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Outcome Analysis of Neonates following Laparotomy for Acute Abdomen: A Prospective Study

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ABSTRACT

Background

Low and middle-income countries (LMIC) bear the majority of the global pediatric surgical burden. Despite increasing volume of pediatric surgeries being performed in LMIC, outcomes of these surgeries in low and middle-income countries remain unknown due to lack of robust data.

Objective

The objective of our study was to collect data on and evaluate neonatal surgical outcomes at a tertiary level center in India.

Method

The surgical outcomes data of all neonates undergoing laparotomy between February 15, 2015 and October 14, 2015, at Sir Ganga Ram Hospital, New Delhi, India was collected prospectively. Descriptive statistics were used to determine the rates of various postoperative outcomes.

Result

A total of 37 neonatal surgeries were performed during the study period. The mean age of the neonates on the day of surgery was 7 days (range: 1-30 days). Most of the neonates (72.9%, n=27) were males. About 40% (n=15) of the neonates were preterm and 15 (40.5%) of them were small for gestational age. In our study, 10 neonates (28.6%) needed ventilation for 48 hours or less after surgery and 5 neonates (13.5%) were kept Nil per Oral (NPO) postoperatively for more than 10 days. Out of 37 neonates, 4 (10.80%) developed a surgical site infection and 8 neonates (21.6%) had postoperative sepsis. The in-hospital mortality rate among neonates undergoing laparotomy during the study period was 8.1 deaths per 100 neonates.

Conclusion

Co-ordination of care among pediatric surgeons, neonatologists, nursing and anesthesia team is required for optimal surgical outcome.

KEY WORDS

Laparotomy, Mortality, Neonatal surgery

INTRODUCTION

Neonatal death is one of the leading causes of global pediatric deaths.[1] Surgically correctable pathology is a major contributor to Global Burden of Disease (GBD) and it has been estimated that 11% of GBD can be treated with surgery. Congenital anomalies account for majority (approximately 9%) of surgical burden and 4% of them are due to perinatal conditions.[2]

Low and Middle Income Countries (LMIC) disproportionately bear the burden of these conditions. In LMICs, the burden associated with surgically treatable conditions is 401 million DALYs/year and surgically preventable deaths is 1.8 million deaths/year. The Lancet Commission for Global Surgery has identified safe and accessible pediatric surgery in LMIC as top priorities for global surgery.[3] Hence surgical outcome data from LMIC aid in improving surgical care in LMICs. India, with population of 1.2 billion has neonatal mortality rate of 33 per 1000 live births.[4] Congenital malformations that are surgically correctable account for 8-15% of perinatal deaths in India.[5] Bhatnagar et al. reported neonatal mortality rate ranging from 5 to 16% among neonates undergoing surgical intervention and sepsis as major contributor (80%) to morbidity and mortality.[6] Gangopadhyay et al. found post-operative complications following neonatal surgeries as high up to 35% but survival is up to 65-70%.[7]

There remains a dire need for better access to neonatal surgery in India and also need for surgical outcome registry to track neonatal outcomes after surgery.

The objective of our study was to collect and evaluate neonatal surgical outcomes following laparotomy for acute abdomen and also to test the feasibility of implementing neonatal surgical outcomes registry.

METHODS

This prospective observational study was conducted from 15 February 2015 to 14 October 2015 in the Department of Pediatric Surgery of Sir Ganga Ram Hospital, New Delhi, India. Sir Gangaram Hospital is a high volume, well equipped tertiary center in India with 654 beds. The hospital has well equipped NICU with 26 beds, 15 ventilators. We have two consultant pediatric surgeons, two pediatric anesthesiologists and 6 neonatologists. The annual turnover in NICU is 1200 admissions/year.

For the first objective of our study, we designed a form to collect pre-operative, intra-operative and post-operative information from all the patients undergoing surgery at Sir Gangaram Hospital with the parent's consent. This form was developed with input from a panel of experts that consisted of pediatric surgeons, neonatologists, anesthesiologists, NICU nursing team and administrative staff. The form was pilot tested, revised incorporating feedback from pilot tests and a final form for data collection (Appendix A) was approved by the panel. An operating guide on how to complete the form was prepared and each member was trained to complete the form in correct manner. After implementation, team members met on regular basis to discuss data collection. Data was extracted at regular intervals (15 days) to check for accuracy and any errors were identified and were corrected immediately. Once all the information were recorded, proper registry was formed. We then extracted data from the outcome registry from 15 February 2015 to 14 October 2015. All the surgical neonates who were referred to our department and required laparotomy were included in our study. Neonates who required additional neurological or cardiac surgery in addition to laparotomy were excluded. Informed consent was obtained from parents of all neonates included in our study as per SGRH IRB guidelines. Ethical clearance for this study was obtained from "The Ethical Committee Sir Gangaram Hospital" on 14 February 2015 with clearance code EC/02/15/780.

