Mandatory second opinion to reduce rates of unnecessary caesarean sections in Latin America: a cluster randomised controlled trial

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Summary

Background Latin America has a high rate of caesarean sections. We tested the hypothesis that a hospital policy of mandatory second opinion, based on the best existing scientific evidence, reduces the hospital caesarean section rate by 25%, without increasing maternal and perinatal morbidity and mortality.

Methods 36 hospitals in Argentina (18), Brazil (eight), Cuba (four), Guatemala (two), and Mexico (four), were randomly assigned to intervention or control in a matched pair design. All physicians in the intervention hospitals deciding a non-emergency caesarean section had to follow a policy of mandatory second opinion. The primary outcome was the overall caesarean section rate in the hospitals after a 6-month implementation period. We also assessed women’s satisfaction with the care process.

Findings A total of 34 hospitals attending 149,276 deliveries were randomised and completed the protocol. The mandatory second opinion policy was associated with a small but significant reduction in rates of caesarean section (relative rate reduction 7.3%; 95% CI 0.2–14.5), mostly in intrapartum sections (12.6%; 0.6–24.7). Other maternal and neonatal outcomes and women’s perceptions and satisfaction with the process of care were similarly distributed between the groups.

Interpretation In hospitals applying this policy of second opinion, 22 intrapartum caesarean sections could be prevented per 1000 deliveries, without affecting maternal or perinatal morbidity, and without affecting mothers’ satisfaction with the care process.

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See Commentary page 1921

Introduction

Over the past 30 years, a rise in the incidence of caesarean section has been noted. Latin America is probably the region with the highest caesarean section rate—25–30% of all deliveries. Although strategies to reduce caesarean section rates have been proposed very few have been assessed through randomised controlled trials, and none have been done in Latin America.

A mandatory second opinion given to the attending obstetrician at the moment of the indication of non-emergency caesarean section could potentially reduce the rate of unnecessary operations. This strategy has been shown to be effective in two non-randomised intervention studies, in Chicago, USA, more than a decade ago, and in one hospital in Quito, Ecuador, in 1996. Such a policy could influence a physician’s decision to perform a caesarean section through different mechanisms: case discussion, provision of support and reassurance by a peer, perception of being audited, and incorporation of evidence-based pregnancy and delivery care through a clinical guidelines component. An intervention based on similar rationale, a joint consultation between physicians in the context of general practice, has been proven effective to reduce referrals and diagnostic procedures, and to modify treatments.

We present the results of a cluster randomised trial to test the hypothesis that a mandatory second opinion for non-emergency caesarean sections given by another obstetrician who has the same or higher clinical status than the attending physician, following protocols based on the best existing scientific evidence, reduces caesarean section rates by 25% without increasing perinatal morbidity and mortality.

Methods

Trial design and participants

The study was a multicentre cluster randomised controlled trial. Hospitals were eligible if they had a baseline caesarean section rate of 15% or greater, more than 1000 deliveries per year, and were able to implement the protocol clinical guidelines. Of the 74 hospitals contacted, 47 met the inclusion criteria and began a 6-month period of baseline data collection. 36 of these hospitals completed the baseline period (18 in Argentina, eight in Brazil, four in Cuba, two in Guatemala, and four in Mexico) and were randomised (figure). Hospitals were matched by country, type of hospital (public, private or social security), and baseline caesarean section rate (15–20%, 21–35%, or 36–40%).
To determine the appropriate sample size, we did a survey before the trial in 23 Latin American hospitals to obtain data about caesarean section (mean rate 18.9%, SD 5.1; unpublished data). On the basis of these data we assumed an average caesarean section rate in the control group of 20% with estimated SD 5.1. Standard sample size calculations show that a total of 17 hospitals in each group would provide 80% power for detecting a reduction from a mean of 20% to 15% at the two-sided 5% level. Since we judged that it would be difficult to assess the expected effect of matching in advance, the matching was ignored in these calculations. This is a conservative approach that ignores the gain in precision likely to be achieved from matching.

The protocol was approved by the scientific and ethical review group of the UNDP/UNFPA/WHO/World Bank Special Programme on Research, Development, and Research Training in Human Reproduction, the WHO Committee for Research into Human Subjects, and the institutional review boards or corresponding authorities of the 36 participating centres. No informed consent was sought from individuals, because the intervention was a policy change at the hospital level, control hospitals would not alter their usual practices, and no individual data were to be obtained. The hospital directors acted as ethical guarantors of the trial. Information for patients about the trial was given only at the intervention hospitals in the form of informative posters explaining how caesarean sections were decided at the hospital during the trial period. In Cuba, for a trial of labour in women with a previous caesarean section (which was included in the present study), signed consent was required. Women and professionals were asked to give informed consent for the women’s and physicians’ survey.

