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# Changing the outcomes of newborns with surgical conditions at a tertiary-level hospital in Kenya: a cluster randomized trial

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## Abstract

**Background:** Globally, 10% of neonatal mortality in low-/middle-income countries (L/MIC) is directly attributed to surgical conditions, and appropriate referral and transport of newborns to tertiary-level hospitals for surgical care often underlie their survival. This study aimed at evaluating the outcomes of newborns with surgical conditions in a low-resource setting, in the context of a structured standard operating procedure (SOP) for newborn transport.

**Methods:** A cluster randomized controlled trial was conducted. Ten county hospitals that refer newborns with surgical conditions to the Moi Teaching and Referral Hospital (MTRH) were selected and randomized into intervention group (A) and control group (B). A structured standard operating procedure (SOP) for transport of newborns was introduced in the hospitals in group A via an education module. Thereafter, 126 newborns (63 in group A and 63 in group B) were enrolled, upon their admission to the MTRH. All the newborns from both groups of referring hospitals were given standard surgical care upon admission. Data on study variables was collected and analyzed, and the outcomes of the newborns in the two groups were compared to assess the effect of the structured SOP.

**Results:** The median age at admission was 4.1 days in group A and 4.6 days in group B. The top 4 surgical conditions were gastroschisis, hydrocephalus, Hirschsprung's disease, and anorectal malformations. There was a statistically significant difference ( $p < .05$ ) in all parameters that measured the clinical status of the newborns at admission, in the two groups. Mortality rate was 3.2% in group A and 28.6% in group B ( $p < .001$ ), and hospital stay was 11 days in group A and 18 days in group B.

**Conclusion:** Appropriate transport of newborns with surgical conditions significantly improved their outcomes at the MTRH.

**Level of evidence:** II

**Keywords:** Newborns, Transport, Surgical conditions, Outcomes, Kenya

## Introduction

Globally, neonatal mortality has been demonstrated to contribute significantly to the under-five mortality rate [1], and 10% of the neonatal deaths in L/MICs are due to surgical conditions [2]. The major contributors to neonatal mortality in L/MICs are captured in a 3-delay model

that includes improper transport of the sick newborns during referral to tertiary-level hospitals for specialized care [3].

Despite the introduction of guidelines on referral and inter-facility transfer of sick neonates by WHO in 2003 [4], Kenya's public health sector has no existing policy on organized newborn transport [5]. Moreover, locally domesticated standard protocols on this important element of newborn care are lacking at the tertiary-level and county hospitals in Kenya. Therefore, the import of

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organized transport of newborns with surgical conditions during their inter-facility transfer is not known.

Hence, this study aimed at evaluating the effect of appropriate referral and transport of newborns with surgical conditions on their outcomes in a resource-limited setting, specifically the North Rift and western regions of Kenya.

## Methods

A cluster randomized controlled trial that was based on post-test only control-group design was conducted, upon obtaining an approval from the Institutional Research Ethics Committee (FAN: IREC 1861). This design was deemed practical, pragmatic, and appropriate for the study objective. Ten clusters (county hospitals that refer neonates with surgical conditions to the Moi Teaching and Referral Hospital (MTRH) were randomly selected and randomized into two groups (intervention group A and control group B) of 5 hospitals each.

The clusters (county referral hospitals) had shared characteristics. They all belonged to the third tier of care in the Kenya's healthcare system that provides county referral health services (levels 4 and 5). Hence, they had similar infrastructure and equipment indicators, as well as distribution of healthcare workforce [6]. However, none of the hospitals provided newborn surgical care due to lack of specially equipped operating rooms, unavailability of specially trained surgeons, and lack of newborn intensive care (NICU) facilities. MTRH is the only tertiary-level hospital in North Rift and western regions of Kenya that offers specialized surgical care to newborns.

A structured SOP for transport of newborns, which was based on the WHO guidelines on transfer and referral of sick neonates [4], was introduced in the newborn units/labor wards of the referring county hospitals in the intervention group (group A) via an education module.

