

are protected by sleeping under a treated bed net. Our results on the effect of the repellent on the incidence of *P falciparum*, however, probably reflect insufficient statistical power because of the overall low incidence of falciparum cases during the study. We found clear evidence to support the use of a combination of insect repellent and treated bed nets as personal protection against malaria. This is particularly important to the growing number of tourists and business travellers, who have no immunity to malaria. This trial provides evidence for health professionals and specialist travel health organisations to advocate such combined measures in high risk areas, particularly with early evening or outdoor feeding vectors.

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Maternal and neonatal individual risks and benefits associated with caesarean delivery: multicentre prospective study

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EDITORIAL by Shorten

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Objective To assess the risks and benefits associated with caesarean delivery compared with vaginal delivery.

Design Prospective cohort study within the 2005 WHO global survey on maternal and perinatal health.

Setting 410 health facilities in 24 areas in eight randomly selected Latin American countries; 123 were randomly selected and 120 participated and provided data

Participants 106 546 deliveries reported during the three month study period, with data available for 97 095 (91% coverage).

Main outcome measures Maternal, fetal, and neonatal morbidity and mortality associated with intrapartum or elective caesarean delivery, adjusted for clinical, demographic, pregnancy, and institutional characteristics.

Results Women undergoing caesarean delivery had an increased risk of severe maternal morbidity compared with women undergoing vaginal delivery (odds ratio 2.0 (95% confidence interval 1.6 to 2.5) for intrapartum caesarean and 2.3 (1.7 to 3.1) for elective caesarean). The risk of antibiotic treatment after delivery for women having either type of caesarean was five times that of women having vaginal deliveries. With cephalic presentation, there was a trend towards a reduced odds ratio for fetal death with elective caesarean, after adjustment for possible confounding variables and gestational age (0.7, 0.4 to 1.0). With breech presentation, caesarean delivery had a large protective effect for fetal death. With cephalic presentation,

however, independent of possible confounding variables and gestational age, intrapartum and elective caesarean increased the risk for a stay of seven or more days in neonatal intensive care (2.1 (1.8 to 2.6) and 1.9 (1.6 to 2.3), respectively) and the risk of neonatal mortality up to hospital discharge (1.7 (1.3 to 2.2) and 1.9 (1.5 to 2.6), respectively), which remained higher even after exclusion of all caesarean deliveries for fetal distress. Such increased risk was not seen for breech presentation. Lack of labour was a risk factor for a stay of seven or more days in neonatal intensive care and neonatal mortality up to hospital discharge for babies delivered by elective caesarean delivery, but rupturing of membranes may be protective. **Conclusions** Caesarean delivery independently reduces overall risk in breech presentations and risk of intrapartum fetal death in cephalic presentations but increases the risk of severe maternal and neonatal morbidity and mortality in cephalic presentations.

INTRODUCTION

The increase in rates of caesarean delivery at an institutional level is not associated with any clear overall benefit for the baby but is linked with increased morbidity.¹ There is an urgent need to provide women and care providers with information on the potential individual risks and benefits associated with caesarean delivery.

METHODS

Participating women were involved in the 2005 WHO global survey on maternal and perinatal health.^{1,2} The survey explored the relation between rates of caesarean delivery and perinatal outcomes among women delivering in medical institutions from 24 geographic areas in eight randomly selected Latin American countries. A total of 410 institutions were identified, from which 123 were randomly selected for this survey; three refused to participate.

In each institution, we studied all women admitted for delivery during a fixed period, depending on the total annual number of expected deliveries, arbitrarily defined as three months in institutions with 6000 or fewer deliveries and two months in those with more than 6000. Data collection took place from 1 September 2004 to 30 March 2005.

Data collection

Trained staff reviewed medical records of all enrolled women within a day after delivery and abstracted information during the period that the woman or newborn remained in the hospital. A nurse or midwife was responsible for data collection on a day to day basis at each institution. A hospital coordinator supervised data collection, and regional coordinators evaluated data quality.^{1,2}

For each woman we collected information on demographic characteristics, risk before conception, events during pregnancy, mode of delivery, and outcomes up to hospital discharge.