Variables of interest included birth date, age at the time of surgery (in days), gender, birth weight(grams), small for gestational age (yes/no), referral status to SGRH (yes/no), birth type(vaginal/cesarean delivery), multiple births (yes/no), assisted reproduction(yes/no), consanguinity yes/no), CRP (positive/negative), infection at the time of surgery (yes/no) and pre and post-operative diagnosis.

Surgical outcomes those were collected through the registry included number of days on ventilator, number of days Nil per Oral (NPO), surgical site infection (SSI), post-operative sepsis (yes/no), Length of stay (LOS) and in hospital mortality. Descriptive statistics were used to determine the rates of various post-operative outcomes in our study cohort. All the statistical analysis were performed using stata version 13.0

RESULTS

During the study period from 15 February 2015 to 14 October 2015, a total of 37 neonatal surgeries were performed. Clinical and demographic characteristic of the neonates who underwent surgery are presented in Table 1. The mean age of the neonates on the day of surgery was 7 days (SD: 11.11 days). Most of the neonates (72.9%, n=27) were males. About 40% (n=15) of the neonates were preterm and 15 (40.5%) of them were small for gestational age. The mean birth weight was 2224 grams (SD: 848 grams) and mean gestational age was 36.26 weeks (SD:4.21 weeks). Majority of the cases (67.5%) were refereed to Sir Ganga Ram Hospital (SGRH), New Delhi and were delivered by cesarean section (n=25, 67.5%).

Most of the neonates (n=18, 48.64%) were diagnosed as having Necrotizing Enterocolitis (NEC) preoperatively and it remained the most common intra-operative/ final diagnosis as well. About 40% (n=15) of the neonates had positive blood culture tests.

Table 1. Clinical and demographic characteristics

Characteristics	Number	%
Gender		
Male	27	72.9
Gestational Age (in weeks)		
<37 weeks (Preterm)	15	40.5
Small for Gestational Age	15	40.5
In Hospital Delivery at SGRH	12	32.4
Birth Type		
Normal Delivery	11	29.7
Multiple Births	1	2.7
Assisted Reproduction	3	8.1
Antenatal Visit	37	100
Consanguinity	2	5.4
Birth Weight (in grams)		
Normal (>2500 grams)	15	40.5
Low Birth Weight (1000-2500 grams)	16	43.23
Very Low Birth Weight (<1000 grams)	6	16.2
Diagnosis		
Necrotizing Enterocolitis(NEC)	18	48.64
Congenital Diaphragmatic Hernia (CDH)	7	18.91
Intestinal Obstruction	7	18.91
Duodenal Atresia	3	8.10
Others	2	5.40

Table 2. Outcomes among neonates undergoing surgical intervention at SGRH

Characteristics	Total (n)	Percent (%)
Days on Ventilation		
Zero	20	57.1
<2 days	10	28.6
3-6 days	5	14.3
Days Nil Per Oral (NPO)		
1-5 days	21	56.7
6-10 days	11	29.7
>10 days	5	13.5
Surgical Site Infection		
No	33	89.2
Yes	4	10.8
Post-operative Sepsis		
No	29	78.4
Yes	8	21.6
length of stay (LOS)		
Extended LOS (>39 days)	10	27
Non-extended LOS (<=39 days)	27	73
Mortality		
Yes	3	8.1
No	34	91.9

The outcomes of the surgeries performed within a year span at SGRH are presented in Table 2. A total of 10 neonates (28.6%) needed ventilation for 48 hours or less after surgery, 5 of them (14.3%) needed ventilation for 3-6 days. Only 5 (13.5%) neonates were kept Nil Per Oral (NPO) for more than 10 days after surgery. Majority of them (n=33, 89.2%) didn't develop a surgical site infection but 8 neonates (21.6%) were diagnosed to have post-operative sepsis. The average length of stay (LOS) was 22 days (SD: 18.83 days). Neonates who had LOS more than 75th percentile (39 days) were categorized as "neonates with extended LOS" and those with LOS under 75th percentile were categorized as "neonates with non-extended stay". Neonates in "extended LOS" group tended to be younger (mean age: 10 days vs. 27 days, p<0.001). There were no females in the "extended LOS" group. Birth weight, gestation age and small for gestational age were not found to be statistically different among "extended LOS" and "non-extended LOS" group. The mortality rate among neonates undergoing a laparotomy at SGRH during study period was 8.1%.