A month after the intervention, a total of 126 newborns referred and transported from the selected county hospitals, and admitted to the newborn unit of the MTRH for specialized surgical care, were consecutively enrolled into the study (63 from the hospitals in group A and 63 from the hospitals in group B). All the newborns were accorded standard care for their surgical conditions.

Data was collected on their sociodemographic, referral, and transport characteristics, clinical diagnosis, and clinical status at admission. The newborns were then followed up until discharge or death.

The main measure of outcomes was the clinical status of the newborns at admission. The outcomes of the newborns in the two groups were compared to assess the effect of the structured SOP. The statistical analysis included the use of chi-square and Fisher's exact tests for the categorical variables and Wilcoxon rank-sum test for

the continuous variables.  $p$ -values  $< 0.05$  were considered statistically significant.

## Results

### Sociodemographic characteristics

The median age at admission was 99 h ( $IQR=77,128$ ), which was approximately 4.1 days, for the newborns in group A and 112 h ( $IQR=75,137$ ), which was approximately 4.6 days, for the newborns in group B. Their male:female ratio was 1.1:1 for group A and 1:1 for group B. The majority (88.9% in group A and 92.1% in group B) were delivered in health facilities. Table 1 shows the socio-demographic characteristics of the newborns by group.

### Spectrum of surgical conditions

The majority (96.8%) of the newborns who were referred to MTRH had congenital anomalies. The most common surgical conditions in both groups were gastroschisis (27.0% in group A, 19.1% in group B), hydrocephalus (14.3% in group A, 22.2% in group B), Hirschsprung's disease (7.9% in group A, 20.6% in group B), and anorectal malformations (ARM) (17.5% in group A, 11.1% in group B). Figure 1 shows the distribution of the surgical conditions seen in newborns referred to MTRH by group.

### Referral and transport characteristics

In the majority (98.4% in group A, 84.1% in group B) of the referred newborns, MTRH was contacted prior to commencement of the referral and transport process, and the main mode of communication was written (95.2% in group A, 92.1% in group B). The majority of the newborns were transported using government-run road ambulances and were escorted by trained medical personnel. The median duration of transfer was 2.8 ( $IQR=2.0, 4.0$ ) h for the newborns referred from the hospitals in group A, and 4.0 ( $IQR=2.5, 6.0$ ) h for those referred from the hospitals in group B. The elements of referral and transport that showed statistically significant differences between the two groups of newborns were as follows: contact with MTRH prior to referral, mode of communication on referral, and duration of transport. Table 2 shows the distribution of newborns according to their referral and transport characteristics by group.

### Outcomes of newborns with surgical conditions

#### Primary outcomes — clinical status of the newborns at admission

Thirty point two percent (30.2%) of the newborns referred from the hospitals in group A had hypothermia compared to 88.9% of those referred from the hospitals in group B. Delay in capillary refill, which denoted dehydration, was recorded in 4.8% of the newborns referred from the hospitals in group A and 52.4% of the newborns

