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A randomised control trial using soap in the prevention of surgical site infection in Tanzania

Godfrey Sama Philipo[a,b,c,d,*], Zaitun Mohamed Bokhary[a,b], Neema Lala Bayyo[a], Soham Bandyopadhyay[c,e], Miriam Gerd Pueschel[b], Rajabu Athumani Bakari[a], Kokila Lakhoo[a,b,c,e]

[a] Department of Paediatric Surgery, Muhimbili National Hospital, Tanzania
[b] Department of Surgery, Muhimbili University of Health and Allied Sciences, Tanzania
[c] University of Oxford Global Surgery Group (OUGSG), Oxford, UK
[d] University of British Columbia, Branch of Global Surgical Care (BGSC), Vancouver BC, Canada
[e] Nuffield Department of Surgical Sciences, University of Oxford, Oxford, UK

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ABSTRACT

Background: Surgical site infections (SSIs) are common and serious complications of surgery. Guidelines on preventing SSIs have been developed, but the role of preoperative bathing with plain soap among paediatric population is unclear. We aimed to assess the effectiveness of pre-operative bathing using plain soap in preventing SSIs among paediatric surgical patients.

Materials and Methods: An open-label, randomised trial was conducted at Muhimbili National Hospital in Tanzania. Preoperatively, patients in the intervention group washed their body using plain soap, while those in the control group did not. The primary outcome was SSI postoperatively. Statistical tests included $\chi 2$, Wilcoxon rank sum, and univariate and multivariable logistic regression.

Results: Of the 252 patients recruited,114 were randomised to the intervention arm. In the control arm, 40.6% (56/138) of participants developed SSIs compared to 11.4% (13/114) in the intervention arm ($p < 0.01$). After adjusting for confounding factors in multivariable analysis, the intervention reduced the odds of an SSI by 80% (OR: 0.20 [95% CI: 0.10, 0.41]; $p < 0.01$). Preoperative antibiotics were deemed to be an effect modifier of the association between the intervention and SSI ($p = 0.05$). The intervention significantly reduced the odds of an SSI by 88% among participants not given preoperative antibiotics (OR: 0.12 [95% CI: 0.05, 0.30]; $p < 0.01$).

Conclusion: This study has shown that preoperative bathing with soap significantly reduces SSIs in paediatric surgical patients. It is a simple, cost effective and sustainable intervention.

Level of Evidence: Level II

1. Introduction

Surgical site infection (SSI) is the most frequent health-care-associated infection and a serious surgical complication occurring up to 30 days after surgery or up to one year in patients receiving implants [1]. It leads to increased length of hospital stay, hospital costs, antibiotics use, revision surgery, as well as patient suffering, morbidity and/or mortality [2,3]. SSI can be superficial involving the skin only, or more serious involving other tissues, organs, and implanted material. The most commonly isolated organisms in SSIs are *Staphylococcus aureus, coagulase-negative staphylococci, Enterococcus* spp. *and Escherichia coli* [4]. *Staphylococcus aureus* persistently colonises the skin and the nasopharynx of approximately a quarter of the population. Higher incidence rates are noted among young children contributing to SSIs [3].

SSI is estimated to be up to 20 times higher in low- and middle-income countries (LMICs) than in high-income countries (HICs) [5]. Children and adults are both affected by SSIs with approximately 3% mortality associated with SSI and a 2- to 11-fold increase in risk of death [3]. The World Health Organization (WHO) review reported SSIs affect up to a third of patients who have had surgery [6]. The African Outcome Study reported that patients receiving surgery were twice as likely to die, with infection being the most common complication accounting for 9.7% of deaths [5]. The incidence is higher among children ranging from 1.8% to 5.4%, and can be as high as 40% depending on the type of surgical procedure [7–9].

A number of guidelines have been developed by the WHO aiming at preventing SSIs, with pre-operative bathing or shower-

* Corresponding author at: ECSA Health Community Secretariat, 157 Olorien, Njiro Road, P.O Box 1009, Arusha, Tanzania.
E-mail address: godfreysama2@yahoo.com (G.S. Philipo).