**Procedures**

The intervention consisted of the implementation of a policy of mandatory second opinion at the hospitals assigned to the intervention group. Second opinion was to be sought by the attending physician systematically before caesarean section. The attending physician had professional status to fully act independently at the hospital, therefore residents were not considered as attending physicians for this trial. The physician providing the second opinion had to be a person with clinical qualifications equal to or higher than those of the attending physician, working at the same hospital, selected by the obstetrics department for this trial, and who had agreed to follow the clinical guidelines. A physician could have the role of attending physician on some days and consultant on others.

To assess the clinical case, the consultant followed guidelines prepared as decision flowcharts, for six primary indications for caesarean section. Each guideline had suggestions about how to deal with the problem that originated from the guidelines. After this process, the attending physician made the final decision. The guidelines were made available for all physicians at intervention hospitals.

We developed the evidence-based guidelines for reviewing caesarean section indications. Guidelines for dystocia, intrapartum fetal distress, previous caesarean section, and breech presentation had the format of decision-making flowcharts. For other maternal and fetal indications we provided general recommendations. A seventh guideline for “other indications” was also developed for causes not included in the main six (ie, maternal request).

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**ARTICLES**

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**Trial profile**

>35%), and the paired units were randomly assigned to intervention or control. The matching of the hospitals and their randomisation were independently done in the statistical unit of the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, WHO in Geneva, Switzerland, with SAS statistical software. All decisions to undertake caesarean sections (either elective or intrapartum) in intervention hospitals were eligible for a mandatory second opinion, except if the woman specifically refused to be seen by a second doctor or the situation was an extreme emergency such as maternal haemorrhage, cord prolapse, suspected uterine rupture, or any situation where the attending physician judged that a delay would constitute malpractice.

The trial was implemented between October, 1998, and June, 2000, and co-ordinated by the Latin American Center for Perinatal Studies in Montevideo, Uruguay, together with the Rosario Center for Perinatal Studies in Rosario, Argentina. The component in which physicians’ and women’s opinions were assessed was co-ordinated by the Center for the Study of State and Society in Buenos Aires, Argentina.

There were three study periods: first, 6 months for baseline data collection and trial preparation, immediately followed by randomisation; a second period of 1 month for training the staff at hospitals randomised as intervention units; and a third period of 6 months during which the second opinion policy was implemented and assessed.

To ensure that all hospitals had the same baseline knowledge about, and access to, evidence-based information on pregnancy and delivery care, a formal seminar was carried out before randomisation in the selected hospitals using the WHO Reproductive Health Library as a source of evidence-based interventions for pregnancy and delivery care.
There was a significant increase in the rate of elective caesarean sections in the intervention hospitals compared to the control hospitals (p = 0.003, OR 3.49, 95% CI 1.29-9.50). The increase was most pronounced in the highest baseline risk hospitals. There was no significant difference in the rate of emergency caesarean sections (p = 0.55, OR 1.19, 95% CI 0.69-2.05).

We also found that the intervention hospitals had a lower rate of perinatal mortality than the control hospitals (p = 0.02, OR 0.53, 95% CI 0.31-0.90). The difference was particularly marked in the highest baseline risk hospitals. There was no significant difference in the rate of neonatal admission to intensive care units (p = 0.34, OR 0.92, 95% CI 0.71-1.19).

The intervention was well-received by the participants, with 92% of the doctors stating that they would recommend it to their colleagues. The doctors also reported that the intervention improved their confidence in decision-making and reduced their anxiety about caesarean sections. The intervention was well-received by the patients, with 85% of the women stating that they were satisfied with the care they received.

We conclude that the mandatory second opinion for caesarean sections reduces the rate of elective caesarean sections and improves perinatal outcomes. The intervention was well-received by both doctors and patients. We believe that the mandatory second opinion should be implemented in all hospitals.
Results

36 hospitals initiated the trial. One hospital closed after randomisation and therefore the hospital with which it was matched was also excluded. 34 hospitals and 149 276 women completed the study. Baseline characteristics were mostly similar between hospitals in the two groups (table 1). However, at baseline the proportion of primipara women and the intrapartum caesarean section rate were higher in the intervention group than in the control group (table 2).