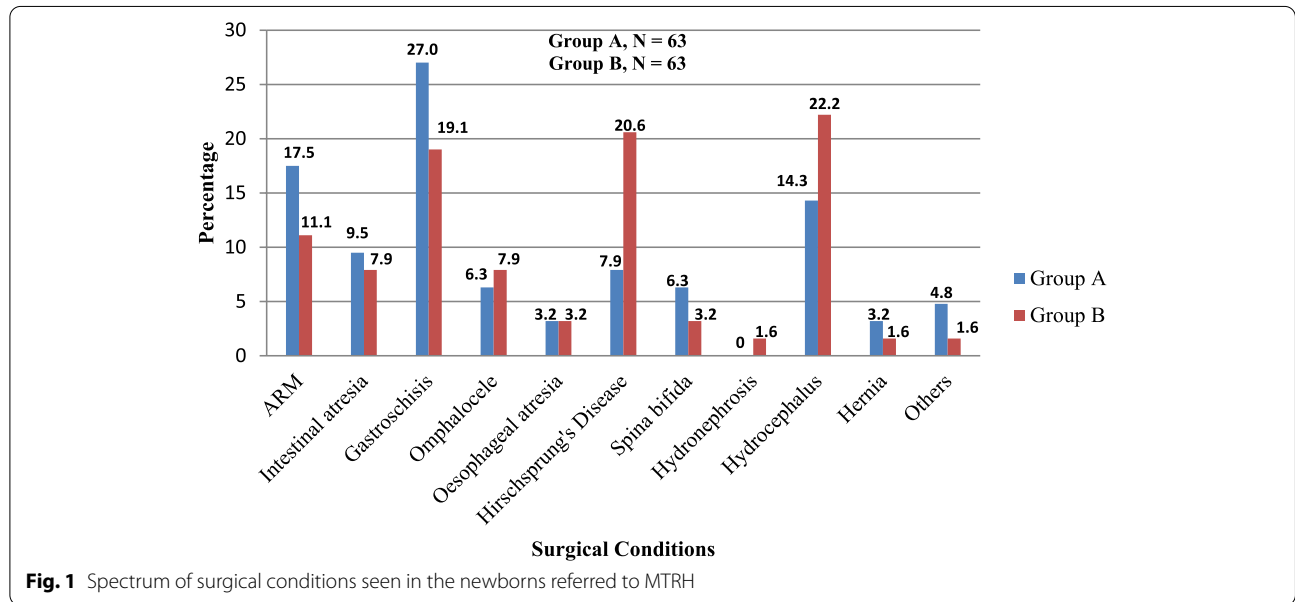
**Table 1** Sociodemographic characteristics of the newborns

Variable	Group A (n = 63)	Group B (n = 63)	Test statistic	p-value
<b>Age at admission (hours)</b>			0.312 <sup>a</sup>	
Median (IQR)	99 (77, 128)	112 (75, 137)		0.755
<b>Birth weight (grams)</b>			0.342 <sup>a</sup>	
Median (IQR)	2695 (2160, 3100)	2700 (2300, 3300)		0.732
<b>Weight at admission (grams)</b>			0.161 <sup>a</sup>	
Median (IQR)	2600 (2100, 3000)	2630 (2150, 3100)		0.872
<b>Sex</b>			0.127 <sup>b</sup>	
Male (%)	33 (52.4)	31 (49.2)		
Female (%)	30 (47.6)	32 (50.8)		0.722
<b>Gestational age (weeks)</b>			2.154 <sup>b</sup>	
Preterm (< 37), (%)	28 (44.4)	20 (31.7)		
Term (≥ 37), (%)	35 (55.6)	43 (68.3)		0.142
<b>Place of birth</b>			0.368 <sup>c</sup>	
Home (%)	7 (11.1)	5 (7.9)		
Health facility (%)	56 (88.9)	58 (92.1)		0.544
<b>Birth order</b>			0.141 <sup>b</sup>	
1 (%)	27 (42.9)	30 (47.6)		
> 1 (%)	36 (57.1)	33 (52.4)		0.708

Note: <sup>a</sup>Wilcoxon rank-sum test (Z)

<sup>b</sup>chi-square test ( $\chi^2$ )

<sup>c</sup>Fisher's exact test



referred from the hospitals in group B. There was a statistically significant ( $p$ -value < 0.05) difference in the clinical status of the newborns at admission, between those that were referred from hospitals in group A and those that were referred from the hospitals in group B. Table 3 shows the distribution of the newborns according to the

parameters indicating their clinical status at admission by group.

