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Effect of maternal death reviews and training on maternal mortality among cesarean delivery: post-hoc analysis of a cluster-randomized controlled trial

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ABSTRACT

Objectives: To explore the differential effect of a multifaceted intervention on hospital-based maternal mortality between patients with cesarean and vaginal delivery in low-resource settings.
Study design: We reanalyzed the data from a major cluster-randomized controlled trial, QUARITE (Quality of care, Risk management and technology in obstetrics). These subgroup analyses were not pre-specified and were treated as exploratory. The intervention consisted of an initial interactive workshop and quarterly educational clinically oriented and evidence-based outreach visits focused on maternal death reviews (MDR) and best practices implementation. The trial originally recruited 191,167 patients who delivered in each of the 46 participating hospitals in Mali and Senegal, between 2007 and 2011. The primary endpoint was hospital-based maternal mortality. Subgroup-specific Odds Ratios (ORs) of maternal mortality were computed and tested for differential intervention effect using generalized linear mixed model between two subgroups (cesarean: 40,975; and vaginal delivery: 150,192).
Results: The test for homogeneity of intervention effects on hospital-based maternal mortality among the two delivery mode subgroups was statistically significant (p-value: 0.0201). Compared to the control, the adjusted OR of maternal mortality was 0.71 (95% CI: 0.58–0.82, $p = 0.0034$) among women with cesarean delivery. The intervention had no significant effect among women with vaginal delivery (adjusted OR 0.87, 95% CI 0.69–1.11, $p = 0.6213$). This differential effect was particularly marked for district hospitals.
Conclusion: Maternal deaths reviews and on-site training on emergency obstetric care may be more effective in reducing maternal mortality among high-risk women who need a cesarean section than among low-risk women with vaginal delivery.

Introduction

The reduction in maternal and perinatal mortality is a great challenge for most countries in sub-Saharan Africa [1]. Improving access to cesarean delivery should save many lives [2]. Some African countries have already implemented total or partial exemption fees for cesarean section [3,4]. In this context, while pre-labor cesarean decreases the risk of fetal/immediate neonatal death compared to women with a trial of labor, intrapartum cesarean delivery is associated with two- to six-fold higher risks of hospital-based maternal and neonatal mortality compared to spontaneous vaginal delivery, independent of women's, newborns' and hospitals' characteristics [5,6]. These findings can be explained by delays in: (1) deciding to seek appropriate medical help for an obstetric emergency; (2) reaching an appropriate obstetric facility; (3) receiving adequate care when a facility is reached [7]. In a rural African setting, hospital-based maternal mortality among patient referred with an obstetric complication increases with increasing travel time to the hospital; and this effect is particularly marked for

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patients who delivered by cesarean section [8]. Moreover, key evidence-based interventions are not implemented in women with complication and with a cesarean delivery [9].

In low-resource settings, training programs on emergency obstetric care are effective to increase knowledge and skills, and to improve behavior of health care professionals after training [10]. The audit approach is also promising to improve the performance of health professionals. Observational studies resulting from local initiatives in sub-Saharan countries on the effect of maternal deaths reviews (MDR) showed improved maternal outcomes [11–14]. Large-scale implementation of MDR combined with on-site training on emergency obstetric care is effective to reduce hospital-based maternal and neonatal mortality in first-level African referral hospitals [15]. The "active ingredients" of the multifaceted intervention are typically directed toward developing local leadership and empowering obstetric teams by providing health care professionals with the knowledge and confidence to make quality improvement suggestions. However, these strategies proven effective for women who deliver in referral hospitals have not been evaluated for high risk patients with cesarean delivery. We did not find experimental published effectiveness studies on any intervention targeting women with cesarean delivery.

In this article, we reanalyzed the data of a major cluster-randomized controlled trial, QUAlity of care, RIsk management and TEchnology in obstetrics (QUARITE), conducted in Mali and Senegal [15]. This trial tested the impact of a multifaceted intervention based on MDR and training on emergency obstetric care. Given the knowledge gap which is higher in this context for the management of complicated delivery than for vaginal normal delivery, we took the opportunity to conduct a post-hoc analysis on the trial data to explore whether the effect of the educational intervention of the QUARITE trial was stronger among women who underwent a cesarean delivery than among women who delivered vaginaly and whether this differential effect varied by hospital type.