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ing being one of the recommended preventive measure [6,10,11]. However, there is limited evidence looking into its effectiveness among children during the development of these recommendations [10,11]. Existing recommendations are based on the available evidence mainly from adult population studies. Hence there remains clinical uncertainty on the effectiveness of this recommendation for children. In addition, the majority of the studies were on antimicrobials or antiseptics, some are expensive and unavailable for most patients in LMICs, and may not be suitable for use on children. We aimed to assess the effectiveness of pre-operative bathing practice using plain soap in preventing SSIs among paediatric surgical patients in Tanzania.

2. Materials and methods

2.1. Study design

This was a prospective open randomized controlled trial (RCT). On admission, parents or carers of children undergoing surgery were consented for participation onto the study.

Intervention Group: This group preoperatively washed their body using plain soap and water. Here, plain soap is considered as soap that has no antimicrobial activity or active ingredients found in Tanzania such as Duru, Dalan, Linda or Mbuni [12]. A trained research assistant educated parents and carers on a standardized bathing method for their children, emphasising washing around the nose, the axillae, the navel, genital areas, and the hair, and drying using a clean towel.

Control Group: This group followed the existing practice, where preoperative body wash was not a strict recommendation, nor did parents receive instructions on standardized bathing practice.

2.2. Study location

This study was undertaken at Muhimbili National Hospital (MNH), a National Referral Hospital, Research Centre and Teaching Hospital in Dar Es Salaam Tanzania. The hospital has a 1500-bed capacity, attends to 1000 to 1200 outpatients per day and admits 1000 to 1200 inpatients per week. It is a tertiary level hospital, with capacity to provide surgery for complex paediatric conditions. MNH's Paediatric Surgery Unit is one of the specialized paediatric surgery centres in the country, receiving patients referred from various health facilities in different parts of the country [9]. It is responsible for the surgical care of children up to the age of 11 years. It has a capacity of 64 beds with 8 to 10 operations done per day in two paediatric operating rooms. The most common elective surgical conditions managed under this firm includes tumours, anorectal malformations, Hirschsprung's disease, abdominal wall defects and complex hernias. The most common emergency conditions are laparotomies for peritonitis and intestinal obstruction, obstructed hernias and trauma. The operating theatre of MNH paediatric unit is for children only – separate from the adult theatre complex – and is the largest in the country.

2.3. Patient recruitment and data collection

All children admitted for general elective in-patient surgery involving a skin incision were consented for participation in the study. The inclusion criteria were 11 years old and below, elective surgery patients who agreed to give informed consent. We excluded those known to have nasal carriage of Staphylococcus aureus, children on antibiotics for existing infection, those with intercurrent infections, those undergoing emergency surgery, patient with known skin allergies, patients using other body wash and patients with surgical implants. Simple randomization was used to assign study participants into intervention and control group. An online software was used (https://www.randomizer.org) to generate random numbers assigned to study participants. Participants in the intervention group were given plain soap [12]. All the intraoperative conditions remained the same for both groups. Postoperatively in the ward, a trained research assistant assessed the wound for any signs of infection until discharge using a score system (Supplemental S1). This SSI scoring system was adopted from Westen et al. 2015 to guide the identification of all signs of SSI in our population [13]. Data collection was done by research assistants who were medical doctors and registrars in the department of Paediatric Surgery for at least 2 years who received prior training on a data collection tool and group assignment to the study populations. A pilot study was conducted to assess if the study was feasible and to validate the data collection tool. Assessment of wounds were done while the assessor was not aware of which patient belonged to the intervention or control group. Following discharge, all participants in the control and interventional group were followed up for up to 30 days at clinic visit or via phone call for surveillance on development of an SSI. All discharged patients were provided with an assessment report form for the doctor/research nurse to complete when the patient came for a clinic visit. The study hypothesis was unexpectedly proven early within predesignated criteria.

