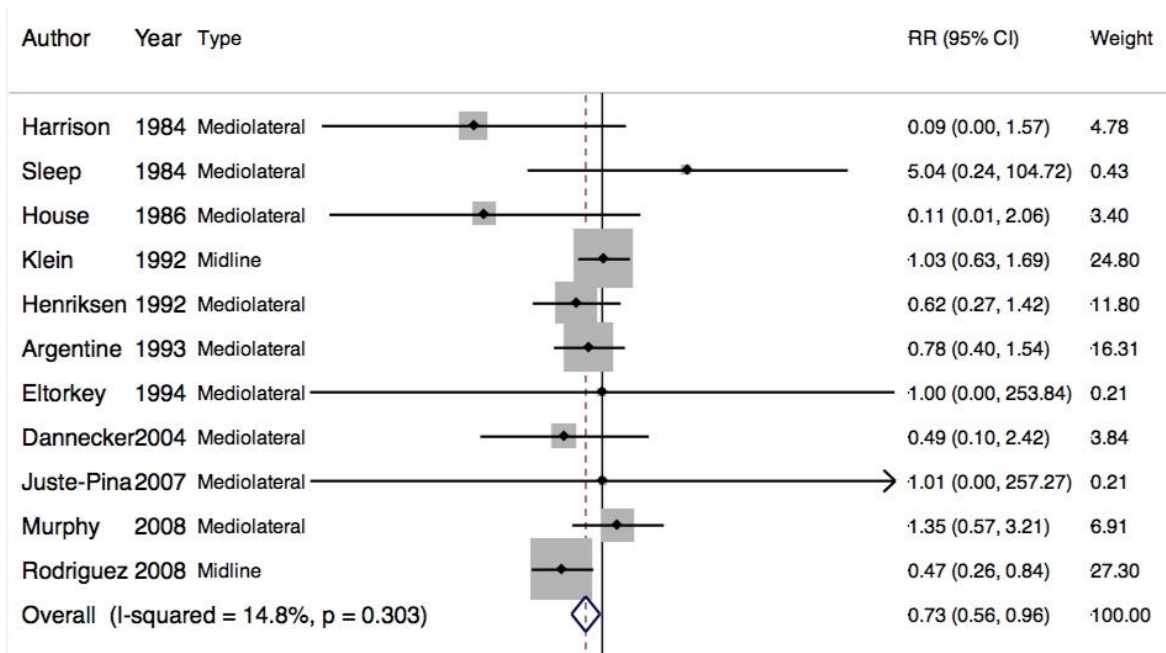


Figure: Forest plot of included studies, with RR, 95%CI and event rates (left side favours restrictive use; plot includes zero event trials)

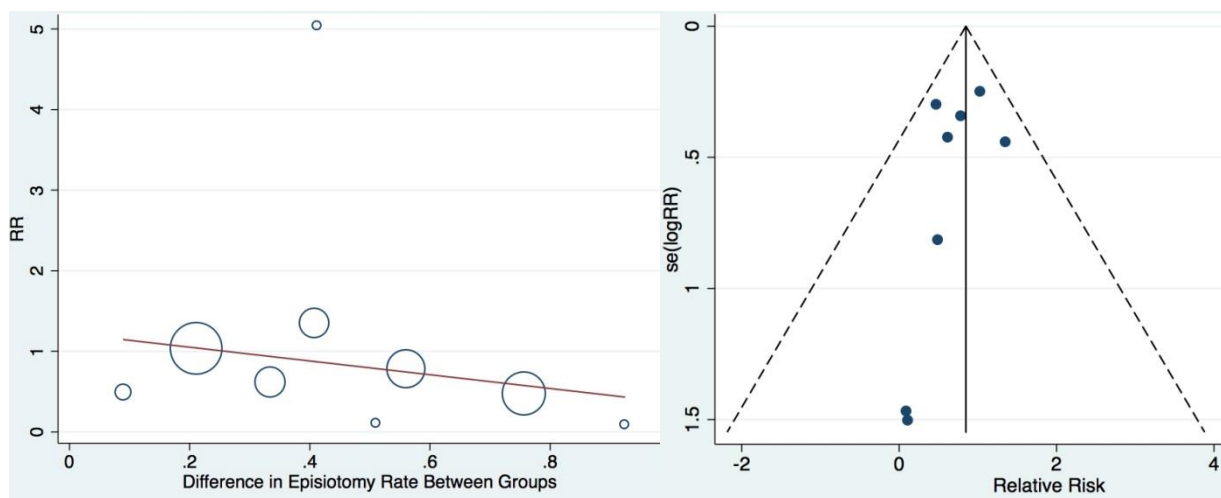


Figure: Bubble plot of difference in episiotomy rates between arms on effect size; funnel plot

Interpretation of results

This updated meta-analysis includes four additional RCTs [1], and demonstrates reduced OASIS rates with restrictive use only when pooling studies of mediolateral and midline episiotomy. With substantial evidence from observational studies of clinical heterogeneity between different episiotomy techniques and for women in different risk categories, we ran analyses stratified by episiotomy technique, parity, and mode of delivery. With non-significant results throughout, the findings are compatible with the conflicting evidence from observational studies of benefit or harm from medio-lateral episiotomy [2]. In light of other favourable outcomes from restrictive episiotomy, this practice should continue to be recommended.

Concluding message

Current RCTs provide insufficient evidence of association between midline or mediolateral episiotomy and OASIS. Well designed RCTs of restrictive versus routine lateral episiotomy, of restrictive versus routine medio-lateral episiotomy among high risk women, and of restrictive use of lateral versus mediolateral episiotomy are still needed.

References

1. Cochrane Database Syst Rev. 2009 Jan 21;(1):CD000081
2. BJOG. 2008 Jan;115(1):104-8
3. Am J Obstet Gynecol. 2012 Apr;206(4):347

Disclosures

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