

## Effectiveness and acceptability of lidocaine spray in reducing perineal pain during spontaneous vaginal delivery: randomised controlled trial

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### Abstract

**Objectives** To evaluate the effectiveness and acceptability of a lidocaine spray in reducing perineal pain during spontaneous vaginal delivery.

**Design** Randomised controlled trial.

**Setting** Consultant led obstetric unit.

**Participants** 185 women who had a spontaneous vaginal delivery without epidural analgesia.

**Interventions** Topically applied local anaesthetic spray (93 women) and placebo spray (92 women).

**Main outcome measure** Primary outcome measure was pain during delivery (0-100 scale). The 16 secondary outcome measures included second degree perineal trauma during delivery, trauma of the genital tract, and dyspareunia by two months.

**Results** Lidocaine spray did not reduce pain during spontaneous vaginal delivery: mean 77 and 72 on a scale of 0-100 in the lidocaine and placebo groups, respectively (difference between means 4.8, 95% confidence interval -1.7 to 11.2). Lidocaine spray may reduce genital tract trauma during delivery, in particular second degree perineal trauma. The intervention was highly acceptable to the women and midwives.

**Conclusions** Although lidocaine spray applied to the perineum during spontaneous vaginal delivery did not reduce perineal pain, it was acceptable to both the women and the midwives.

**Trial registration** Current controlled trials ISRCTN9732966.

### Introduction

Numerous studies have been published on analgesia during labour.<sup>1</sup> Yet it is common for women having spontaneous vaginal delivery not to be offered analgesia for perineal pain during second stage labour. We compared the effectiveness of a local anaesthetic spray with a placebo spray in reducing perineal pain in women having a spontaneous vaginal delivery. We also ascertained the views of the women and midwives on acceptability of the sprays.

### Participants and methods

Between February 2003 and May 2004 midwives provided written and verbal information about the trial to potentially eligible women more than 30 weeks'

pregnant who attended antenatal clinics in the area served by the participating hospital. (See [bmj.com](http://bmj.com) for exclusion criteria.)

Women who had expressed an interest in the trial were identified by hospital based midwives when they were admitted to hospital in labour or for induction of labour. After obtaining written consent, the midwife asked a member of the medical staff to prescribe the trial solution.

### Trial interventions

The active trial solution was formulated to equate to Xylocaine spray (AstraZeneca, Bedfordshire). The active and placebo solutions were of similar appearance, consistency, and odour. Attending midwives were to apply five sprays of the solution, each of 0.1 ml, to the woman's perineum and inside aspect of the labia at least three minutes before delivery to have time to take effect. The number of sprays administered was recorded, and the time between application and delivery was calculated.

### Outcome measures

The primary outcome was pain during delivery, self reported by the women before leaving the delivery suite and assessed on a 0-100 scale from 0 (no pain) to 100 (worst possible pain). The 16 secondary outcomes included second degree perineal trauma (including women who had an episiotomy); genital tract trauma and its management; and dyspareunia by two months (see [bmj.com](http://bmj.com) for other secondary outcomes). Midwives collected a sample of cord blood for ascertainment of lidocaine levels. They also completed a questionnaire on deliveries. We obtained data on sociodemographic characteristics and the acceptability of the intervention to women through a questionnaire given 6-8 days after delivery. Acceptability to 14 midwives was ascertained through semistructured interviews, the transcripts of which were subjected to a thematic analysis.

### Analysis

We analysed the data using SPSS. The primary comparative analyses were carried out on an intention to treat basis, with data analysts blind to treatment

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Comparison of perineal pain between women assigned to lidocaine spray topically applied to the perineum or to placebo spray. Values are means (SDs) unless stated otherwise

	Lidocaine group (n=91)	Placebo group (n=90)	Difference between means (95% CI)	P value
Perineal pain*	76.9 (21.6)	72.1 (22.2)	4.8 (-1.7 to 11.2)	0.14

Positive difference between means indicates increase in pain for lidocaine spray compared with placebo spray.  
\*Scale from 0 (no pain) to 100 (worst possible pain).

group. We used regression analysis to compare the outcomes between groups. Secondary analyses also involved regression models (see *bmj.com* for details). Perineal pain was the primary outcome. Before inspection of the data, we considered mechanisms by which the intervention might affect this outcome. As a consequence we identified perineal trauma as a secondary outcome of interest, the reason being that perineal pain could be closely related to perineal integrity. We therefore calculated the number needed to treat for perineal trauma, along with a 95% confidence interval.<sup>2</sup>

## Results

Of the 2200 women delivering at the participating unit during the recruitment period, 680 were interested during their antenatal period in participating (see *bmj.com*). All 185 women approached in labour provided consent and were randomised: 93 to lidocaine spray and 92 to placebo spray.

### Characteristics at baseline and delivery of the interventions

The women in the trial groups were similar for several baseline obstetric and sociodemographic characteristics (see *bmj.com*). Since these variables could be associated with the outcomes they were adjusted for in secondary analyses.

The mean (SD) number of sprays administered in both groups was 4.8 (0.9). Almost two thirds of women received the intervention as intended. The mean difference in time between intervention and delivery was also similar between the groups: lidocaine group 11.0 minutes and placebo group 12.5 minutes. Although these times varied between individual women (standard deviations of about 10 minutes), about 80% of women delivered within 15 minutes of receiving the spray in both groups.

Of the 88 cord blood samples collected from women who had received lidocaine, 86 contained low levels of lidocaine and two contained levels at

the upper limit of the therapeutic range (5.60 and 5.70 µg/ml; see *bmj.com*).

Ten women in the lidocaine group and six in the placebo group reported an unpleasant experience with the spray. In contrast, 32 women in the lidocaine group compared with 22 in the placebo group reported either a cooling or analgesic effect. The midwives unanimously considered perineal analgesia during second stage labour to be an acceptable addition to current practice.