Definitions and outcomes

Caesarean deliveries were classified as elective if the operation was decided by the attending staff before the onset of labour and the woman was referred either from an antenatal clinic or a high risk ward to the delivery unit for caesarean delivery regardless of the diagnosis. Intrapartum caesarean delivery was when a caesarean was indicated during labour, whether labour was spontaneous or induced. We excluded emergency caesarean delivery without labour (see *bmj.com*).

The perinatal outcomes were fetal death, admission to neonatal intensive care unit for seven or more days, and neonatal mortality up to hospital discharge. Severe maternal morbidity was evaluated with proxy events, mostly severe conditions, rather than the clinical diagnosis itself because of problems in standardising definitions. The second primary maternal outcome was postpartum antibiotic treatment. The third maternal outcome was third and fourth degree perineal laceration or postpartum fistulae, or both.

Health institutions were classified as either private or belonging to the public health system or to the social security system (associated with trade union related systems). Maternal risk factors were used in regression models as possible confounding factors. See *bmj.com*.

Analysis

For each outcome variable of interest, we developed the model using generalised estimating equations, an

extension of multiple logistic regression that takes into account clustering effects. Each model included mode of delivery defined at three levels: vaginal (reference category), elective caesarean delivery, and intrapartum caesarean delivery (see *bmj.com*). Variables that failed to show significance at the 5% level in the resulting model were then removed one by one until all remaining variables were significant.

Finally, institutional level variables were tested one by one for possible inclusion in the model. These variables were type of facility (public, social security, private), country (eight levels), and financial incentive for caesarean section (two levels). Of main interest in these models was the estimated independent effect on outcomes of each type of caesarean delivery compared with vaginal delivery. The increased risk associated with caesarean delivery was expressed by an adjusted odds ratio with corresponding 95% confidence interval.

RESULTS

The target patient population represented 106 546 deliveries reported in hospitals' records, yielding data on 97 095 (91% coverage). We excluded multiple births, emergency caesarean deliveries, and women with incomplete delivery data, which left 94 307 deliveries for analysis. Of these, 31 821 (33.7%) were caesarean deliveries: 58.5% intrapartum and 41.5% elective. We included all vaginal deliveries in our analysis regardless of the method of delivery.

Most of the hospitals included were of medium complexity; 12 had limited capacity and 11 had complex resources. Twelve hospitals were private, 86 belonged to the public health system, and 22 to the social security system. In seven of the 12 private institutions (58%) there was evidence of economic incentives for caesarean delivery (for instance, hospitals that charged more to patients or senior attending staff received additional income) compared with 45% (10) in social security institutions and only 25% (22) in public hospitals. Specialists or residents in obstetrics and gynaecology performed 99% of caesarean deliveries and 62% of vaginal deliveries.

The most commonly reported indications for elective caesarean delivery were previous caesarean delivery (44%), breech presentation (12%), pre-eclampsia (13.5%), other maternal complications (12%), and tubal ligation sterilisation (7.4%). For intrapartum caesarean delivery the most common indications were cephalopelvic disproportion (35%), fetal distress (26%), and previous caesarean delivery (32%).

Maternal outcomes

Compared with women who underwent elective caesarean delivery, those with vaginal deliveries were at higher risk in terms of sociodemographic characteristics (such as single, young age, and low education, gravidity, and primiparity), while the caesarean group had higher risk in terms of women with previous complicated pregnancies or perinatal

outcomes, problems related to current pregnancy, and being referred from other institutions for delivery. We observed similar patterns for intrapartum caesarean, although the magnitude of the differences was smaller. Risk factors in women who had an elective caesarean delivery were more prevalent than in women having an intrapartum caesarean. See bmj.com.