2.4. Data analysis

Descriptive statistics were used to summarise demographic and clinical characteristics and outcomes. The primary outcome measure was SSI. Subanalysis was conducted to assess associations between inpatient and outpatient SSIs. Secondary outcomes were reoperation and length of admission. Comparison of proportions between independent groups was made with $\chi 2$ or Fisher's exact test when there were low event rates. Comparison of proportions between paired groups was made with McNemar's analysis. The Wilcoxon rank-sum test were used to compare medians between groups. Univariate logistic regression was used to examine the association between the primary outcome, and patient characteristics and secondary outcomes. Multivariable logistic regression was used to adjust for the effect of confounding factors and effect modifiers on the primary outcome provided the variables had less than 10 missing data points. Mantel-Haenszel analysis was conducted to determine if these factors were confounders or effect modifiers, and calculate odds ratios. All data analyses were done using STATA/IC 16.1.

2.5. Ethics and dissemination

This research received local ethical approval (Study number Reg No: MNH/IRB/2019/027), and respective permission as well as informed consent from parents or careers of study participants.

3. Results

A total of 252 patients were recruited from 1st January 2020 to 28th February 2022 to participate in the trial and all completed follow up (Fig. 1). 114 participants were randomized to the intervention arm. Most participants were male (n = 144/252, 57.1%). Clinical characteristics of included patients are summarised in Table 1. There were no significant differences between the demographic characteristics of the control and intervention groups. For example, the median age of participants in the intervention arm was 36 months (IQR: 21 – 48) with a weight of 12 kg (IQR: 10– 16.8) (p = 0.78). Participants in the control arm had a similar median age (36 months, IQR: 18 – 60; p = 0.78) and weight (12 kg, IQR: 10 – 16.5; p = 0.61).The median WCC level was significantly different between the two arms of the study, but both

Table 1
Demographic and outcome information by exposure group.

Demographic Characteristics		Control group(N = 138)	Intervention group(N = 114)	P-value
Sex	Female	55 (40%)	53 (46.5%)	0.29[a]
	Male	83 (60.1%)	61 (53.5%)	
Age (months)		36 (18–60)*	36 (21–48)	0.78[b]
Weight (kg)		12 (10–16.8)	12 (10–16.5)	0.61[b]
Hb level (g/dL)		11 (10.2–12.0)	11.2 (10.4–12.1)	0.50[b]
WCC (x 10^9)		8.1 (6.5–10.6)	9.9 (7.0–12.0)	0.01[b]

Outcome Characteristics		Control group(N = 138)	Intervention group(N = 114)	P-value
Given preoperative antibiotics	No	96 (69.6%)	85 (74.6%)	0.48[a]
	Yes	41 (29.7%)	29 (25.4%)	
	Missing	1 (0.7)	0 (0.0)	
Length of surgery (hours)		1.5 (1–2)	1 (1–2)	0.11[b]
Postoperative destination of the patient	Ward	119 (86.2%)	105 (92.1%)	0.14[a]
	Intensive Care Unit	19 (13.8%)	9 (7.9%)	
Re-operation	No re-operation	130 (94.2%)	110 (96.5%)	0.61[a]
	Re-operated	7 (5.1%)	3 (2.6%)	
	Missing	1 (0.7%)	1 (0.9%)	
Length of admission (days)		14 (6–23)	12 (6–26)	0.98[b]

[a] Chi-squared test P-values.
[b] Wilcoxon rank sum P-values.
* Results expressed as median (IQR).

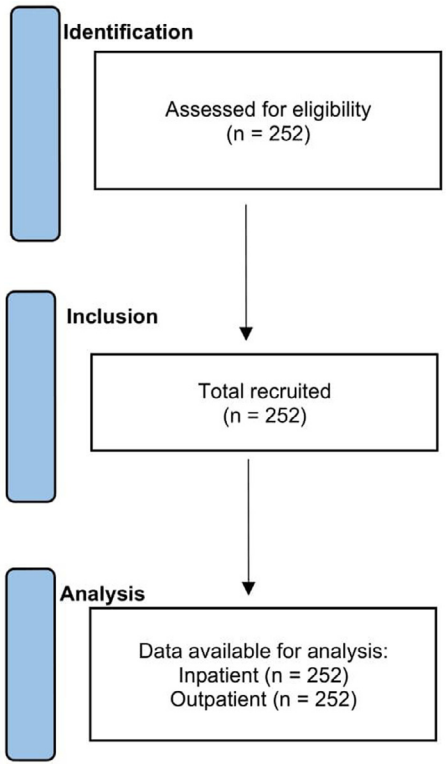

Fig. 1. STROBE flow chart of participants in this study.

were within normal ranges (p = 0.01) (Table 1). Supplemental S2 lists the procedures participants underwent in both the control and the intervention arms.