### Primary outcome

Mean pain scores were high and similar for both groups. No evidence was found of a sizeable reduction in pain using lidocaine spray compared with placebo spray (table); the suggestion was that pain may have been slightly increased.

Adjusting for imbalances at baseline had little effect on the results, as did restricting the analysis to the 124 women who received five doses of the lidocaine spray as intended at least three minutes before delivery (see *bmj.com*). Although power is limited for subgroup analysis, no evidence was found that the effect of the intervention differed by parity.

### Secondary outcomes

Most secondary outcomes were similar between the groups (see *bmj.com*). However, a smaller proportion of women who received the lidocaine spray compared with the placebo spray sustained second degree perineal trauma. Of the 59 women in the lidocaine group and 67 in the placebo group who sustained any genital tract trauma, 17 and 14, respectively, experienced first degree perineal trauma, and 26 and 41 experienced second degree perineal trauma. Women in the lidocaine group were also less likely to experience dyspareunia when resuming sexual intercourse.

## Discussion

Although a local anaesthetic (lidocaine) spray applied to the perineum of women during spontaneous vaginal delivery was acceptable to the women and midwives, it was not associated with any reduction in delivery pain; if anything the trend was to worse pain. The intervention may reduce the occurrence of second degree perineal trauma and have longer term benefits—namely, a reduction in the proportion of women reporting dyspareunia two months after delivery. These findings seem to be contradictory. This may be because the findings are due to chance or because the spray enables a more controlled delivery of the fetal head and therefore prolongs this process. If so, the intervention could prevent trauma while not reducing pain.

The levels of lidocaine in the cord blood were almost always within acceptable limits except in two cases. These two exceptions may have occurred through contamination of the cord sample after delivery, placental transfer, or direct absorption through the fetal scalp during delivery. Placental transfer is unlikely at these levels.<sup>3-7</sup> Contamination is also unlikely—the spray comprised free lidocaine in ethanol, which evaporates rapidly, and both lidocaine and ethanol were detected in the cord samples. Lidocaine hydrochloride does not readily permeate the skin of neonates, but free lidocaine as used here may do so.<sup>8 9</sup>

This trial was powered to detect a difference in the primary outcome of delivery pain. In the event, the

### What is already known on this topic

Spontaneous vaginal delivery is associated with severe pain and trauma to the genital tract, resulting in short and long term morbidity

Perineal analgesia is not normally offered to women having a spontaneous vaginal delivery

### What this study adds

Perineal analgesia during second stage labour was acceptable to women and midwives

A lidocaine spray had no noticeable effect on perineal pain during spontaneous vaginal delivery

confidence interval for this outcome was moderately wide, including the null and extending close to the target difference in a direction not favouring lidocaine spray. The trial was not powered for binary outcomes, and the confidence intervals for secondary outcomes of this type, including second degree perineal trauma, were commensurately wide.

In terms of generalisability, only one maternity unit was involved in the trial but a large number of midwives were involved in recruitment (n=101), serving a wide area encompassing a socioeconomically diverse population. In addition, recruitment took place over 16 months. Although only a third of the 2200 women booked to deliver at the unit were approached antenatally about the trial, just 18% of invited women declined participation. All those who were eligible in labour were randomised.

Other strengths of the study include the successful blinding of the women, midwives, and data analysts; a high and similar level of adherence to the protocol for administration of the lidocaine and placebo sprays; and negligible attrition.

The pain scores recorded in this trial were similar to those obtained in previous studies of second stage labour, including high mean levels and considerable variability.<sup>10 11</sup> In keeping with the findings of previous randomised trials of second stage care,<sup>12 13</sup> overall levels of genital trauma were higher than generally reported. This may result from trauma being recorded in more detail in the trial questionnaires than would normally be required in clinical notes or on a computer.

In conclusion, the use of a topically applied local anaesthetic during second stage labour was acceptable to women and midwives. The lidocaine spray during delivery did not, however, reduce perineal pain.

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Competing interests: None declared.

Ethical approval: This trial was approved by the Medicines Control Agency, the local research ethics committee and the participating NHS trust research and development directorate.

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## Deaths from injury in children and employment status in family: analysis of trends in class specific death rates

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### Abstract

**Objective** To examine socioeconomic inequalities in rates of death from injury in children in England and Wales.

**Design** Analysis of rates of death from injury in children by the eight class version of the National Statistics Socio-Economic Classification (NS-SEC) and by the registrar general's social classification.

**Setting** England and Wales during periods of four years around the 1981, 1991, and 2001 censuses.

**Subjects** Children aged 0-15 years.

**Main outcome measures** Death rates from injury and poisoning.

**Results** Rates of death from injury in children fell from 11.1 deaths (95% confidence interval 10.8 to 11.5 deaths) per 100 000 children per year around the 1981 census to 4.0 deaths (3.8 to 4.2 deaths) per 100 000 children per year around the 2001 census.

Socioeconomic inequalities remain: the death rate from all external causes for children of parents classified as never having worked or as long term unemployed (NS-SEC 8) was 13.1 (10.3 to 16.5) times that for children in NS-SEC 1 (higher managerial/professional occupations). For deaths as pedestrians the rate in NS-SEC 8 was 20.6 (10.6 to 39.9) times higher than in NS-SEC 1; for deaths as cyclists it was 27.5 (6.4 to 118.2) times higher; for deaths due to fires it was 37.7 (11.6 to 121.9) times higher; and for deaths of undetermined intent it was 32.6 (15.8 to 67.2) times higher.

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A table of the results stratified by age group can be found on [bmj.com](http://bmj.com).