**Secondary outcomes**

The overall all-cause in-hospital mortality rate of the newborns referred to MTRH with surgical conditions

**Table 2** Distribution of the newborns according to their referral and transport characteristics

Variable	Group A (n = 63)	Group B (n = 63)	Test statistic	p-value
<b>MTRH contacted prior to referral</b>			8.068 <sup>b</sup>	
°Yes (%)	62 (98.4)	53 (84.1)		
°No (%)	1 (1.6)	10 (15.9)		<b>0.005*</b>
<b>Mode of communication on referral</b>			9.797 <sup>b</sup>	
°Written (%)	60 (95.2)	53 (84.1)		
°Verbal (%)	2 (3.2)	0 (0.0)		
°None (%)	1 (1.6)	10 (15.9)		<b>0.007*</b>
<b>Mode of transportation</b>			1.874 <sup>b</sup>	
°Road ambulance (%)	62 (98.4)	59 (93.7)		
°Public motor vehicle (%)	1 (1.6)	4 (6.3)		0.171
<b>Escort during transport</b>			2.800 <sup>b</sup>	
°Trained medical personnel (%)	62 (98.4)	58 (92.1)		
°Parent/guardian (%)	1 (1.6)	5 (7.9)		0.104
<b>Time to start of transfer, from time of decision to transfer</b>				
° Duration of pre-transport preparation Hours			1.444 <sup>a</sup>	
°Median (IQR)	2.5 (1.3, 5.5)	2.8 (1.5, 9.2)		0.222
<b>Time to admission, from time of start of transfer</b>				
° Duration of transport Hours			2.913 <sup>a</sup>	
°Median (IQR)	2.8 (2.0, 4.0)	4.0 (2.5, 6.0)		<b>0.004*</b>

Note: <sup>a</sup>Wilcoxon rank-sum test (Z)<sup>b</sup>Fisher's exact test

\* Statistically significant p-value

**Table 3** Distribution of newborns according to parameters indicating their clinical status at admission

Variable	Group A (n/%)	Group B (n/%)	Test statistic	p-value
<b>Body temperature (°C)</b>	<b>n = 63</b>	<b>n = 63</b>	51.294 <sup>a</sup>	
32–36.4	19 (30.2)	56 (88.9)		
36.5–37.5	44 (69.8)	7 (11.1)		<b>&lt; 0.001*</b>
<b>Capillary refill time (seconds)</b>	<b>n = 63</b>	<b>n = 63</b>	35.000 <sup>b</sup>	
< 3	60 (95.2)	30 (47.6)		
≥ 3	3 (4.8)	33 (52.4)		<b>&lt; 0.001*</b>
<b>Random blood sugar (Mmol/L)</b>	<b>n = 63</b>	<b>n = 63</b>	29.461 <sup>b</sup>	
< 2.5	1 (1.6)	26 (41.3)		
≥ 2.5	62 (98.4)	37 (58.7)		<b>&lt; 0.001*</b>
<b>Respiratory rate (breaths/minute)</b>	<b>n = 63</b>	<b>n = 63</b>	6.690 <sup>b</sup>	
30–60	59 (93.7)	53 (84.1)		
> 60	4 (6.3)	10 (15.9)		<b>0.010*</b>
<b>Oxygen saturation (SpO<sub>2</sub>)</b>	<b>n = 63</b>	<b>n = 63</b>	45.853 <sup>a</sup>	
< 90	13 (20.6)	51 (81.0)		
≥ 90	50 (79.4)	12 (19.0)		<b>&lt; 0.001*</b>
<b>Immediate resuscitation done</b>	<b>n = 9</b>	<b>n = 48</b>	40.367 <sup>b</sup>	<b>&lt; 0.001*</b>
Airway blocked — re-established	0 (0.0)	5 (10.4)		
Breathing ceased — assisted	3 (33.3)	12 (25.0)		
Collapse of circulation — supported	2 (22.2)	13 (27.1)		
Others	4 (44.5)	18 (37.5)		

Note: <sup>a</sup>chi-square test ( $\chi^2$ )<sup>b</sup>Fisher's exact test

\* Statistically significant p-value

was 15.9%. All-cause in-hospital mortality rate for the newborns referred from the hospitals in group A was 3.2% while that for those referred from the hospitals in group B was 28.6%. The median time to death from time of admission was 23 (*IQR*=11, 35) days in group A and 11 (*IQR*=4, 27) days in group B. The differences in the variables that measured secondary outcomes between the two groups were statistically significant ( $p$ -values < 0.05). Table 4 shows the distribution of the newborns according to their secondary outcomes by group.