Materials and methods

The QUARITE trial protocol has been presented in detail elsewhere [16]. Briefly, we used a 4-year cluster-randomized controlled trial, with hospitals as the unit of randomization and patients as unit of analysis. Twenty-four health care facilities in Senegal and 22 in Mali were stratified by level of care and randomly assigned after a 1-year baseline period to either an intervention or a control group. Data for all deliveries during the baseline and the post-intervention periods were collected prospectively. The intervention was implemented over a 2-year period. The primary analyses verified whether the intervention's effect varied according to country (Mali vs Senegal) and hospital type (Hospital in the Capital Dakar or Bamako, Regional hospital, District hospital) [15]. Sub-group analysis according to the mode of delivery was not planned a priori. But this variable was a baseline maternal characteristic of the QUARITE trial.

The intervention was implemented at the hospital level in the experimental group and targeted qualified health-care professionals who were involved in obstetric care: doctors, midwives and nurses. The activities during the 2 years of the intervention period were directed toward developing local expertise in maternal death reviews and increasing the performance of the health care professionals for emergency obstetric care. The program consisted of an initial 6-day training session on evidence-based clinical practices and on clinical audit of one physician and one midwife per hospital, using the Advances in Labour and Risk Management (ALARM) international program [17] and provided by certified instructors. The trainees then played the role of local opinion leaders (without financial incentives) in their own hospitals and launched MDR and on-site training workshops with the support of the local audit committees and external facilitators during their quarterly educational outreach visits. The audit committees made various quality improvement suggestions during the audit sessions. The most recurrent actions implemented were: organizational changes to improve 24 h service availability and patient monitoring. Training topics were selected by the audit committees depending on the principal causes of maternal mortality in a given hospital, as identified during the reviews. The most recurrent topics were the management of pre-eclampsia and post-partum hemorrhage.

The hospitals randomized to the control group did not receive any intervention from the research team. However, we could not avoid contamination since maternal death reviews were introduced in 8 of the 23 control hospitals.

The primary outcome was hospital-based maternal death, measured as the vital status of the mother (dead or alive) at hospital discharge. We also assessed the effects of the intervention on three types of secondary outcomes: resource availability in each hospital, medical practice for emergency obstetric care, and perinatal mortality. The multifaceted intervention led to a reduction by 15% of maternal mortality. This effect was limited to capital and district hospitals. The intervention also increased ante-partum cesareans and decreased intra-partum cesareans. Independent of the mode of delivery, the intervention was effective in reducing neonatal mortality, but not stillbirth. More details can be found in the published protocol and findings of this trial [15].

Participant's characteristics at baseline period (residence, age, parity, prenatal visit attendance, pathology diagnosed during pregnancy, mode of admission and complication at admission) were compared between the two delivery mode subgroups using chi-square test. The intervention effect on the primary outcome was estimated as the difference between the allocation groups in the change of individual mothers' risk of hospital-based mortality from the baseline (year 1) to the post-intervention (year 4) periods, using the odds ratio (OR) with 95% CIs for the interaction between groups (intervention vs control) and time (post-intervention vs baseline). We used generalized linear mixed models to account for clustering. ORs were tested by the two-sided Wald test at $\alpha = 0.05$. Interaction with the mode of delivery (cesarean vs vaginal) was tested to assess whether the intervention effect varied between subgroups. The intervention effects were reported separately for each delivery mode subgroup and for each hospital type. Secondary binary outcomes, related to either maternal morbidity or perinatal mortality were assessed as primary outcomes. Interactions with the mode of delivery were not tested for secondary outcomes to avoid multiple subgroups testing. All analyses were adjusted for variables selected a priori as potential risk factors for hospital-based maternal or neonatal mortality, at a hospital and patient (mother or child) level, in order to take into account differences in both hospital resources and characteristics of the women and newborn who delivered in each hospital. There are three types of factors: common factors of maternal and fetal: (a) residence, maternal age $\geq$35 years, nulliparous, no prenatal visit, induction of labor, any pathology during current pregnancy (pyelonephritis or urinary infection, malaria, severe maternal anemia ($<$70 g/L), gestational diabetes, pregnancy-induced hypertension, vaginal bleeding near full-term, or chorioamnionitis), ante/per-partum obstetric complication (pre-eclampsia/eclampsia, ante-partum hemorrhage, prolonged/obstructed labor, uterine rupture), referred from another health facility, country, availability of anesthetist, availability of gynecologist–obstetrician; (b) specific maternal factors: availability of adult intensive care unit, availability of blood bank; (c) specific fetal factors: availability of neonatal intensive care unit. All analyses were performed with *glmer* process of R software, version 2.15.1 (The R Foundation for Statistical