Reviewer’s report

Title: A cluster-randomized field trial to reduce cesarean section rates with a multifaceted intervention in Shanghai, China

Version: 0 Date: 03 Oct 2019

Reviewer: Barry Schifrin

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REVIEW
In China a one-child policy was created in 1979 with the expectation of achieving zero population growth by 2000. For families who observed the rule, there were higher wages, better schooling and employment, and preferential treatment in obtaining governmental assistance. For families who violated the policy, there were sanctions: fines, wage cuts, employment termination, and difficulty in obtaining governmental assistance. Despite exceptions and "outs" to the rule, it was enormously successful in reaching its objective - 7 years earlier than expected. By 2015, China had an estimated 150 million single-child families two-thirds of whom were thought to be a direct result of the one-child policy. At that time, the total fertility rate had dropped to 1.6 children per woman, well below the replacement value of 2.1. The rule was rescinded on January 1, 2016.

The cesarean section rate in China began to rise shortly after the implementation of the one-child policy with a sharp rise in the mid-1990s, and a further rise from 28.8% in 2008 to 34.9% in 2014 [2, 3]. The authors state that the rise in the cesarean section rate in China was multifactorial [4-6], citing fear of labor pain, concerns about complications genito-urinary impediments and misconceptions of CS being safer than vaginal delivery for the baby, poor experience of previous vaginal delivery, and auspicious dates [3, 4]. The shortage of nurses/midwives and the large volume of deliveries often lead to more convenient and scheduled CS. The constrained doctor-patient relationship and insufficient training in vaginal delivery also exacerbated the situation [5, 7]. Higher financial incentives for CS versus vaginal delivery may lead to the preferred choice of CS [2, 4, 5]. The authors offer the statement that vaginal delivery (presumably if successful) is associated with fewer complications than is cesarean section (for all deliveries). This may be true, but the statement camouflages the understanding that if you are only going to have one child and the child's outcome is the primary concern, that an elective cesarean section at term is more likely to realize that objective than a attempted vaginal delivery - including operative vaginal delivery. That would seem to be a notion that has not been lost on patients with previously restricted reproductive options that have only very recently been removed.

I offer these comments (derived from Wikipedia and from the authors) to suggest that the situation with regard to obstetrical care and the route of delivery is likely in considerable flux in China (as well as other countries) given the incentives to reduce their very high national cesarean section rate in the face of the very recent abandonment of the one-child restriction. I believe that more attention should be given in this paper to these issues.

The authors set out to implement a multifaceted (3-tier) intervention program to reduce the frequency of cesarean section including more targeted prenatal health education improved hospital policy and training of doulas and midwives. They found that this approach implemented over a rather large
population did not significantly reduce the cesarean section rate, at least over the short term, in the subject hospitals in Shanghai, China.

It is difficult to fault the design of the study in terms of the baseline survey conducted prior to the intervention. This baseline survey involving well over 10,000 deliveries represented about one-sixth of the total births in Shanghai in the 1st half of 2016.

The 1st intervention consisted of an augmentation of the regular prenatal education program now specifically designed to familiarize pregnant women with the process of "natural childbirth" along with the "benefits and risks" of cesarean section. This was accomplished by online brochures, off-line courses, and free outpatient consultations in the intervention hospitals.

The 2nd initiative consisted of focused group discussions with obstetricians, midwives and hospital managers to create an "improved hospital cesarean section policy." The policy included

1) the need for a 2nd opinion from a senior physician
2) encouraging the use of regular peer review of cesarean section indications including a promulgation of monthly cesarean section rates presumably by individual practitioners, including a reward system.
3) Offering several training courses to midwives and doalas in the intervention hospital to improve their skills and presumably their perspective.

The 3rd intervention consisted of providing specially designed courses to midwives and doulas in the intervention hospital to "improve her skills."
The interventions were implemented in September 2016 through April 30, 2017; beginning less than a year after the revocation of the one-child policy.

The primary outcome of the study was the change in cesarean section rate. Secondary outcomes included gestational weight gain and such obstetrical interventions as the timing of the cesarean section (planned or intrapartum), the timing of artificial rupture of membranes, the need for labor induction, the use of oxytocin during labor, epidural anesthesia, the use of the doula and whether an operative vaginal delivery and / or episiotomy were performed.