#### **Effect of the structured SOP for transport on outcomes of newborns with surgical conditions**

Adverse outcomes on all the parameters used to measure the clinical status of the newborns at admission were noted more in the newborns referred from the county hospitals in the control group. Overall, the need for immediate cardio-pulmonary resuscitation was recorded in 57 (45.2%) newborns (9 (14.3%) in group A and 48 (76.2%) in group B. The differences in the clinical status of the newborns in the two groups were statistically significant ( $p$  < 0.05).

#### **Discussion**

This was a cluster randomized controlled trial that aimed at assessing the effect of a structured standard operating procedure (SOP) for transport of newborns with surgical conditions, on their outcomes at the Moi Teaching and Referral Hospital (MTRH), Eldoret. The structured SOP was adopted from the WHO guidelines on transfer and referral of sick neonates [4] and customized to include locally innovative improvisations.

#### **Sociodemographic characteristics of the newborns with surgical conditions**

Sociodemographic characteristics of the newborns are of great significance, as several studies have linked

various sociodemographic, clinical, referral, and transport characteristics of newborns referred and transported to tertiary-level hospitals for specialized care, to their treatment outcomes. Narang et al., Aggarwal et al., and Sachan et al. reported an inverse relationship between mortality rates of newborns referred to tertiary-level hospitals, and their gestational age, birth weight, and delivery conducted by unskilled birth attendant [7–9].

The sociodemographic characteristics of the newborns with surgical conditions referred to and treated at the MTRH, from the county hospitals in both the intervention group (group A) and the control group (group B), were similar. The long median ages at admission that were found in both groups suggested a delay in accessing neonatal surgical care, which could be explained by the 3-delay model that characterizes barriers to healthcare seeking. This model that comprises the delay in deciding to seek care (delay 1), delay in reaching the healthcare facility (delay 2), and delay in receiving quality care once at the health facility (delay 3), was initially developed for use in analyzing maternal deaths [10]. It was later validated and found to be useful in analyzing perinatal deaths in L/MICs [11, 12]. In this study, there was a delay in accessing neonatal surgical care despite the majority of the newborns being born in health facilities. Studies conducted in the MICs reported lower median ages at admission [13, 14], further suggesting socio-economic status as an important determinant of delay in seeking care.

The distribution of the newborns by gender was similar in both groups, with an almost equal male to female ratio. Many of the congenital anomalies that formed the majority of the surgical conditions found in this study have an even gender distribution.

The median birth weights in both groups were similar to those found in other studies [15, 16]. The median weights at admission of the newborns in both groups

**Table 4** Distribution of newborns according to their secondary outcomes

Variable	Group A	Group B	Test Statistic	$p$ -value
<b>Outcome</b>	<b><math>n = 63</math></b>	<b><math>n = 63</math></b>	15.210 <sup>b</sup>	
Discharged home (%)	61 (96.8)	45 (71.4)		
Died (all-cause in-hospital mortality) (%)	2 (3.2)	18 (28.6)		< 0.001*
Duration of hospital stay (days)	<b><math>n = 61</math></b>	<b><math>n = 45</math></b>	2.850 <sup>a</sup>	
Median ( <i>IQR</i> )	11 (8, 17)	18 (9, 28)		<b>0.004*</b>
Time-to-death, from admission (days)	<b><math>n = 2</math></b>	<b><math>n = 18</math></b>	0.821 <sup>a</sup>	
Median ( <i>IQR</i> )	23 (11, 35)	11 (4, 27)		0.412

Note: <sup>a</sup>Wilcoxon rank-sum test ( $Z$ )

<sup>b</sup> Fisher's exact test

\* Statistically significant  $p$ -value

denoted a median physiological weight loss of 3.0 to 3.5%, which is normal.

The majority of the newborns transported to MTRH with surgical conditions were term a finding that was similar to other studies done in the L/MICs [12, 13]. Studies done in India reported varying proportions of term newborns that ranged from 40.0 to 78.5% [9, 15–17].