In the crude analysis, the maternal morbidity and mortality index in women in the elective caesarean delivery group (5.5%) was higher than that in the intrapartum caesarean group (4.0%) and vaginal delivery (1.8%) groups. The need for antibiotic treatment after delivery was highest in the two caesarean groups. Vaginal complications were lowest among them (table 1). Table 2 also presents the adjusted results for the relation between mode of delivery and these indicators of maternal morbidity. A woman with an elective caesarean was more likely to have at least one of the events included in the maternal morbidity and mortality index compared with a woman with vaginal delivery. Similarly, a woman with an intrapartum caesarean was more likely to experience maternal morbidity and mortality. We also independently explored each of the five conditions included in this index as secondary outcomes following the same adjustment strategy. For all conditions, a caesarean delivery (either elective or intrapartum) was associated with a significantly higher risk than a vaginal delivery after adjustment for possible confounding variables.

Furthermore, the odds ratio for antibiotic treatment after delivery in women who underwent a caesarean (elective or intrapartum) was four to five times that for women with vaginal delivery (both significant). As expected, both elective and intrapartum caesarean delivery had a large protective effect on the incidence

of postpartum fistula or third or fourth degree perineal laceration, or both.

Fetal and neonatal outcomes

In the crude analysis for fetal and neonatal outcomes, the highest rates of neonatal morbidity and mortality were seen in the elective caesarean group but fetal death rates were similar in the three groups (table 2). The rates of preterm delivery were 7% for vaginal deliveries, 12% for elective caesarean, and 9% for intrapartum caesarean. We then studied the association between the mode of delivery and the three primary fetal and neonatal outcomes, stratifying the analysis for fetal presentation at delivery and adjusting for possible confounding variables and gestational age at delivery (table 2). With cephalic presentation, elective caesarean was associated with a marginally significant reduction in the risk of fetal death compared with vaginal delivery, but this effect was not observed for intrapartum caesarean. The 35 fetal deaths in the elective caesarean group were similarly distributed among women with or without any labour before the caesarean. In these 35 women, the indication for caesarean was previous caesarean in 10, pre-eclampsia in nine, and fetal indications in 11. With breech presentation, however, both types of caesarean were associated with a large reduction in risk of intrapartum fetal death compared with vaginal delivery (table 2).

With cephalic presentation, after adjustment for possible confounding variables and gestational age, both elective and intrapartum caesarean delivery were associated with almost double the risk of admission to a neonatal intensive care unit for seven or more days. With breech presentation, however, elective and intrapartum caesarean delivery were not independently associated with significantly higher risk.

Table 1 | Relation between caesarean delivery and maternal morbidity and mortality according to mode of delivery

| | No (%) with vaginal delivery | Elective caesarean | | Intrapartum caesarean | |
|--|------------------------------|--------------------|------------------------------|-----------------------|------------------------------|
| | | No (%) | Adjusted odds ratio (95% CI) | No (%) | Adjusted odds ratio (95% CI) |
| Maternal morbidity and mortality index*: | | | | | |
| Overall | 1125/62 078 (1.8) | 723/13 081 (5.5) | 2.30† (1.69 to 3.14) | 742/18 463 (4.0) | 1.97† (1.57 to 2.46) |
| Death | 7/62 455 (0.01) | 5/13 198 (0.04) | 3.38 (1.07 to 10.65) | 11/18 605 (0.06) | 5.28 (2.05 to 13.62) |
| Admission to ICU | 339/62 415 (0.54) | 359/13 197 (2.72) | 3.05‡ (1.44 to 6.46) | 265/18 598 (1.42) | 2.22‡ (1.45 to 3.40) |
| Blood transfusion | 274/62 267 (0.44) | 129/13 167 (0.98) | 1.75§ (1.33 to 2.30) | 131/18 522 (0.71) | 1.39§ (1.10 to 1.76) |
| Hysterectomy | 33/62 230 (0.05) | 46/13 109 (0.35) | 4.57¶ (2.84 to 7.37) | 54/18 483 (0.29) | 4.73¶ (2.79 to 8.02) |
| Hospital stay >7 days | 550/62 463 (0.88) | 336/13 201 (2.55) | 2.54** (2.01 to 3.20) | 406/18 610 (2.18) | 2.31** (1.72 to 3.11) |
| Antibiotic treatment after delivery | 15 322/62 333 (24.6) | 8177/13 194 (62.0) | 4.24†† (2.78 to 6.46) | 12 949/18 598 (69.6) | 5.53†† (3.77 to 8.10) |
| 3rd/4th degree perineal laceration and/or postpartum fistula | 477/62 226 (0.77) | 23/13 106 (0.18) | 0.10‡‡ (0.03 to 0.30) | 23/18 479 (0.12) | 0.07‡‡ (0.01 to 0.97) |

