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SURGERY IN LOW AND MIDDLE INCOME COUNTRIES

Surgical Safety Checklist Use and Post-Caesarean Sepsis in the Lake Zone of Tanzania: Results from Safe Surgery 2020

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Abstract

Background Maternal sepsis accounts for significant morbidity and mortality in lower income countries, and caesarean delivery, while often necessary, augments the risk of maternal sepsis. The aim of this study was to investigate the effect of Safe Surgery 2020 surgical safety checklist (SSC) implementation on post-caesarean sepsis in Tanzania.
Methods We conducted a study in 20 facilities in Tanzania's Lake Zone as part of the Safe Surgery 2020 intervention. We prospectively collected data on SSC adherence and maternal sepsis outcomes from 1341 caesarian deliveries. The primary outcome measure was maternal sepsis rate. The primary predictor was SSC adherence. Multivariable logistic regression was used to estimate independent associations between SSC adherence and maternal sepsis.
Results Higher SSC adherence was associated with lower rates of maternal sepsis (<25% adherence: 5.0%; >75% adherence: 0.7%). Wound class and facility type were significantly associated with development of maternal sepsis (Wound class: Clean-Contaminated 3.7%, Contaminated/Dirty 20%, $P = 0.018$) (Facility Type: Health Centre 5.9%, District Hospital 4.5%, Regional Referral Hospital 1.7%, $P = 0.018$). In multivariable analysis, after controlling for wound class and facility type, higher SSC adherence was associated with lower rates of maternal sepsis, with an adjusted odds ratio of 0.17 per percentage point increase in SSC adherence (95% CI: 0.04, 0.79; $P = 0.024$).
Conclusions Adherence to the SSC may reduce maternal morbidity during caesarean delivery, reinforcing the assumption that surgical quality interventions improve maternal outcomes. Future studies should continue to explore additional synergies between surgical and maternal quality improvement.

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Introduction

Maternal sepsis, defined as organ dysfunction from infection after pregnancy, has long been recognized as a pressing public health issue. Maternal sepsis accounts for 10.7% of maternal deaths globally [1], with most sepsis deaths occurring in developing regions [2]. The recent results from the Global Maternal Sepsis Study demonstrate different levels of maternal infection (the precursor to maternal sepsis) based on income group, with a 7.4% infection rate in low-income countries (LICs) compared to 3.86% in high-income countries (HICs) [3].

Caesarean delivery (CD) is an important risk factor for maternal sepsis. Patients with CD are up to 6.2 times more likely to develop maternal sepsis [4]. There are at least 50% more cases of infection related severe maternal outcomes in CD compared to vaginal delivery [3]. A certain number of pregnancies will require CD, with current estimates of the optimal rate for CD between 10 and 19% [5, 6]. Regardless of the precise optimal rate, CD accounts for 7.3% of the global volume of surgery [7] and more than 40% of district level surgeries in Tanzania [8], suggesting a substantial need to focus on surgical maternal care. Current efforts to reduce morbidity and mortality due to CD must focus on improving caesarean quality while optimizing appropriate indication for CD.

The surgical safety checklist (SSC), developed by the WHO to reduce surgical complications, has demonstrated effectiveness in multiple settings. Early study of the SSC, which took place in eight countries from various economic circumstances, demonstrated a reduction of surgical site infection from 6.2 to 3.4% [9]. A systematic review and meta-analysis on papers published through 2013 demonstrated strong evidence of the SSC effectiveness on reducing post-operative complications [10]. Further studies have demonstrated a sustained effect of SSC two years after SSC implementation [11]. The SSC, while not explicitly designed for CD, has the potential to improve maternal outcomes. CDs contribute significantly to the burden of postpartum infection, with a nearly fivefold increase compared to vaginal delivery [12]. Studies on the use of SSC and CD tend to focus on surgical site infection, which may be explained by a better statistical power to detect differences in the more common outcome. One randomized controlled trial demonstrated a beneficial effect of the SSC on maternal sepsis, with 0.619 times decreased rate of maternal sepsis in the intervention group [13].

Despite previous success of the SSC on improving outcomes in surgery, there is currently little literature on the efficacy of this surgical safety intervention on maternal sepsis. Safe Surgery 2020, (SS2020), a multicomponent intervention to improve the quality of surgical and obstetric care in Tanzania through surgical safety checklist training and additional surgical quality/infrastructure improvements, was implemented in 2018. We sought to examine the association of surgical safety checklist use with post-caesarean sepsis among CD patients in 20 facilities in Tanzania.