#### **Spectrum of the surgical conditions seen in newborns referred and transported to MTRH**

The majority of the neonatal surgical conditions were congenital anomalies, with the leading anomalies in both groups being gastroschisis, hydrocephalus, Hirschsprung's disease, and ARM. Ikol et al. reported similar findings in a previous study [18]. Ekenze et al. reported that 2.6 million children are born with congenital anomalies in sub-Saharan Africa, many of which are only amenable to surgery during the neonatal period [19]. Hospital-based studies in Africa have reported incidences of congenital anomalies at 1.5% in Egypt and 2.5% in East Africa [20–22].

These findings further conform to the WHO estimates that approximately 10% of all neonatal deaths in sub-Saharan Africa and southern Asia are due to congenital anomalies [23]. Whereas ARM had previously been reported to be the most prevalent congenital anomaly in African children [24], and in Egypt [25], gastroschisis remains the most prevalent congenital anomaly at MTRH. Opara et al. reported similar findings in a retrospective study done in Nigeria [26].

The spectrum of the surgical conditions in newborns referred from the county hospitals in the intervention group (group A) had more acute conditions (ARM, intestinal atresia, and gastroschisis) compared to that of newborns referred from the county hospitals in the control group (group B). This could perhaps be due to the fact that the intervention (training of the clinicians and subsequent introduction of the structured SOP) may have sensitized the clinicians to promptly refer and transport more acutely ill newborns with surgical conditions. On the contrary, more acutely ill newborns in the county hospitals in the control group could have succumbed to their surgical illness before referral.

#### **Referral and transport characteristics of newborns with surgical conditions**

The majority of the newborns referred from the county hospitals in the intervention group received appropriate pre-transport stabilization. Aggarwal et al. underscored the importance of stabilization before transport of referred newborns [8]. In the contrary, Buch et al. in a similar study in India reported that pre-referral

treatment was given only to a paltry 23.5% of their referred newborns [27].

This study further demonstrated the positive effect of the introduction of a structured SOP for transport of newborns with surgical conditions on their referral and transport characteristics. In the majority of the referred newborns, MTRH was contacted prior to commencement of the referral and transport process. This could perhaps be indicating the effect of the referral strategies that were initiated by the Ministry of Health in 2014 [5]. However, this characteristic showed a statistically significant difference between the newborns referred from the county hospitals in group A and those referred from the county hospitals in group B. The main mode of communication on referral of the newborns in both groups was written. This was in contrast to the finding by Butt et al. in a study done in Pakistan, in which they reported that only 11.1% of the referred newborns had referral letters [28]. Their study further concluded that maintaining good standards in medical note keeping and referral documentation is important in planning further patient management and counseling parents on their newborns' prognosis. Mutlu et al. in a study done in Turkey found that 71% of the referred neonates had referral notes [29], and Buch et al. in a study done in India reported a paltry 41.9% of referred newborns that had referral letters [27], which is in contrast to the findings in this study.

This study further showed that the majority of the newborns with surgical conditions, who were referred to MTRH, were transported by road ambulances. The ushering in of the devolved system of governance in Kenya following the enactment of a new constitution in 2010 enabled many county governments to procure fleets of road ambulances as part of equipping their county health systems. Prior to this, Barker et al. reported that the number of road ambulances per hospital in Kenya was at 0.06–3.63 [6]. This could perhaps explain this finding, which is similar to that of a study in India [16]. In the contrary, a study done in Nigeria reported the use of road ambulances at a paltry 4% [14], and another study done in India reported the use of road ambulance at 26.8% [27]. However, there was no statistically significant difference in this characteristic, between the newborns referred from the county hospitals in the intervention group and those referred from the county hospitals in the control group.

The majority of the newborns in both groups were accorded escort by trained medical personnel during transport, which was appropriate. In the contrary, Buch et al. in a study done in India found that only 11.4% of the referred newborns were accompanied by skilled attendants [27]. Aggarwal et al. noted that survival rates were

higher when trained medical personnel accompanied the newborns during transport [8].

