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Curved versus straight scissors to avoid 3rd and 4th degree perineal tears: A randomised feasibility study $\stackrel{\star}{\approx}$



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ABSTRACT

Background: Severe perineal tears sustained during childbirth cause significant distress and morbidity amongst women. The objective of this study was to compare the use of straight scissors for cutting an episiotomy with the use of curved scissors, which are designed to curve away from the anal sphincter. *Methods:* We used a single-centre, randomised feasibility trial. The intervention was the use of curved scissors. Women were recruited during a prenatal visit and randomised in the delivery suite, when it became clear that an episiotomy was required. The feasibility outcomes were the proportion of women able to be recruited, randomised and followed up. We also calculated the incidence of obstetric anal sphincter injury when either straight or curved scissors were used to cut an episiotomy. Other outcomes assessed were pain, length of hospital stay, perineal infection and perineal dehiscence.

Results: Of the 155 patients recruited in the prenatal period, only 20 (12.9%) were eventually randomised at birth. The main reasons for the high loss were that women either did not have a vaginal delivery (38, 24.5%), or they did not need an episiotomy (72, 46.5%). Rates of obstetric anal sphincter injury and other outcomes were similar between groups.

Discussion: Anal sphincter injury during childbirth remains an important problem. Although the use of curved scissors provides a theoretical solution, we found that the high attrition rate made feasibility of conducting a suitably powered, randomised trial using the current design untenable. Alternative strategies have been suggested to make any future study more viable.

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1. Introduction

Obstetric anal sphincter injuries (OASI) occur in a significant proportion of women in Queensland during child birth. The occurrence of OASI is highest among primiparae and affected 3.4% (n = 719) of all vaginal births during 2011 ²². Perineal tears are defined using specific criteria (Table 1).

In an attempt to prevent severe anal sphincter injuries that might be difficult to repair and may cause serious morbidity for the woman, the accoucher may decide to cut an episiotomy.^{1–3} This intervention might also be used to expedite the birth where there is delay or suspected foetal compromise. The episiotomy is then repaired with sutures in the same manner as a 2nd degree tear. At our hospital during 2010, of the 328 primiparae who had an episiotomy, 44 (13.4%) also sustained an OASI despite the intervention.

Restrictive (as clinically indicated, e.g. foetal compromise, selectively for instrumental delivery) right mediolateral episiotomy is the policy at the study hospital. This approach has been shown to reduce posterior perineal trauma, lead to less suturing and fewer complications, with no observed differences for most pain measures and severe vaginal or perineal trauma, when compared to routine episiotomy, where an episiotomy is cut for other than a clinically indicated reason.^{3,4} The method is advocated as best practice in several guidelines.^{5–7} However, episiotomy has been identified as an independent risk factor for OASI in other studies that did not demonstrate a reduction in the overall incidence of OASI when an episiotomy was performed.^{8–10} One reason for this has been attributed to inappropriate technique by the clinician. For example two UK studies^{8,11} found that

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Table 1

Definitions of perineal injury

Intact

No tissue separation at any site

First degree

Injury to the skin only (i.e. involving the fourchette, perineal skin and vaginal mucous membrane; but not the underlying fascia and muscle, sometimes referred to as a 'graze')

Second degree

Injury to the perineum involving perineal muscles but not involving the anal sphincter

Third degree

Injury to perineum involving the anal sphincter complex

- •3a: Less than 50% of external anal sphincter thickness torn
- •3b: More than 50% of external anal sphincter thickness torn
- •3c: Both internal and external anal sphincter torn

Fourth degree tear

Injury to perineum involving the anal sphincter complex (external and internal anal sphincter) and anal epithelium (i.e. involving anal epithelium and/or rectal mucosa)

mediolateral episiotomies performed by both midwives and obstetricians were more midline than mediolateral, falling short of the recommended 45 degree angle from the forchette,⁵ and therefore education of clinicians in correct technique has been recommended.^{8,11}

The surgical repair of an OASI, followed by an extended stay in hospital and subsequent follow up and ongoing care has considerable financial implications to health providers. More importantly, these severe tears may lead to ongoing morbidity and distress for the women affected. For example it is estimated that between one third and two thirds of women with anal sphincter injuries suffer from persistent anal incontinence that worsens with age.^{5,10,12}

In order to reduce the number of severe tears women experience, other strategies need to be investigated. One such strategy is the use of curved or angled episiotomy scissors designed specifically for this purpose. Theoretically, curved scissors make an incision that curves away from the anal sphincter thus reducing the likelihood of extension to the anal sphincter. Although this intervention to reduce the extension of episiotomies seems plausible, no studies to test the effectiveness of curved scissors have been conducted. Obstetric guidelines do not provide direction for clinicians in this area. Straight scissors were used exclusively at the hospital to perform an episiotomy prior to the study.