DISCUSSION

We were able to successfully develop and implement a surgical outcomes registry for neonates undergoing laparotomy at Sir Ganga Ram Hospital,India. We collected data on 37 neonatal surgeries during the study period. In our study, 21.6% neonates were diagnosed to have post-operative sepsis and the mortality rate among neonates undergoing laparotomy at SGRH during study period was 8.1 per 100 surgeries.

Surgical correction leads to a dramatic improvement in quality of life for children born with congenital anomalies and significantly decrease disability-adjusted life year.[8] It also increases chances of survival in surgical neonates with major intra-abdominal pathology. Attributable to the lack of access to care along with technical and expert human resources, these surgeries are performed infrequently in LMIC. Among the surgeries that are performed, the dearth of outcomes data makes it impossible to benchmark the quality of care being provided. It is hence of insurmountable importance to collect outcomes data of these surgical procedures from LMIC. In a study by K Murthy, authors found that neonatal outcomes database provides a national benchmark of short term outcomes for infants with uncommon perinatal illnesses. These data will also be valuable in counseling and conducting observational and collaborative quality improvement initiatives.[9]

We attempted to create a registry at a single tertiary center in India, which could be expanded other institutions in LMIC. During implementation, the prime factor that was crucial to the implementation was the co-ordination of care among multi-disciplinary team. Other factors that contributed to successful implementation were support from the department of pediatric surgery and NICU. A separate personal was appointed who look after all records and manage them properly.

Globally, the neonatal surgical mortality is variable. It ranges from 6.7% in developed countries to 45% in LMIC.[7,10,11,12] Studies from South Korea, Japan and Nigeria reported a neonatal surgical mortality rate of 6.7%. 7.5% and 45% respectively.[10-13] A study from India conducted at Institute of Medical Sciences, Varanasi reported neonatal surgical mortality rate of 35%.[7] In our study, we find a neonatal surgical mortality rate of 8.1% which is significantly lower than that reported from other institutions in India. In our study, along with lower neonatal surgical mortality, other surgical outcomes were also superior compared to data from other centers. We report a post-operative sepsis rate of 21.6% which is lower than a reported rate of 73.75% from another tertiary center in India.[14] SGRH is a tertiary care center with experts who perform high volume of neonatal surgeries and multi-disciplinary team for neonatal care. We believe that lower mortality rate at SGRH is attributable to these factors. These lower mortality rates in a center in India demonstrate that it is possible to achieve superior surgical care for neonates in India.

The consanguineous marriages and assisted reproduction technology adds more to the births of neonates with some form of malformations requiring surgeries.[15-18] However, in our study only two neonates (5.4%) were born from consanguineous couple and only three neonates (8.1%) were born with assisted reproduction. As the data is very small it is difficult to comment about these variables contributing to the neonatal complications requiring laparotomy.

Our study does have its limitations. This is a single center pilot study conducted for a span of eight months. We were only able to include data from 37 neonatal surgeries which is a limited sample of patients. However, we believe that these outcomes are reflective of the care provided at SGRH in general. These findings may not be comparable to non-tertiary centers in India, but because complicated neonatal surgeries only occur at tertiary centers, outcomes from this registry can be compared to other tertiary centers in India and other LMICs. We were not able to follow up the patient after discharge from the hospital and were unable to report the 30-day mortality and readmission rates, which are more standardized measures to assess surgical quality of care.[19]

The strength of our study is that it is the study to promote a neonatal surgical outcomes registry in India so that it can be used to compare surgical outcomes from other countries. Also this study demonstrate that good optimal outcome in terms of survival and post-operative sepsis is possible in LMIC with dedicated team effort.

CONCLUSION

Our study demonstrates the feasibility of data collection to study neonatal surgical outcomes in low and middle-income countries. We have also found, the neonatal surgical outcomes following laparotomy can be improved with good survival rate if we provide effective surgical service along with good coordination with our neonatologists. This study might help encourage other centers in LMIC to conduct pediatric surgical outcome research.

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