There was no statistically significant difference in the median duration of pre-transport preparation of the newborns referred from the county hospitals in both groups. However, the median duration of transport was longer for the newborns referred from the county hospitals in the control group. Ashokcoomar et al. reported similar findings, with a mean time-to-complete inter-healthcare facility transfer of 3 h, 49 min, in a study done in South Africa [30]. In their study, inadequate pre-transport preparation and lack of dedicated transport teams were important determinants of survival of transported surgical newborns. Waiswa et al. and Upadhyay et al. further used the three-delay-model to demonstrate that transport delays do contribute significantly to neonatal mortality [12, 15]. Mori et al. reported similar findings in Japan in which they found that transported newborns with long duration of transport had 85% higher hazard of neonatal death [31]. In this study, the difference in the median duration of transport of newborns referred and transported from the two groups of county hospitals was statistically significant.

#### Outcomes of newborns with surgical conditions

In this study, the measure of primary outcomes following the intervention in the county hospitals in group A was the clinical status of the newborns at their admission to MTRH. Hypothermia, hypoperfusion, hypoglycemia, and hypoxia have been shown to be associated with high mortality in transported newborns [32]. Studies have shown that proper pre-transport stabilization and adequate care during transport are important factors in decreasing the incidences of clinical deterioration, adverse events, and mortality [33].

At admission to MTRH, 88.9% of the newborns referred from hospitals in group B and 30.2% of the newborns referred from hospitals in Group A had hypothermia. Goldsmit et al. and Sachan et al. reported findings on hypothermia that were similar to those found in the newborns referred from the county hospitals in the intervention group [9, 13]. However, the incidences of hypothermia found in this study were in contrast to those reported in other previous studies [7, 8, 34]. Care of newborns during transport, which involves maintaining warmth using effective methods such as *kangaroo mother care*, use of polythene bag wraps, use of aluminum foil wraps, and use of infant incubator does mitigate hypothermia at admission.

The majority of the newborns referred from the county hospitals in the control group had hypoperfusion (capillary refill time  $\geq 3$  s). Hypoglycaemia (random blood sugar  $< 2.5$  Mmol/L) was reported in 26 (41.3%)

newborns referred from the county hospitals in the control group and in only 1 (1.6%) newborn referred from the county hospitals in the intervention group. Whereas the incidence of hypoglycaemia in the newborns referred from the county hospitals in the control group was much higher than that of the newborns referred from the county hospitals in the intervention group, the incidence of hypoglycaemia in newborns referred from the county hospitals in the intervention group was comparable to those reported in previous studies [7–9]. Adequate pre-transport stabilization and care during transport are key mitigating factors of physiological decompensation during newborn transport.

Hypoxia ( $SpO_2 < 90\%$ ) was found in 51 (81.0%) newborns referred from the county hospitals in the control group and 13 (20.6%) newborns referred from the county hospitals in intervention group, which were comparable to those reported by Sachan et al. in a study done in India [9]. Need for immediate cardio-respiratory resuscitation was noted in 48 (76.2%) newborns referred from the county hospitals in the control group, as opposed to 9 (14.3%) newborns referred from the county hospitals in the intervention group. Overall, 45.2% of the referred newborns had need for immediate cardiorespiratory resuscitation, which was lower than that found in a similar study in Argentina [13].

The incidences of hypothermia, hypoperfusion, hypoglycemia, and hypoxia were significantly higher in newborns transported from the county hospitals in the control group (group B) than in those transported from the county hospitals in the intervention group (group A), further demonstrating the positive effect of introducing a structured SOP for transport of newborns with surgical conditions in the hospitals in group A. Martínez et al. in a before-and-after (quasi-experimental) study in Mexico found that more transported newborns had normal body temperature, normal range of blood sugar, more infant incubator use, and normal oxygen saturation following training on the *S.T.A.B.L.E.* program [35]. Similar findings were earlier reported by Spector et al. in a study done in Panama [36].