The overall proportion of SSI was 27.38% (69/252). In the control arm 40.6% (56/138) developed SSI compared to those in the intervention arm 11.4% (13/114) ($p < 0.01$) (Table 2). The intervention reduced the odds of an SSI by 81% (OR: 0.19 [95% CI: 0.09, 0.38]). Most participants with an SSI developed them as an inpatient (n = 61/69, 88.4%), of these 83.6% (n = 51/61) were in the control arm. There was a significant difference in the incidence of inpatient SSIs between the two arms of the study (control arm: 51/ 138, 37.0%; intervention arm: 10/114, 8.8% [$p < 0.01$]). The intervention reduced the odds of an inpatient SSI by 84% (OR: 0.16 [95% CI: 0.08, 0.36]).

Most participants were not given pre-operative antibiotics (n = 181/251, 72.1%; one missing data) and were admitted to a ward postoperatively (n = 224/252, 88.9%).

During follow up after discharge, 8 extra participants developed an SSI as an outpatient; 5 (62.5%) were from the control group. 37 of the 61 patients with an inpatient SSI (60.7%) were found to also have an SSI as an outpatient. There was a significant association between having an outpatient SSI and having had an inpatient SSI ($p < 0.01$). 32 of these 37 patients (86.5%) were from the control arm, with a greater proportion of participants in the control arm who developed an inpatient SSI continuing to have an outpatient SSI (n = 32/51, 62.7%) compared to the intervention arm (n = 5/10, 50.0%). Most outpatient SSIs occurred among participants in the control arm (n = 37/45, 82.2%). There was a significant difference in the incidence of outpatient SSIs between the two arms of the study (control arm: n = 37/138, 26.8%; intervention arm: n = 8/114, 7.0% [$p < 0.01$]). The intervention reduced the odds of an outpatient SSI by 79% (OR: 0.21 [95% CI: 0.09, 0.48]).

Participants in the intervention arm who developed an SSI had a significantly longer length of surgery ($p < 0.01$) (Table 2). No other factors were significantly associated with an increased incidence of SSI among participants in the intervention arm. Participants in the control arm who developed an SSI were younger (p = 0.03), weighed less (0.02), and were not given preoperative antibiotics ($p < 0.01$). There was no difference in the age (p = 0.60) or weight (p = 0.29) of participants who received preoperative antibiotics.

Participants who developed an SSI in the control arm tended to have a significantly longer length of hospital stay than participants who did not develop an SSI in the control arm ($p < 0.01$).

In univariate logistic regression analysis, being in the control arm of the study, having a longer length of surgery, and having a reoperation were significantly associated with an increased odds of SSI (Table 3). After adjusting for confounding factors in multivariable analysis, the intervention reduced the odds of an SSI by 80% (OR: 0.20 [95% CI: 0.10, 0.41]; $p < 0.01$). Multivariable analysis also indicated that pre-operative antibiotics were associated with a significant decrease in the odds of developing an SSI (OR: 0.42 [95% CI: 0.19, 0.91]; p = 0.03) and longer surgeries were associated with a significant increase in the odds of developing an SSI (OR: 1.94 [95% CI: 1.21, 3.11]; p = 0.01).

Table 2
Relationship between surgical site infection and demographic/outcome information.