ICU=intensive care unit.

*Maternal morbidity and mortality index. Presence of at least one of: blood transfusion, hysterectomy, maternal admission to intensive care unit, maternal death, or maternal stay in hospital >7 days. For maternal death the odds ratios are crude; adjusted ratios cannot be computed because there were too few events.

†Adjusted for parity, any pathology previous to current pregnancy, any pathology during current pregnancy, hypertensive disorders, vaginal bleeding in second half of pregnancy, suspected intrauterine growth restriction, and other medical conditions.

‡Adjusted for gravity, any pathology previous to current pregnancy, any pathology during current pregnancy, hypertensive disorders, and other medical conditions.

§Adjusted for any pathology previous to current pregnancy, hypertensive disorders, vaginal bleeding in second half of pregnancy, other medical conditions, referral status, and country.

¶Adjusted for marital status, maternal age, gravity, any pathology previous to current pregnancy, vaginal bleeding in second half of pregnancy, and referral status.

**Adjusted for parity, caesarean section in previous delivery, any pathology previous to current pregnancy, any pathology during current pregnancy, hypertensive disorders, suspected intrauterine growth restriction, other medical conditions, fetal presentation, anaesthesia during labour and country.

††Adjusted for parity, previous reproductive tract surgery or fistula, any pathology previous to current pregnancy, vaginal bleeding in second half of pregnancy, urinary infection, rupture of membranes before labour, fetal presentation, and type of onset of labour (induced/not induced).

‡‡Adjusted for maternal education.

With cephalic presentation, intrapartum caesarean was associated with twice the risk of neonatal death. A similar but smaller effect (1.7, 1.3 to 2.2) was observed for elective caesarean delivery. With breech presentation, however, both types of caesarean were associated with lower neonatal mortality up to hospital discharge, although the odds ratios were not significant (table 2).

A sensitivity analysis excluding all caesareans with the indication of “intrapartum fetal distress” adjusted for gestational age and other confounding variables found the negative effect of caesarean delivery on neonatal morbidity with cephalic presentation remained.

We further explored the lack of labour before surgery as a possible mechanism for the consistent negative effect of elective caesarean delivery. Elective caesarean delivery without labour was associated with an increased risk for admission to a neonatal intensive care unit for seven or more days (adjusted odds ratio 2.2, 1.8 to 2.7)

and for neonatal mortality (1.8, 1.4 to 2.3), both higher than the corresponding observed increased risk for elective caesarean delivery with labour before surgery (odds ratio 1.4, 0.6 to 3.4) for neonatal mortality and for admission to neonatal intensive care (adjusted odds ratio 1.4, 1.0 to 2.0). See bmj.com.

Intended method of delivery

Women with intended caesarean remained at higher risk for morbidity and mortality as well as for antibiotic treatment after delivery compared with women with intended vaginal delivery (1.7, 1.3 to 2.2, for maternal morbidity index and 2.8, 2.0 to 4.0, for antibiotic treatment after delivery) even if some of them eventually delivered by intrapartum caesarean. We observed a similar pattern for the individual components of the index as presented in table 1. For the fetal and neonatal outcomes with cephalic presentations, the patterns observed in the previous analysis also remained. There was no differential risk for intended caesarean delivery versus intended vaginal delivery for fetuses in breech presentation.

