Alternative techniques and materials for caesarean section

01 April 2009

There is no clear evidence to suggest that extra-abdominal repair of the uterine incision is superior to the intra-abdominal procedure. Since some indirect evidence suggests that leaving the peritoneum unsutured could be beneficial, a policy of non-closure of the peritoneum could be considered. As to closure versus non-closure of the subcutaneous tissues, there is not enough evidence to justify a change in practice.

RHL Commentary by Abalos E

1. INTRODUCTION

Caesarean section is the most common major surgical operation performed in the USA (1). Caesarean section rate in the USA increased from about 5% in 1970 to about 24% in 2001 (2, 3). In an urban area of India, during June 1997 to May 1999, total caesarean section rates in public, charitable, and private sector clinics were 20%, 38% and 47%, respectively (4). In Latin America, Brazil reported a caesarean section rate of 32% in 1986 (5), reaching over 70% in some health-care facilities (6-9). The WHO Global Survey on Maternal and Perinatal Health was conducted between 2004 and 2005 in 24 regions of eight countries in Latin America. The survey obtained data for all women admitted for delivery in 120 randomly selected institutions (10). The median rate of caesarean delivery was 33%, with the highest rates of caesarean delivery noted in private hospitals being 51%.

Many factors have contributed to the global rise in caesarean section rates, including improved surgical and anaesthetic techniques, reduced risk of short-term post-operative complications, demographic and nutritional factors, and providers’ and patients’ perception of the safety of the procedure. The latter in particular is a factor in the increasing numbers of women worldwide opting for an elective caesarean section without medical indication (11). However, results from the WHO Global Survey on Maternal and Perinatal Health show that increased caesarean section rates are associated with a higher risk of postpartum antibiotic treatment and severe maternal morbidity and mortality. Increase in the rate of caesarean delivery is also associated with an increase in fetal mortality rates and higher numbers of babies admitted to intensive care for 7 days (10). Given that the operation is conducted so frequently, any attempt to reduce its associated risks (even with relatively modest alterations to the surgical procedure for a particular outcome) is likely to yield significant benefits in terms of costs and health benefits for the women.

This commentary covers three Cochrane reviews: Extra-abdominal versus intra-abdominal repair of the uterine incision at caesarean section (12); Closure versus non-closure of the peritoneum at caesarean section (13); and Techniques and materials for closure of the abdominal wall in caesarean section (14).
2. METHODS

Overall, the three reviews are comprehensive. They include all adequately controlled trials that could be identified. The respective authors of the reviews contacted authors of published abstracts unpublished data or ongoing studies for details on methodology and/or results, evaluated the trials for methodological quality and appropriateness for inclusion, and followed generally sound methods in the conduct of the reviews. Details of specific pitfalls of individual reviews are discussed in section 4.1 below.

3. RESULTS

3.1. Extra-abdominal versus intra-abdominal repair of the uterine incision at caesarean section

This review sought to evaluate the effects of exteriorization of the uterus versus intra-abdominal repair of the uterine scar after delivery of the baby and the placenta. It includes six trials involving 1221 women who had undergone a caesarean section either as an emergency or an elective procedure. The primary outcome measures were blood loss (pre- and postoperative laboratory measures) and postoperative sepsis (defined by trial authors). Secondary outcomes included a range of variables measuring infection-related complications (such as postoperative pyrexia, wound infection), haemorrhage (blood transfusion, intra-operative blood loss), surgical complications, satisfaction with the procedure reported by women and health-care providers, and costs, among others.

Neither blood loss nor postoperative sepsis were significantly different in external or intra-abdominal repair groups. Postoperative drop in haematocrit was evaluated in two trials involving 324 women. The weighted mean difference (WMD) was -0.47 and the 95% confidence interval (CI) ranged from -1.48 to 0.54. Two other trials (482 women) measured postoperative drop in haemoglobin, with similar results (WMD 0.02; 95% CI -0.62 to 0.65). Postoperative sepsis was reported in one trial involving 308 women [relative risk (RR) 0.94; 95% CI 0.19–4.17].

One of the trials excluded more than 20% of women after randomization due to the need to perform surgical manipulations during the operation. Antibiotic use was not consistently reported in the trials and only about one third of the patients received prophylactic antibiotics during surgery.

Subgroup analyses were added post-hoc by the reviewers, taking into account whether the placenta was manually removed or spontaneously delivered, as three of the included studies pre-specified these subgroups.

3.2. Closure versus non-closure of the peritoneum at caesarean section

This review, which includes 14 trials involving 2908 women, makes the following comparisons: (i) non-closure of both visceral and parietal peritoneum versus suturing of both the layers; (ii) non-closure of the visceral peritoneum only versus suturing of both parietal and visceral peritoneum; and (iii) non-closure of the parietal peritoneum only versus suturing both parietal and visceral peritoneum. The main outcome measures were operating time, analgesic requirement, postoperative fever, endometritis, length of hospital stay, wound infection, wound dehiscence, and adhesions at the subsequent operation. There were no data evaluating the last two outcomes.