Materials and methods

Study design

This study examines post-caesarean sepsis data from the SS2020 study in Tanzania. The design of the study is a longitudinal, prospective, multicentre study with a control and intervention group and baseline measures for each. We received ethical approval from Tanzania's National Institute for Medical Research and Harvard Medical School (Ref. NIMR/HQ/R.8a/Vol.IX/2515).

Study setting and participants

This study took place in the Lake Zone of Tanzania, encompassing five regions. Twenty hospitals were selected and divided into two groups, intervention and control, based on geographic location to reduce spillover effect between intervention and control sites. Facilities included district hospitals, regional hospitals and medical centres (Table 1). Facilities were in largely rural and poor areas. Study participants included any patient receiving a caesarean delivery at any of the study sites during the study period. Patients were excluded if we were not able to get consent.

Intervention and control

The SS2020 intervention contained multiple components, including SSC implementation, an infection prevention bundle, mentoring, facility grants and data quality training. Sites in the control group did not receive these components. Full description of the SS2020 study in Tanzania can be found at Alidina et al. 2019 [14].

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Data collection

Data were collected from 2018 to 2019. Data were collected by 25 Tanzanian medical physicians trained on identification and classification of post-caesarean sepsis and SSC completion. These data collectors were not involved in patient care or checklist implementation. Paper forms for both SSC adherence during surgery and development of maternal sepsis were filled and transcribed to Research Electronic Data Capture (REDCap) software daily. The SSC Observation Tool, adapted from Huang et al. [15] included 38 items on components of the SSC. The maternal sepsis screening tool (see Supplementary Materials), adapted from the Surviving Sepsis Campaign guidelines [16], included branching questions on development of sepsis in the hospital. Data collectors observed and recorded SSC item completion through direct observation in the OR. After CD, data collectors followed patients daily in the wards and recorded development of post-operative complications, including post-caesarean sepsis. Patients were monitored from the day of surgery until the discharge date, up to 30 days. Data were separated into "Intervention" versus "No Intervention" groups. More information on the methods for this distinction is included in the supplementary.

Statistical analysis

Overall SSC adherence was calculated by dividing the number of SSC items completed by the total possible number of SSC items. Univariate analysis was conducted using the Wilcoxon rank-sum test and Fisher's exact test, as appropriate. Significant variables with $P < 0.05$ from univariate analysis were included in the multivariable logistic regression to estimate independent associations between risk factors and the post-caesarean sepsis. Multivariable modelling was performed using generalized estimating equations (GEE) with specific hospital as a random effect to account for clustering of patients within hospitals. Intervention status was included as covariate in multivariable analysis, and sensitivity analyses between SSC adherence and outcomes were performed within the intervention subgroup. Hospital type was included as a fixed effect in the multivariable model as well. The results of multivariable logistic regression modelling are presented as adjusted odds ratios (OR), 95% confidence intervals and P values. Additional univariate analysis was completed to evaluate specific SSC items on post-caesarean sepsis and is included in the supplemental materials section. All statistical analyses were performed using Stata (version 16.0, StataCorp LLC, College Station, Texas).

Results

The results are presented in Table 2. Age group had no significant effect on the rate of maternal sepsis ($P = 0.482$). The risk of maternal sepsis was 4.1 times greater in emergent cases than in non-emergent cases, although the difference was not significant ($P = 0.177$). Regional referral hospitals had the lowest rate of maternal sepsis (1.7%) compared to district hospitals (4.5%) and health centres (5.9%). SSC adherence, grouped by per cent of SSC adherence, significantly effected the maternal sepsis rate ($P = 0.018$). Patients that had high SSC adherence (> 75%) had a maternal sepsis rate of 0.7%, compared to patients with low SSC adherence (< 5%, maternal sepsis rate = 5.0%). Contaminated/dirty wound class cases had significantly higher rates of maternal sepsis compared to clean-contaminated cases (20% versus 3.7%, $P = 0.018$), although the number of Contaminated/dirty cases was low (15 cases). Patients who received the SS2020 intervention were significantly less likely to develop maternal sepsis (4.8% versus 1.3%, $P = 0.002$).