Characteristics		No surgical site infection in the intervention group($N = 101$)	Surgical site infection in the intervention group ($N = 13$)	*P*-value
Sex	Female	48 (47.5%)	5 (38.5%)	0.54 [a]
	Male	53 (52.5%)	8 (61.5%)	
Age (months)		34 (20–48)*	39 (28–60)*	0.29 [b]
Weight (kg)		12 (10–16)	15 (11.5–19)	0.30 [b]
Hb level (g/dL)		11.1 (10.3–12.1)	11.7 (11.2–11.8)	0.26 [b]
WCC (x 10^9)		9.6 (6.7–11.9)	10.4 (9.4–12.6)	0.09 [b]
Given preoperative antibiotics	No	76 (75.2)	9 (69.2)	0.43 [c]
	Yes	25 (24.8)	4 (30.8)	
Length of surgery (hours)		1 (1–2)	2 (2–3)	<0.01 [b]
Postoperative destination of the patient	Ward	95 (94.1%)	10 (76.9%)	0.07 [c]
	Intensive Care Unit	6 (5.9%)	3 (23.1%)	
Re-operation	No re-operation	98 (97.0%)	12 (92.3%)	0.31 [c]
	Re-operated	2 (2.0%)	1 (7.7%)	
	Missing	1 (1.0%)	0 (0.0%)	
Length of admission (days)		12 (6–25)	19.5 (7–33)	0.41 [b]
Characteristics		No surgical site infection in the control group($N = 82$)	Surgical site infection in the control group ($N = 56$)	P-value
Sex	Female	37 (45.1%)	18 (32.1%)	0.13 [a]
	Male	45 (54.9%)	38 (67.9%)	
Age (months)		36 (23–67)	25 (12–60)	0.03 [b]
Weight (kg)		12.5 (10–18)	10.1 (7.8–16)	0.02 [b]
Hb level (g/dL)		11.0, (10.5–11.8)	11.0 (9.9–12.2)	0.47 [b]
WCC (x 10^9)		8.3 (6.7–10.6)	8.0 (5.4–10.4)	0.48 [b]
Given preoperative antibiotics	No	49 (59.8%)	47 (83.9%)	<0.01 [a]
	Yes	32 (39.0%)	9 (16.1%)	
	Missing	1 (1.2%)	0 (0.0)	
Length of surgery (hours)		1.5 (1–2)	1.6 (1–2)	0.40 [b]
Postoperative destination of the patient	Ward	71 (86.6%)	48 (85.7%)	0.88 [a]
	Intensive Care Unit	11 (13.4%)	8 (14.3%)	
Re-operation	No re-operation	80 (97.6%)	50 (89.3%)	0.09 [c]
	Re-operated	2 (2.4%)	5 (8.9%)	
	Missing	0 (0.0)	1 (1.8%)	
Length of admission (days)		11 (5–21)	22 (14–32)	<0.01 [b]

[a] Chi-squared test *P*-values.
[b] Wilcoxon rank sum *P*-values.
[c] Fisher's exact test *P*-values.
* Results expressed as median (IQR).

Table 3
Univariate analysis, and multivariable analysis of surgical site infection (SSI).

Characteristics		Univariate analysis odds ratio of SSI (95% CI)	*P*-value	Multivariable analysis odds ratio of SSI (95% CI)	*P*-value
Arm of the Control		1.00 (Reference)	<0.01	1.00 (Reference)	<0.01
Study Intervention		0.19 (0.09, 0.37)		0.20 (0.10, 0.41)	
Sex	Female	1.00 (Reference)	0.06	1.00 (Reference)	0.16
	Male	1.73 (0.97, 3.09)		1.62 (0.83, 3.16)	
Age (months)		1.00 (0.99, 1.00)	0.37	0.99 (0.98, 1.00)	0.28
Weight (kg)		0.95 (0.90, 1.00)	0.05	Excluded	-
Hb level (g/dL)		1.02 (0.83, 1.26)	0.83	1.07 (0.85, 3.16)	0.55
WCC (x 10^9)		1.01 (0.95, 1.07)	0.81	1.00 (0.93, 1.08)	0.98
Given pre-operative antibiotics	No	1.00 (Reference)	0.05	1.00 (Reference)	0.03
	Yes	0.51 (0.26, 1.00)		0.42 (0.19, 0.91)	
Length of surgery (hours)		1.80 (1.25, 2.60)	<0.01	1.94 (1.21, 3.11)	<0.01
Postoperative destination of the patient	Ward	1.00 (Reference)	0.14	1.00 (Reference)	0.03
	Intensive Care Unit	1.85 (0.82, 4.18)		1.06 (0.37, 3.03)	
Re-operation	No re-operation	1.00 (Reference)	0.03	1.00 (Reference)	0.07
	Re-operated	4.31 (1.18, 15.77)		4.28 (0.91, 20.21)	
Length of hospital stay (days)		1.01 (1.00, 1.02)	0.07	Excluded	-