Non-closure of both layers (10 trials, 1521 women; WMD 6.05 minutes; 95% CI (6.74 to 5.37), only the visceral layer (one trial, 544 women; WMD 6.30 minutes; 95% CI range 9.22 to 3.38 minutes) or only the parietal layer (one trial, 248 women; WMD 5.10 minutes; 95% CI range 8.71 to 1.49 minutes), all
seemed to reduce the operation time. However, this finding is not surprising as the intervention involved avoidance of one (or two) steps of the standard procedure performed in the control group. Postoperative fever was significantly lower (14.2% in the intervention group versus 15.4% in the control group) when both layers were left unsutured (seven studies, 1263 women). However, the results must be interpreted with caution as there was clinical heterogeneity among the trials, with incidences ranging from 0% to 23% in the experimental arm, and from 0% to 30% in the control group. When both visceral and parietal peritonea were not sutured the result was shorter stay in hospital (six trials, 974 women). Only two trials involving 393 women assessed the use of analgesics, showing no differences between groups. Other clinically relevant outcomes such as endometritis and wound infection were evaluated in only two and three trials, respectively, with no statistically significant differences.

3.3. Techniques and materials for closure of the abdominal wall in caesarean section

This review was designed to evaluate the effects on morbidity and utilization of health-care resources of alternative techniques and materials for closure of the rectus sheath and subcutaneous fat at caesarean section. The authors defined short-term outcomes (in terms of infectious and haemorrhagic morbidity, pain, complications and duration of surgery) as well as long-term outcomes (in terms of fertility problems or complications in future pregnancies). Health service use (length of hospital stay or re-admission to hospital) was also evaluated.

Six trials involving 1853 women evaluated the effects of closure versus non-closure of the subcutaneous tissues, and one trial involving 203 women assessed the effects of blunt versus sharp needles for closing of all layers at caesarean section. No trials were found that evaluated different techniques or materials for closing the rectus sheath.

Women recruited in the trials were undergoing their first or repeat caesarean section, either elective or intrapartum. Women with transverse or vertical skin incision were included in the review. Subcutaneous drain was a comparison arm in one of the studies and not in another two. Whether or not subcutaneous drain was part of the surgical procedure was not specifically mentioned in the remaining two. No information was provided regarding prophylactic use of antibiotics.

No differences were found in the incidence of wound infection when the subcutaneous tissues (fat and/or camper fascia) were sutured or left unsutured (five trials, 1348 women; RR 1.02; 95% CI 0.69–1.50). The authors of the review regarded wound haematoma and wound seroma as a single outcome, which was statistically significantly lower in the closure group (RR 0.52; 95% CI 0.33–0.82). However, it is questionable if these outcomes could be combined, as their clinical implications (like the need for extra appointments with the health-care system, re-admission to hospital, surgical drainage or other procedures) may differ. Moreover, seroma (the commonest complication found according to the authors) is a subjective diagnosis that may be influenced by knowledge of the allocated group.

4. Discussion

4.1. Applicability of the results

In the case of the first review (12) all trials were conducted in developed countries, one in the 1970s and the rest in the 1990s. Although the authors of the review suggest a marginal but significant reduction in febrile morbidity in the uterine exteriorization group, these results should be interpreted with caution because they come from only one trial published in 1978 in which more than 20% of women were excluded after randomization, presumably due to surgical complications during caesarean section. Furthermore, this outcome was modified post-hoc into febrile morbidity for more than three days, when in the type of outcome measures section it was described as postoperative pyrexia. Febrile morbidity (as per protocol definition) was reported in at least two other trials (15, 16), not included in the meta-analysis of this review.
Most trials in the second review (13) were conducted in developed countries. Results of this review suggest that when both visceral and parietal peritonea were not sutured the result was shorter stay in hospital. However, clinicians need to evaluate the relevance of this reduction (9-hours, ranging from 6 hours to 12 hours) according to the availability of beds in their own settings. They should be cautious as the postoperative hospital stay in the different trials ranged from 2.9 days to 8.3 days in the experimental group, and from 2.8 days to 9 days in the control group. This could be associated with differences in hospital protocols for post-surgical care at different settings, or to different incidence of postoperative complications in these hospitals.