Table 1 Characteristics of facilities

Characteristic	All facilities (n = 20)	Intervention facilities (n = 10)	Control facilities (n = 10)
Number of functioning major ORs per facility	1.7	1.6	1.7
Average monthly surgical procedures per facility	82	75	90
Average number of certified surgeons per facility	0.35	0.4	0.3
Average number of certified obstetric/gynaecologists per facility	0.1	0.1	0.1
Level of facility			
Health centre	4	2	2
District hospital	11	6	5
Regional referral hospital	5	2	3

Table 2 Univariate analysis of maternal sepsis

	Maternal sepsis rate, n/total (%)	*P* value
Age		
Age < 25	22/634 (3.5%)	0.482
Age > = 25	30/707 (4.2%)	
*Wound class**		
Clean-contaminated	49/1326 (3.7%)	0.018
Contaminated/dirty	3/15 (20.0%)	
Procedure type		
Caesarean delivery	50/1302 (3.8%)	0.6611
Caesarean delivery plus other procedure	2/39 (5.1%)	
Emergent case		
Yes	51/1238 (4.1%)	0.177
No	1/103 (1.0%)	
*Level of facility**		
Health centre	13/220 (5.9%)	0.018
District hospital	32/718 (4.5%)	
Regional referral hospital	7/403 (1.7%)	
*SSC adherence**		
< 25%	42/835 (5.0%)	0.029
25%-50%	4/185 (2.2%)	
50%-75%	5/172 (2.9%)	
> 75%	1/149 (0.7%)	
*Intervention cohort**		
Intervention	5/370 (1.4%)	0.002
No intervention	47/971 (4.8%)	

P values were obtained using the the Chi-square test or Fisher's exact test, as appropriate

Denominators are displayed to represent missing data

*Statistically significant

Multivariable logistic regression using GEE with overall SSC adherence, wound class and hospital type as predictors for post-caesarean sepsis demonstrated that higher SSC adherence is associated with lower odds of post-caesarean sepsis, with an adjusted odds ratio of 0.17 per percentage point increase in SSC adherence (95% CI: 0.04, 0.79; $P = 0.024$). Higher wound class is associated with increased odds of post-caesarean sepsis, with an adjusted odds ratio of 7.82 (95% CI: 2.08, 29.4; $P = 0.002$). Additional wound class analysis demonstrated no significant difference in SSC adherence by wound class status (Clean-contaminated = 19%, Contaminated/dirty = 22%, $P = 0.345$). There were no significant adjusted differences in post-caesarean sepsis by hospital type (health centre vs Regional Referral adjusted OR = 4.12; 95% CI: 0.78, 21.8; $P = 0.069$; District Hospital vs Regional Referral OR = 2.42; 95% CI: 0.52, 11.2; $P = 0.259$).

As a sensitivity analysis, we looked at the association between SSC adherence and maternal sepsis only in the intervention cohort. In this cohort, which contains only endline data from the ten hospitals receiving the intervention, the median overall SSC adherence for patient with post-caesarean sepsis (39%; IQR: 31%, 50%) was lower than the adherence in the non-sepsis patients (56%; IQR: 31%, 94%). Here, after adjusting for wound class, the odds ratio for overall adherence is OR = 0.03 (95%CI: 0.002, 0.47; $P = 0.013$). Figure 1 demonstrates a stepwise decrease in sepsis rate with increased SSC adherence in the intervention group.

Discussion

Surgical safety checklist adherence is associated with reduced post-caesarean sepsis. Wound class and intervention also have an effect. Multivariable analysis demonstrated that SSC adherence and wound class have an independent effect on post-caesarean sepsis. We could not distinguish the effect of SSC adherence and intervention