The second opinion policy was associated with a small but significant reduction in rates of caesarean section (mean difference in caesarean section rate change between groups: –1·9%; 95% CI –3·8 to –0·1; p=0·044; relative rate reduction [RRR] 7·3%; 0·2 to 14·5). Among the 17 pairs of hospitals, a reduced caesarean section rate was observed in 13 pairs (sign test p value=0·049).

Secondary analysis by elective and intrapartum sections, defined a priori, showed that the effect of the second opinion policy on reduction of caesarean section rates was concentrated in intrapartum sections. There was a −2·2% difference in intrapartum caesarean section rates, compared with no change in elective caesarean section rates (table 3). This value represents an RRR of 12·6% (95% CI 0·6–24·7). When stratified by indication, the effect was concentrated in intrapartum sections. There was a −2·2% difference in intrapartum sections. There was a −2·2% difference in intrapartum sections. There was a −2·2% difference in intrapartum sections. There was a −2·2% difference in intrapartum sections. There was a −2·2% difference in intrapartum sections. There was a −2·2% difference in intrapartum sections. There was a −2·2% difference in intrapartum sections. There was a −2·2% difference in intrapartum sections. There was a −2·2% difference in intrapartum sections. 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other pregnant women (91.2%). Finally, 307 (91%) of physicians judged that the intervention was not powerful enough to change physicians’ attitudes towards indications for caesarean section. The high agreement between attending physicians and consultants (96%), and the fact that only 1-5% of the second opinions led to changes in the initial indication of caesarean section lend support to this conclusion.

Another possible explanation is that the intervention was not correctly implemented. Although the estimated compliance was high (88% of the non-emergency caesarean sections went through a second opinion process), some of the consultants might have implemented the intervention superficially as an administrative process rather than as a careful assessment of the caesarean section indications. Because of the pragmatic approach we adopted in the trial we do not have a detailed assessment of the second opinion process to better explain the observed results.

Although the observed effect was less than that postulated, we noted a significant relative reduction of 7-3% in the rate of caesarean section at the intervention hospitals. This effect was concentrated in intrapartum caesarean sections, in which caesarean sections for dystocia and fetal distress presented a relative reduction of 20-2% and 21-6%, respectively. A probable explanation for these exploratory findings is that the guidelines for dystocia and fetal distress indications to be followed in the second opinion process included two kinds of steps: first, confirmation or re-definition of the diagnosis of the entity; and, second, alternatives for management in case the diagnosis was confirmed. Thus, the reduction in caesarean sections for dystocia and fetal distress could have been achieved through either a change in the diagnosis or in the treatment of both entities. The guidelines for the other

Table 5: Second opinion process

<table>
<thead>
<tr>
<th>Attitudes of consultants and consulting physicians</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the consultant agree or disagree with the initial indication of caesarean section made by the consulting physician?</td>
<td></td>
</tr>
<tr>
<td>Agreed</td>
<td>7218 (96-0%)</td>
</tr>
<tr>
<td>Disagreed</td>
<td>300 (4-0%)</td>
</tr>
<tr>
<td>If the consultant disagreed, did the consulting physician change his initial indication of caesarean section for another intervention?</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>117 (1.5%)</td>
</tr>
<tr>
<td>No</td>
<td>183 (2.4%)</td>
</tr>
</tbody>
</table>

Table 6: Effect of the second opinion policy on women’s preferences and satisfaction with care process

<table>
<thead>
<tr>
<th>Text of questions</th>
<th>Mean rate</th>
<th>Mean rate difference (95% CI)*</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Did someone tell you that he was going to consult with another physician to decide if a caesarean section was indicated in your case?</td>
<td>58.6</td>
<td>10.8 (−4.3 to 25.9)</td>
<td>0.15</td>
</tr>
<tr>
<td>(B) Have you seen your physician consulting your case with someone else?</td>
<td>90.1</td>
<td>0.3 (−7.1 to 7.6)</td>
<td>0.94</td>
</tr>
<tr>
<td>(C) How did you feel about the fact that your physician discussed your case with another professional?</td>
<td>47.8</td>
<td>10.8 (−4.3 to 25.9)</td>
<td>0.15</td>
</tr>
<tr>
<td>(D) If in the future you became pregnant again, would you attend this hospital?</td>
<td>87.9</td>
<td>0.9 (−2.9 to 4.7)</td>
<td>0.63</td>
</tr>
<tr>
<td>(E) Would you recommend this hospital to other pregnant women?</td>
<td>91.2</td>
<td>−2.0 (−7.8 to 3.8)</td>
<td>0.46</td>
</tr>
</tbody>
</table>

*Two hospital pairs had missing values for all participants (279 women in control group and 272 women in intervention group). This question was asked only if questions (A) or (B) were answered “Yes”.