All but one trial in the third review (14) were conducted in developed countries between 1991 and 2001. Although the authors of the review concluded that the methodology of the seven trials appeared to be generally satisfactory, there is a high probability of selection, attrition and/or detection bias. One of the trials (164 women) had possibly not concealed the allocation sequence (randomized from a “list” in theatre). The rest had attempted allocation concealment through the use of sealed opaque envelopes. However, the trials did not mention if the envelopes were consecutive and numbered. Thus, it is not possible to determine whether a woman was excluded after an envelope was opened. Assessment at follow-up was blinded in two trials, not blinded in other two, and not documented in the others. One of the trials excluded nearly 40% of the women after randomization, as one of the inclusion/exclusion criteria was applied afterwards. All trials followed-up women until hospital discharge. After discharge, in two studies women “were encouraged to return to hospital only if they developed problems”. In another, women were followed-up using a retrospective chart review. The trials that systematically and prospectively tried to follow-up women failed to find more than 20% of them. One of the studies (451 women) did not report results on an intention-to-treat basis. The authors of the review stated that some of the trial reports were unclear about the number of women assessed for each outcome, and that assumptions were made when conducting the review. No conclusions could be drawn regarding the use of blunt versus sharp needles for closure of the abdominal wall. The only trial included in the review was too small to arrive at any reliable estimate.

In conclusion, the universal applicability of the interventions studied in the three reviews at secondary-care settings is debatable. Also, there is little information in the reviews about the ability and skills of physicians performing the surgeries, as well as whether the hospitals were in the public or private sector, or whether they were teaching hospitals. No information is given in many trials about the concomitant use of prophylactic antibiotics during the procedure, which may have implications for the reductions in postoperative fever rates.

Based on the results of the reviews, it is difficult to specify the main outcomes since different caesarean section techniques and procedures were used in the trials included in the three reviews. Febrile morbidity, postoperative infection rates, antibiotic use, wound complications, haemorrhage, pain, need for analgesia and length of stay in hospital reflect short-term maternal morbidity. However, a surrogate measure for maternal morbidity (i.e. duration of operation, is the most often recorded outcome for trials evaluating closure versus non-closure of the peritoneum at caesarean section. Because it is an easy-to-measure outcome and is expressed as a continuous variable, a smaller sample size is needed to demonstrate a given statistically significant difference. But the use of surrogate outcomes may not be always appropriate because their use assumes a correlation between maternal morbidity and the outcome measured. This relationship may be misleading. A longer operation time may not necessarily be associated with postoperative maternal morbidity if, for example, the technique being used causes less tissue damage or introduces less foreign material into the wound, thus reducing the likelihood of morbidity complications. The long-term morbidity outcomes are difficult to evaluate within the context of randomized controlled trials. Adhesions may be asymptomatic in most cases and to show a difference among the symptoms (pain, dyspareunia) or other morbidity (such as secondary infertility) a large number of women would need to be evaluated. Direct and indirect costs to both the health system and users were not evaluated in these trials.

4.2. Implementation of the intervention
Extra-abdominal versus intra-abdominal repair of the uterine incision at caesarean section. There is no clear
evidence for superiority of one type of uterine incision repair over the other. Practitioners need to evaluate
the potential advantages of exteriorizing the uterus (better accessibility to the uterine angle, better
haemostasis), with its possible risks (exposure of the fallopian tubes to trauma, nausea and vomiting,
complications with the utero-ovarian veins).

Closure versus non-closure of the peritoneum at caesarean section. There is some proxy evidence suggesting
that leaving the peritoneum unsutured could be of benefit for the woman. In settings with adequately skilled
personnel, a policy of non-closure of the peritoneum could be considered, along with implementation of
preventive measures, such as the use of prophylactic antibiotics, to reduce short-term morbidity and hospital
costs. In health-care facilities considering a change in practice, some education and training of health-care
staff would be necessary (see video on caesarean section) to ensure that the health-care workers will have
the skills to identify intra-operative complications such as abnormal bleeding of the peritoneal layers. If a
change in policy is planned, adequate record-keeping and follow-up of women for detection of clinically
relevant complications in both the short and long term will be desirable.

Closure versus non-closure of the subcutaneous tissues. There is not enough evidence from this review to
justify a change in practice related to this aspect of the caesarean section operation in the hospital settings.

4.3. Implications for research

Future research should be aimed at evaluating the costs of the operation and women's views on postoperative
discomfort associated with particular surgical techniques. Clinically relevant short- as well as long-term
benefits or complications of the above-mentioned procedures need to be evaluated in large randomized
controlled trials. Closure versus non closure of the peritoneum was one of the interventions evaluated in
3031 women recruited to the CAESAR Study ? a multicentre factorial randomized controlled trial conducted
in 47 hospitals throughout the United Kingdom and Italy (17). Results are expected to be published in 2009.
Another international, fractional factorial randomized controlled trial and is being conducted in 20 hospitals
in Argentina, Chile, Ghana, India, Kenya, Pakistan and Sudan (18). Exteriorization of the uterus for repair
versus intra-abdominal repair, and closure versus non-closure of the peritoneum (pelvic and parietal) are two
of the five pairs of interventions being compared. The trial aims to recruit 15 000 women worldwide and is
expected to finish recruitment by the end of 2010.

Sources of support: Centro Rosarino de Estudios Perinatales, Rosario, Argentina.

Acknowledgements: none.

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This document should be cited as: Abalos E. Alternative techniques and materials for caesarean section: RHL commentary (last revised: 1 April 2009). The WHO Reproductive Health Library; Geneva: World Health Organization.

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