Table 2 | Relation between caesarean delivery (CD) and neonatal outcomes according to fetal presentation at delivery among singletons

| Neonatal outcome | No (%) | Adjusted odds ratio (95% CI) |
|---|-------------------|------------------------------|
| Fetal death | | |
| Cephalic presentation*: | | |
| Vaginal delivery (reference) | 242/61 870 (0.39) | 1.00 |
| Elective CD v vaginal delivery | 35/11 300 (0.31) | 0.65 (0.43 to 0.98) |
| Intrapartum CD v vaginal delivery | 73/16 543 (0.44) | 1.25 (0.93 to 1.67) |
| Breech and other presentations†: | | |
| Vaginal delivery (reference) | 53/547 (9.69) | 1.00 |
| Elective CD v vaginal delivery | 18/1874 (0.96) | 0.27 (0.14 to 0.50) |
| Intrapartum CD v vaginal delivery | 14/2043 (0.69) | 0.20 (0.09 to 0.43) |
| Stay for ≥7 days in neonatal intensive care unit | | |
| Cephalic presentation‡: | | |
| Vaginal delivery (reference) | 1162/61 264 (1.9) | 1.00 |
| Elective CD v vaginal delivery | 562/11 239 (5.0) | 2.11 (1.75 to 2.55) |
| Intrapartum CD v vaginal delivery | 568/16 428 (3.5) | 1.93 (1.63 to 2.29) |
| Breech and other presentations§: | | |
| Vaginal delivery (reference) | 55/422 (13.0) | 1.00 |
| Elective CD v vaginal delivery | 126/1845 (6.8) | 1.28 (0.76 to 2.14) |
| Intrapartum CD v vaginal delivery | 141/2014 (7.0) | 1.31 (0.79 to 2.18) |
| Neonatal mortality up to hospital discharge | | |
| Cephalic presentation¶: | | |
| Vaginal delivery (reference) | 231/61 299 (0.38) | 1.00 |
| Elective CD v vaginal delivery | 87/11 237 (0.77) | 1.66 (1.26 to 2.20) |
| Intrapartum CD v vaginal delivery | 107/16 434 (0.65) | 1.99 (1.51 to 2.63) |
| Breech and other presentations**: | | |
| Vaginal delivery (reference) | 36/421 (8.55) | 1.00 |
| Elective CD v vaginal delivery | 33/1846 (1.79) | 0.69 (0.35 to 1.34) |
| Intrapartum CD v vaginal delivery | 33/2021 (1.63) | 0.55 (0.30 to 1.02) |

*Odds ratios adjusted for gestational age, maternal age, education, previous stillbirth or neonatal death, vaginal bleeding in second half of pregnancy, other medical conditions, type of onset of labour (induced/not induced), and country.

†Odds ratios adjusted for gestational age and type of onset of labour (induced/not induced).

‡Odds ratios adjusted for gestational age, maternal age, caesarean section in previous delivery, any pathology during current pregnancy, hypertensive disorders, suspected intrauterine growth restriction, other medical conditions, rupture of membranes before labour, and country.

§Odds ratios adjusted for gestational age, any pathology previous to current pregnancy, and country.

¶Odds ratios adjusted for gestational age, hypertensive disorders, any anaesthesia during labour, and type of facility.

**Odds ratios adjusted for gestational age.

DISCUSSION

Women undergoing caesarean deliveries, either intrapartum or elective, independent of demographic and clinical characteristics or experience of pregnancy had double the risk for severe maternal morbidity and mortality and up to five times the risk of a postpartum infection compared with women undergoing vaginal delivery. Though caesarean delivery carries almost no risk of severe vaginal complications and a slightly reduced risk of intrapartum fetal death, it is significantly associated in cephalic presentation with an increased risk of severe neonatal morbidity and mortality, independent of fetal distress and gestational age. With breech presentation, caesarean delivery substantially reduced the risk to the baby with cephalic presentation. Labour and rupture of membranes before spontaneous labour before an elective caesarean delivery also reduced the risk associated with this mode of delivery.