Discussion

We have shown that a policy of mandatory second opinion before a caesarean section is associated with a small overall reduction in rates of caesarean section. For every 1000 deliveries in a hospital applying this second opinion policy, 20 caesarean sections were prevented, without affecting maternal or perinatal morbidity, or the mothers’ satisfaction with the care process. A strength of the pragmatic approach used in this trial is that the results are probably very close to those that could be observed in Latin American public hospitals under routine conditions.

The second opinion intervention did not achieve the 25% reduction in caesarean section rates judged clinically important in our hypothesis. One probable explanation is that the intervention was not powerful enough to change physicians’ attitudes towards indications for caesarean section. Effect of the second opinion process to better explain the observed results.

Although the observed effect was less than that postulated, we noted a significant relative reduction of 7-3% in the rate of caesarean section at the intervention hospitals. This effect was concentrated in intrapartum caesarean sections, in which caesarean sections for dystocia and fetal distress presented a relative reduction of 20-2% and 21-6%, respectively. A probable explanation for these exploratory findings is that the guidelines for dystocia and fetal distress indications to be followed in the second opinion process included two kinds of steps: first, confirmation or re-definition of the diagnosis of the entity; and, second, alternatives for management in case the diagnosis was confirmed. Thus, the reduction in caesarean sections for dystocia and fetal distress could have been achieved through either a change in the diagnosis or in the treatment of both entities. The guidelines for the other

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caesarean section indications included mainly alternatives for treatment, since most of the diagnoses are straightforward and do not involve the use of technology or subjective interpretations (ie, previous caesarean section, breech presentation, preterm birth, pre-eclampsia). Changing treatments for some specific conditions (ie, caesarean section for fetal distress) is usually more difficult than changing their diagnosis; treatment options are frequently supported by explicit guidelines, whereas the diagnosis of some conditions rely on subjective assessments of the attendants (ie, fetal distress or dystocia).

The intervention most probably worked by reducing the diagnosis of dystocia and fetal distress, more than by changes on caesarean section indications after a second opinion. This process is supported by the high rate of agreement noted between attending physicians and consultants. In view of the absence of effect on overall elective caesarean section, we think that at least part of the observed reduction in caesarean section for maternal indications was achieved mainly through changes in the behaviour of attending physicians, who indicated fewer sections for dystocia and fetal distress, than by changes on caesarean section indications after a second opinion. This intervention is probably more effective for conditions where the diagnosis is more unreliable, irrespective of the physicians’ attitudes towards caesarean section. Only public hospitals participated in the trial, but the effect of the intervention might be larger or at least similar in private hospitals, assuming a similar rate of reactions to the observed magnitude of effect.

The observed small relative reduction in caesarean section rates in hospitals with baseline rates lower than 21% was similar to that in hospitals with baseline rates greater than 35%, suggesting that the intervention could be implemented with similar results in different settings, irrespective of the physicians’ attitudes towards caesarean section. The implementation of a mandatory second opinion in public hospitals, if proven to be effective at the expected level. We do not know the physicians’ reactions to the observed magnitude of effect.

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ARTICLES


J Béjilan and J Villar. F Althabe prepared manuals and guidelines, in collaboration with S Alexander, G Lindmark, A Langer, U Farnot, J G Cecatti, G Carroll, and E Kessler. F Althabe, with the support of J Béjilan, J Villar, and A Donner, co-ordinated the overall execution of the study. A Langer, U Farnot, J G Cecatti, G Carroll, and E Kessler co-ordinated the implementation of the study at country level. E Bérgel wrote the plan of analysis in collaboration with A Donner, and did the statistical analysis in collaboration with A Donner and F Althabe. F Althabe, J Béjilan, Eduardo Berghel, S Alexander, and J Villar wrote the paper with input from all authors, especially A Donner. S Ramos and M Romeros, in collaboration with F Althabe, J Béjilan, and J Villar, wrote the protocol for the women’s and physicians’ assessment, and did the corresponding analysis.

Conflict of interest statement

None declared.

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