Mantel-Haenszel analysis suggests that preoperative antibiotics is not a confounding factor, but an effect modifier of the association between the intervention and SSI ($p = 0.05$). The intervention significantly reduced the odds of an SSI by 89% among participants not given preoperative antibiotics (OR: 0.11 [95% CI: 0.04, 0.28]; $p < 0.01$). The intervention also reduced the odds of an SSI among participants given preoperative antibiotics, but this was not statistically significant (OR: 0.56 [95% CI: 0.13, 2.42]; $p = 0.39$). Adjusting the multivariable model to include preoperative antibiotics as an effect modifier rather than a confounder found that patients in the intervention arm of the study who were not given preoperative antibiotics (OR 0.13 [95% CI 0.06–0.31]; $p < 0.01$) and patients

in the control arm of the study given preoperative antibiotics (OR 0.26 [95% CI 0.10–0.66]; $p < 0.01$) had a significantly lower odds of developing an SSI. The model also showed that patients in the intervention arm of the study who were given preoperative antibiotics had a reduced odds of developing an SSI, but this was not significant (OR 0.77 [95% CI 0.20–3.03]; $p = 0.71$). Longer surgeries remained significantly associated with an increase in the odds of developing an SSI (OR: 1.99 [95% CI: 1.23, 3.22]; $p = 0.01$). No other variables were identified to be significantly associated with developing an SSI on multivariable analysis.

Creating a multivariable model for inpatient SSIs only had similar findings. Patients in the intervention arm of the study who were not given preoperative antibiotics (OR 0.11 [95% CI 0.05–0.28]; $p< 0.001$) and patients in the control arm of the study given preoperative antibiotics (OR 0.21 [95% CI 0.08–0.57]; $p < 0.01$) had a significantly lower odds of developing an inpatient SSI. The model also showed that patients in the intervention arm of the study who were given preoperative antibiotics had a reduced odds of developing an inpatient SSI, but this was not significant (OR 0.73 [95% CI 0.16–3.31]; $p< 0.678$). Longer surgeries remained significantly associated with an increase in the odds of developing an inpatient SSI (OR: 1.76 [95% CI: 1.07, 2.88]; $p = 0.03$). No other variables were identified to be significantly associated with developing an inpatient SSI on multivariable analysis. The effect modification of preoperative antibiotics was not present among participants with outpatient SSIs. After adjusting for confounding factors in multivariable analysis, the intervention reduced the odds of an outpatient SSI by 79% (OR: 0.21 [95% CI: 0.09, 0.51]; $p < 0.01$). Multivariable analysis also indicated that pre-operative antibiotics were associated with a significant decrease in the odds of developing an outpatient SSI (OR: 0.37 [95% CI: 0.14, 0.94]; $p = 0.04$) and longer surgeries were associated with a significant increase in the odds of developing an outpatient SSI (OR: 1.93 [95% CI: 1.15, 3.23]; $p = 0.01$).

4. Discussion

SSI is a global public health problem with the largest burden in LMICs. In children particularly, the burden of SSIs is higher in LMICs than in HICs [5,14,15]. In our previous study in the same setting we noted a SSI incidence of 10.2% among children [9]. Preoperative washing is relatively cheap and feasible to deliver in resource constrained settings. A meta-analysis on preoperative use of antiseptic soap (containing chlorhexidine gluconate) against plain soap in adults found no significant difference between the soap types in reducing SSI incidence [6]. Our study shows that preoperative washing using plain soap is an effective intervention that can significantly reduce SSI. The incidence of SSI among inpatients and during surveillance after being discharged significantly reduced in the intervention group compared to the control group ($p < 0.01$). The intervention with soap reduced the odds of SSI as an inpatient by 84% (OR:0.16 [95%CI: 0.08,0.34]) and as an outpatient by 79% (OR:0.21[95% CI:0.09, 0.46]). These findings are reliable as our study found risk factors for SSIs in keeping with existing literature: younger age, lower weight, no preoperative antibiotics, and having an increased length of surgery [16,17].