There were inevitable difficulties in working with a large number of health institutions, staff, medical protocols, and records formats, as well as a fairly limited standardisation of diagnoses and indications for caesarean delivery, which could have produced some misclassification between elective and intrapartum caesarean. To minimise these, we restricted outcomes to severe morbidity and mortality and abstracted data immediately after delivery. Nevertheless, a few inconsistencies remained in the dataset. We therefore recommend caution in the interpretation of the fetal death results.

We focused on hospitals with high rates of caesarean delivery (median 34%) in the context of a wide range of care providers, antenatal care systems, and the socio-cultural circumstances within a particular geographic region. Therefore our observations may not be relevant to institutions with lower rates of caesarean sections or to other regions of the world.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Rates of caesarean delivery have increased dramatically

Caesarean delivery increases the risk of maternal morbidity but the risks and benefits to the baby are still debated

WHAT THIS STUDY ADDS

In a range of practice settings and outcomes, non-emergency caesarean delivery increased morbidity and mortality among cephalic presentations

Delivery by caesarean is recommended for breech presentations, regardless of the gestational age

Incidence of fetal death and vaginal complications may be reduced by caesarean section

Finally, we have considered maternal morbidity and mortality only up to the time of women's hospital discharge. Some women could have had complications after discharge. This could be relevant among women after vaginal deliveries as they tend to be discharged earlier, possibly leading to an exaggeration of the risks after caesarean. A full discussion of confounders is on bmj.com. Similar data have been reported from a low risk primiparous population in Massachusetts, United States, at a similar time period,³ which found women with "intended" caesarean delivery had double the risk for maternal readmission to hospital during the first 30 days after delivery than women with "intended" vaginal delivery.

We confirmed the protective effect of caesarean delivery with breech presentation, similar to that seen in a multicentre randomised trial.⁴ It is clear that these babies, regardless of gestational age, should be delivered by planned caesarean. We observed an increase in neonatal morbidity and mortality associated with both elective and intrapartum caesarean delivery with cephalic presentation, which remained significant after adjustment for several confounding variables including previous caesarean delivery and gestational age at delivery. Sensitivity analyses excluding cases with "fetal distress" also did not change the results. In another US study, primary caesarean deliveries with "no indicated risk" were significantly associated with neonatal mortality (2.0, 1.6 to 2.6), thus supporting the concept that caesarean delivery has a true biological effect.⁵

Which factors can explain such a negative effect with cephalic presentation? By reducing fetal death, caesarean delivery might increase the pool of sick babies, thus transferring deaths from the fetal to the neonatal period. Nevertheless, exclusion of all caesareans associated with fetal distress did not change the observed increased risk.

Elective caesarean delivery could increase neonatal morbidity and mortality because lack of labour affects the physiological process for initiation of respiration. Caesarean delivery is known to be associated with respiratory distress syndrome and transient tachypnoea, possibly mediated by the lower release of catecholamine and prostaglandins, as well as the lack of the mechanical compression of the lungs during labour needed to facilitate postnatal lung adaptation. The reduced risk we have described among elective caesarean deliveries in

women who underwent labour and ruptured their membranes before surgery tends to support this suggestion.

Implications of results

Three main paths could lead to the decision to perform a primary caesarean delivery in cephalic presentation. The first consists of severe emergency complications for which the operation is mandatory. As a second path, caesarean delivery might be used to prevent possible perinatal complications based on intrapartum screening methods, usually electronic fetal monitoring or some clinical parameters. These methods are known to have high false positive rates. Recent attempts to reduce the numbers of caesareans by adding fetal pulse oximetry have not been successful.⁶ Finally, some caesareans are related to a range of social-cultural-economical-legal factors, including women's demand,⁷ without a clear clinical indication. Our data strongly suggest that the surgical procedure in cephalic presentation itself is independently associated with increased maternal and neonatal morbidity and mortality in a wide range of medical practices and sociocultural settings, although with clear short term protective effect for vaginal complications.

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