Perinatal outcomes were measured by a composite score in which each of 10 outcomes was assigned a weighted score weighted by severity. A number of maternal and fetal / neonatal covariates were used to inform the outcomes including maternal age, height, weight, parity, use of assisted reproductive technology, previous cesarean section and gestational age at delivery.

Pregnancies were considered morbid (at risk) when serious medical or obstetrical features were present. They were considered "low risk" if the newborn was born in cephalic presentation, to a mother whose BMI was between 17 and 28, who were between 18 and 40 years of age and who delivered at 37 to 41 weeks.

An intention-to- treat analysis used generalized estimating equations (GEE) to assess the effects of these multifaceted interventions on cesarean section rates. The authors further evaluated the intervention effect in each group according to the classification of the timing and urgency of cesarean section. In this respect, the authors do not mention the use of operative vaginal delivery - statistics which should be included if one is to make sense of the outcomes.
As the authors point out, numerous attempts have been made to reduce the cesarean section rate around the world with limited, if any, enduring success. The approaches have either been multifactorial or have focused on one or more indications for interventions. These initiatives have been sponsored by governments, by medical institutions or by medical societies and vary considerably in their apparent efficacy even without long-term follow up. The discussion of the provenance and outcome of these initiatives is one of the stronger points of the article.

There are several features of this study that would seem to have preordained the outcome of the study. Most obvious would appear to be the notion that it is the impact of the cesarean section rate, across-the-board, that is being assessed, irrespective of the fact that certain indications for cesarean section, with marginal room for reduction, contribute only minimally to the overall cesarean section rate. Assessing the impact of interventions on the total cesarean section rate is not likely to be as helpful as a more focused assessment according to the indication for intervention. Thus, success rates of initiatives to lower the cesarean section rate will likely differ according to indication. Attempting to reduce intervention for dysfunctional labor or fetal distress will likely prove more effective than for indications of fetal malposition, compound presentation or catastrophic event. Concentrating on the overall cesarean section rate only camouflages subsets of indication for cesarean section where progress has indeed been made. Indeed, in the study, the authors found a reduction in the use of cesarean section in patients in labor, but an increase in the use of repeat cesarean section. To me, the reduction in intrapartum cesarean section represents progress and is an area that should be explored and offered as a provisional benefit of the study rather than the conclusion that there was no change in the (overall) cesarean section rate. The increase in the cesarean section rate for repeat cesarean sections likely requires a different initiative and a changed demographic. This is likely happening at the present time with the simultaneous introduction of initiatives and the removal of the one-child policy.

I am disturbed by the authors’ use of the term "unnecessary cesarean section," a term that is not defined and indeed is probably undefinable. One really cannot speak of "unnecessary" cesarean sections in an environment where the indications are so diverse and the mother is entitled to make decisions for cesarean section on an elective basis. For example, it seems contradictory, to refer to cesarean section for "fetal distress" or one of its euphemisms as "unnecessary" unless the pH of the umbilical artery is less than 7.0. Such an assessment places more value on the "diagnosis" than on the outcome. A better term is required; perhaps "justifiable/not justified," "defensible / not defensible," or "reasonable / not reasonable". Similarly, a requirement for a "second-opinion" introduces political considerations and cannot be relied upon during an emergency situation. True peer review of both the clinical details along with an authoritative review of the fetal monitor tracing and affirmative feedback to the practitioner will probably provide a more effective teaching (remedial) experience.

To have a material effect on the cesarean section rate which varies so widely by physician, by practice type, by insurance, by patient desires, will ultimately require a cultural change along with more directed initiatives. The authors do not provide an assessment of the variations in practice among the different hospitals. Perhaps, requiring the surgeon to complete a detailed (pre-formatted) reporting form that uncovers the indications (and intentions - behavior) of the surgeon would better inform the approach remedial policies should take. In this respect, an understanding of what created the emergency (excessive contractions, pushing strategy, timely assessment of progress in labor, evolution of the CTG) will better inform the decision to intervene. A program dedicated to the marked reduction of the rate of "emergency" cesarean section during a trial of labor is a measure of the quality of obstetrical care whose understanding and amelioration would likely make labors safer and ultimately reduce the overall cesarean section rate. A measure of urgency should be added to the Robson criteria.
It seems reasonable to view the article, with its considerable effort and large number of patients as an anchor point for subsequent studies on the impact of the various initiatives as the population moves away from the generation-long restriction imposed on reproductive activities by the one-child policy. The authors are encouraged to pursue their efforts over time - the objective of safely reducing the cesarean section rate is a worthy one.


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