Consequently, a trial to test the effectiveness of curved scissors versus straight scissors was proposed, to provide useful and novel information for those involved in maternity care. However, before beginning such a trial we wanted to conduct a feasibility study to test the methods and procedures that will be used on a larger scale. The objective of the current study was to assess recruitment potential, and to identify barriers and facilitators that may assist or hinder a subsequent, larger study.

2. Methods

2.1. Research design

This was a single-centre, feasibility randomised controlled trial (RCT) where the episiotomy was performed with either straight or curved scissors. A feasibility study is a stand-alone, small-scale trial that should result in (1) a decision to proceed to a full scale trial, (2) a thorough revision of the proposed methodology or (3) a decision to abandon a full scale study because it would be unfeasible to continue. According to Thabane et al.¹³ reasons for conducting such a trial are to assess the processes that will be

required for the main study; to calculate what resources will be required; to understand management issues – such as personnel, coordination, and data management; and to assess the actual intervention – is it safe, is it efficacious.

We obtained institutional Ethics approval for the study, which included the right to access the woman's medical records for audit purposes. The trial was pre registered (ACTRN12612000285853).

2.2. Study population

Women, who booked for maternity care at the study hospital between May and September 2013 and who were expecting their first vaginal birth, were potentially eligible for inclusion. Participants were excluded if they had undergone previous perineal surgery or, at the birth, if (1) the woman did not have an episiotomy, (2) had a multiple birth, (3) a pregnancy loss, (4) a water birth, or (5) if the birth occurred at <36 weeks gestation.

2.3. Procedure

Recruitment occurred during a routine prenatal appointment between 30 and 37 weeks of pregnancy. The purpose of the trial was explained and written consent obtained from women willing to participate. A notation was made in the woman's medical record to the effect that she has agreed to participate in the trial. Before the trial started, birth suite staff was offered multiple in-service education sessions to explain the study. Midwives were familiarised with data collection tools and the randomisation process. They were encouraged to contact research staff at any time. This education was vital because delivery room midwives were responsible for allocating patients to their group.

Approximately 24 h after delivery, women were asked by a midwife in the post-natal ward, who was unaware of the group allocation, to complete a Visual Analogue Scale (VAS) to measure perception of pain. The VAS is an ungraded 100 mm long horizontal straight line with the endpoints "no pain" to the left (0) and "worst pain imaginable" to the right (100).¹⁴ Participants were asked to mark a point on the line that matched the amount of pain experienced. The point was then measured against a 0–10 cm gauge. The VAS has been shown to be sensitive to pain intensity and most individuals have no difficulties using it.¹⁵

2.4. Explanatory variables and process measures

At baseline, the research nurse documented demographic data including age, body mass index (BMI), ethnicity, and presence of diabetes. Following the birth, information about type of birth, perineal status, infant weight, Apgar score, analgesic or anaesthetic use and length of hospital stay were recorded by the research nurse. A follow up call was made, two weeks after the birth to identify any postnatal concerns related to the episiotomy wound (see Table 2).

Table 2

Baseline characteristics and birth details for study participants. Results are expressed as number (percent) or mean [SD].

	Straight	Curved	p value
Mean age (yrs)	28.2 [2.9]	29.9 [3.9]	0.27
Mean BMI	24.8 [4.5]	26.1 [7.1]	0.64
Epidural	9/12 (75.0)	5/8 (62.5)	0.45
Lignocaine	9/12 (75.0)	5/8 (62.5)	0.45
Instrumental delivery	6/12 (50.0)	5/8 (62.5)	0.47
Birth weight (g)	3575.5 [442.3]	3710.0 [521.6]	0.54
Head circumference	35.19 [1.96]	35.69 [1.46]	0.57

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