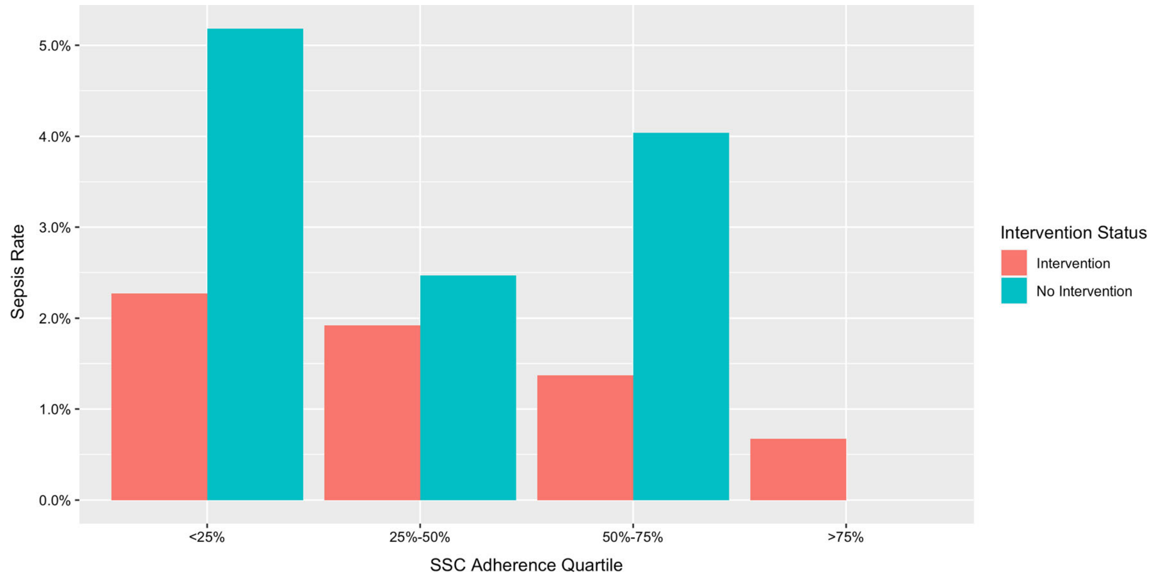

Fig. 1 Post-Caesarean Sepsis Rate by SSC Adherence Quartile and Intervention Status Higher SSC adherence is associated with lower rates of post-caesarean sepsis. This is more apparent in the intervention group, which had a stepwise decline in maternal sepsis with increased SSC adherence

status, due to collinearity. This is to be expected, as SSC implementation is only one part of the full intervention.

By definition, contaminated and dirty wound classes are significantly dirtier than clean-contaminated wound class, strongly effecting the risk of sepsis. Several studies have corroborated this conclusion, noting higher rates of deep surgical site infection, reoperation and mortality [17]. Few studies have demonstrated this concept in CD, although wound class has been proposed as a component of risk stratification for infection in CD [18].

Surprisingly, emergent status does not have a significant effect on post-caesarean sepsis. The literature suggests that emergent cases typically lead to more infectious complications [12], partially due to coexisting comorbidities such as higher ASA score, longer duration of surgery and higher wound class [19]. In our study, nearly all cases of maternal sepsis happened during emergent cases (51/52), although emergent status was not statistically significant. Larger sample sizes may demonstrate a significant effect of emergent indication.

Despite the demonstrated improvement in SSC rates in this study, the rate of adherence to checklist items is still relatively low even among patients with no maternal sepsis. In this study, the SSC adherence among patients that did not develop maternal sepsis is heavily skewed, with a median of 19% and an IQR of 16%-47%. This is largely because of the inclusion of cohorts that did not receive the SSC intervention. In just the intervention cohort, the SSC adherence is higher in patients without maternal sepsis (median: 56%) compared to those with maternal sepsis (median: 39%). Once wound class is controlled, for there is a significant association of higher SSC adherence with lower maternal sepsis rates. By focussing on just this cohort, we can appreciate the stepwise effect of higher adherence with reducing post-caesarean complications.

There are ongoing efforts to modify the SSC to match the CD population. Boekmann et al. 2012 describes a modified SSC that accounts for additional pregnancy concerns [20]. Multiple other focussed checklists have been created, but few have been assessed in the field. Despite this, many have recommended the use of the surgical safety checklist to reduce infection rates after documenting risk factors for SSI and sepsis in CD patients [21, 22].

There are a number of limitations that must be considered in this study. A larger sample size is likely necessary to distinguish the effect of SSC from the overall intervention effect. SSC completion rate was collinear with intervention status, making it inappropriate to include them in the same model. This limitation is partially accounted for in our sensitivity analysis among only the intervention group. By removing the no-intervention data from the analysis, we were able to show that SSC adherence had an effect on maternal sepsis independent of intervention status. The Hawthorne effect limits the interpretation of the study, as it is unfeasible to blind surgical staff to SSC monitoring during surgery, although both the control and intervention sites received the same level of monitoring during surgery.

The surgical safety checklist was designed for surgical procedures, although few studies have demonstrated the effect in CD. Similar safety concerns exist for both CD and other surgical procedures. This study showed a beneficial effect of SSC on post-caesarean sepsis in Tanzania. Efforts to reduce maternal sepsis should include a focus on surgical safety, potentially through use of the SSC. While the effects of the overall SS2020 intervention could not be distinguished from the effect of the SSC in the primary multivariable analysis, the sensitivity analysis on only intervention patients provides evidence that surgical quality interventions can improve maternal care. The nexus of maternal and surgical care presents an opportunity to align specific interventions to reduce morbidity and mortality.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00268-021-06338-3.

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Informed Consent Informed consent was obtained from all individual participants included in the study.

Human and animal Rights We received ethical approval from Tanzania's National Institute for Medical Research and Harvard Medical School (Ref. NIMR/HQ/R.8a/Vol.IX/2515).

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