The overall all-cause in-hospital mortality rate for the transported newborns with surgical conditions was 15.9%, which was similar to that reported by Goldsmit et al.: 17.5% [13], Sachan et al.: 18.3% [9], and Aggarwal et al.: 20% [8] but much lower than those reported by Buch et al.: 32.2% [27], Dalal et al.: 23.7% [37], Narang et al.: 36% [7], and Sehgal et al.: 36% [34]. However, the all-cause in-hospital mortality rate for the newborns referred and transported from the county hospitals in the intervention group was 3.2%, compared to the 28.6% for those referred from the county hospitals in the control group, a difference that was statistically significant

( $p < 0.05$ ). Although this difference in the all-cause in-hospital mortality rate could easily be attributed to the intervention in this study, individual surgical treatments that are specific to each surgical condition were probable confounders.

While the median duration of hospital stay was significantly longer for the newborns referred from the county hospitals in the control group than for those referred from the county hospitals in the intervention group, the median time to death from time of admission was longer for the newborns referred from the county hospitals in the latter group. This perhaps could indicate longer survival of newborns with surgical conditions following the introduction of the structured SOP for newborn transport.

#### **Effect of a structured SOP for transport on outcomes of newborns with surgical conditions, referred and transported to the MTRH**

The study results showed statistically significant differences in the parameters that indicated the clinical status of the newborns at admission. The study provided strong evidence that the introduction of the SOP for transport of newborns with surgical conditions had a positive effect on mainly their primary outcomes at MTRH. The effect of the SOP on the secondary outcomes should be interpreted in the context of the multiple confounders that include the surgical care that was offered to the newborns.

Similar educational programs on newborn transport have previously been shown to improve their outcomes at the tertiary-level hospitals. Kumar et al. noted significant improvement in the clinical status of the newborns at admission following an intervention on pre-transport stabilization by a specialized neonatal transport service [33]. Spector et al. in Panama, and Martínez et al. in México, further demonstrated improvements in the outcomes of transported newborns at the tertiary-level hospitals that directly resulted from the implementation of neonatal provider educational programs — *Sugar and safe care, Temperature, Airway, Blood, Lab work, and Emotional support* (S.T.A.B.L.E.) and newborn transport guidelines, respectively [35, 36]. In India, Ezhumalai reported a significant improvement in the quality of referral letters and a decrease in the proportion of newborns seen at triage with physiological decompensation, following a referral education module [38].

In conclusion, the outcomes of the newborns with surgical conditions referred to and treated at MTRH were good. Nonetheless, the introduction of a structured SOP for transport of newborns with surgical conditions at the county hospitals significantly improved their outcomes at the MTRH. However, the study findings, particularly on

secondary outcomes, need to be interpreted in the light of the study limitations that may accrue from the choice of the study design and the sampling technique.

To the public health sectors in low-resource settings, the study recommends adoption and use the structured SOP for transport of newborns with surgical conditions, an intervention that is context appropriate, implementable, and scalable.

#### **Abbreviations**

ARM: Anorectal malformation; FAN: IREC-Formal approval number: Institutional Research and Ethics Committee; IQR: Interquartile range; L/MIC: Low-/middle-income country; MTRH: Moi Teaching and Referral Hospital; NICU: Neonatal intensive care unit; SOP: Standard operating procedure; S.T.A.B.L.E: Sugar and safe care, Temperature, Airway, Blood, Lab work, and Emotional support; WHO: World Health Organization.

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#### **Authors' contributions**

The study conception and design were done by PS, GK, and YK, while data acquisition was done by PS and IM. Data analysis, data interpretation, and drafting of the manuscript were done by PS and IM, while critical revision of the manuscript was done by GK and YK. The authors read and approved the final manuscript.

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#### **Availability of data and materials**

The datasets are available from the corresponding author on reasonable request.

#### **Declarations**

##### **Ethics approval and consent to participate**

Ethical approval for this study was sought and obtained from the MU/MTRH Institutional Research Ethics Committee (FAN: IREC 1861), and data was collected from the newborns' referral records and interviews with the staff escorting the newborn as well as the parent(s)/guardian(s) upon obtaining a written informed consent.

##### **Competing interests**

The authors declare that they have no competing interests.

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