Whilst previous studies have investigated the risk of SSI as an inpatient in LMICs, our study highlights the importance of capturing the risk of developing of SSI as an outpatient. 45 children (17.9%) developed SSI as outpatient after being discharged home, of this 37 (82.2%) were in the control group. The incidence of SSI was 26.8% and 7% in the control and intervention group respectively, and these results were statistically significant. A previous systematic review noted similar findings with an overall incidence of SSI in elective clean and clean-contaminated surgeries at 6% (10% in LMICs), which increased to 15% (95% CI 6–27%) when postdischarge surveillance data was included [18]. This highlights the importance of the centre in Tanzania, and similar settings in other LMICs, developing a surveillance system to detect and treat SSIs – among other post-operative complications – in discharged patients.

A key finding from our study was that providing preoperative antibiotics to patients in the intervention arm of the study did not significantly reduce their odds of developing an inpatient SSI. Antimicrobial prophylaxis typically aims to reducing the burden of microorganisms during the operative procedure. Preoperative antibiotic prophylaxis likely works best when antibiotic choice and dose is determined by factors such as time to surgery, length and type of procedure. Incorrect usage of antibiotics inadvertently increases the risk of SSI [19]. Considerable variation in the timing of prophylactic administration of antibiotics has been reported in practice [10,20]. Additionally, long-term impact of antibiotic use especially in LMICs where the rate of antimicrobial resistance (AMR) is on the rise, should not be ignored [21,22]. A study done in Rwanda on AMR after cesarean section noted that all pathogens demonstrated resistance to at least one antibiotic, with reduced susceptibility to ampicillin, ceftriaxone (92.1%), and cefepime (84.6%) [23]. In our study, ceftriaxone was the most prescribed antibiotic. Proper usage of antibiotic - especially in children - should therefore be prioritized to protect patients from their side effects and prevent the development of AMR [24–26]. Our study matches the findings of a previous study evaluating the effectiveness of prophylactic antibiotics prior to clean paediatric surgical procedures. They noted a very low rate of postoperative wound infection in clean surgical procedures without prophylactic antibiotics; thus suggesting that antibiotic prophylaxis may be unwarranted in children provided preoperating washing takes place, as it may contribute to AMR without benefiting the child [27]. The use of tools like the National Nosocomial Infections Surveillance score system may guide proper use of antibiotics, as it considers the wound class, ASA physical status scale, duration of operation, and appropriate timing for administering antibiotic prophylaxis to maximize benefits [28].

It is also important to note that in our study patients with an SSI stayed significantly longer in the ward (22 days) compared to those who did not (12 days). This has implications for the through flow of patients, and may contribute to over-crowding of wards or patients having their surgery delayed because of lack of beds. Therefore, SSIs not only have a direct impact on the affected patient, but also indirectly impacts other patients and increases costs incurred by hospitals managing such patients. Furthermore, our findings add evidence to the formulation of SSI prevention guidelines for paediatric surgery population in Tanzania and similar settings. Our intervention raises awareness about SSI among parents and caregivers, as they are trained on a standard bathing practise with soap and taught to pay attention to the areas that are prone to harbour infecting organisms. Engaging parents and caregivers is likely to contribute to uptake, effectiveness and sustainability this intervention, as part of SSI prevention guidelines.

4.1. Limitation

Only a per protocol analysis was conducted, as an intention to treat analysis was deemed unnecessary given all patients remained in the arm they were randomised to (after accounting for the logistical error). In addition, we discontinued the study after learning from preliminary results that subjects in the control arm had additional potential risks and they were being kept from benefitting from a safe and a cheap intervention in the intervention arm; this was not ethically justifiable. Furthermore, ensuring this intervention remains sustainable will require healthcare professional individuals to be responsible for training and disseminating knowledge, and for hospitals to have water and plain soap available.

5. Conclusion

We have shown that our intervention of bathing with soap preoperatively significantly reduces SSI in children undergoing surgery as compared to a control arm. This intervention is simple, cost effective and sustainable.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jpedsurg.2022.10.029.

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