

A STUDY OF NEONATAL SURGERY IN DEVELOPING COUNTRY: MONITORED LOCAL ANAESTHESIA AND SEDATION TECHNIQUERoshan Chanchlani¹, Rakesh Mishra², Vikesh Agarwal³, Nagendra Singh⁴**HOW TO CITE THIS ARTICLE:**

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ABSTRACT: OBJECTIVE: The present study is conducted in a tertiary care institute in central India to develop an effective, safe and minimal anaesthesia technique for neonatal emergency surgery. **METHODOLOGY:** Prospective study conducted from January 2007 to July 2009 in the paediatric surgical OPD in a tertiary care institute in central India. Types of anaesthesia used were either monitored local anaesthesia and sedation technique (MLAST) or general anaesthesia. The allocation of anaesthesia Decision was arbitrary. **RESULT:** A total of 237 cases were studied, most common condition presenting as neonatal surgical emergency in the present study is anorectal malformation (68.35%). Overall mortality observed in MLAST group was 12 out of 120 cases (10%) and in GA group is 43 out of 117 cases (36.75%) [p= 0.0001, significant]. **CONCLUSION:** Anorectal malformation was the most common presenting neonatal surgical condition. There is minimal risk, if surgery is performed under monitored local anaesthesia and sedation technique as compared to General anaesthesia. MLAST should be preferred over GA in setup of developed anaesthesia technique in neonatal surgical emergencies.

KEYWORDS: Anaesthesia, General, Local, Neonate, Surgery.

INTRODUCTION: Common neonatal surgical conditions encountered are Anorectal malformation, Intestinal atresia, Malrotation, Hirschsprung's disease, Gastroschisis, Perforation peritonitis and Omphalocele. Delayed presentation and neonatal sepsis is commonly encountered in developing countries.¹ Success in the management of neonatal surgical emergencies depends on prompt diagnosis adequate resuscitation good nursing care, safe anaesthesia and competent surgery. Considering that, centres for paediatric surgery are few in developing countries; an added requirement is application of the principals of the neonatal transport when neonates are transported to the centres wherever they are born.

Just as infant mortality rate measures the quality of life and health in a country, success of neonatal surgery is an audit of health delivery by any institution. The challenges of offering neonatal surgical service are similar in the developing country. Newborns undergoing emergency operations present several difficult challenges for the anesthesiologist. Many surgical emergencies in the neonate are life threatening and are frequently accompanied by multiple organ system failure.²

Limited human and material resources, poor infrastructure and problems of poverty have had a negative impact on its implementation. J. Cauchi (1998-2003) published, neonates with gastroschisis, whose bowel was reduced without general anaesthesia, have similar outcomes to those whose bowel was reduced under general anaesthesia. Both approaches appear to be safe and effective, but reduction without general anaesthesia was cost-effective.¹ Neonatal surgery under general anaesthesia is always associated with high risk. Procedure in a septic neonate or a physiologically compromised late presenting neonate. General anaesthesia is safe in setup where

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ideal neonatal care referral centres are available. We face high neonatal mortality where surgery is done under general anaesthesia. In our setup this forced us to adopt local anaesthesia technique combined with monitored sedation and assess the utility. With this background the present study is conducted in a tertiary care institute in central India to develop an effective, safe and minimal anaesthesia technique for neonatal emergency surgery.

MATERIALS AND METHODS: This study was carried out at the Paediatric Surgery Unit in a tertiary care institute of central India. It was a prospective study. The study population included all neonates with surgical emergencies managed by the paediatric surgical services. After the institutional ethical committee approval prospective data was recorded from January 2007 to July 2009. All the neonates fulfilling the inclusion and exclusion criteria coming to the paediatrics surgery OPD during the study period were included in the study.

All neonates having following surgical emergencies were included: Anorectal malformations, Intestinal atresias, Neonatal intestinal obstruction, Exomphalos, gastroschisis, Malrotation, Ruptured meningomyelocele with sepsis or meningitis, Pure oesophageal atresias, Perforation peritonitis and Hirschsprung's disease. The exclusion criteria were patients older than 28 days or Neonatal thoracic emergencies. Types of anaesthesia used were either monitored local anaesthesia and sedation technique (MLAST) or general anaesthesia. The allocation of anaesthesia Decision was arbitrary. Lignocaine hydrochloride 2% and tumescent were used as local anaesthetics. Midazolam was used as a sedative either by the intranasal or intravenous route.

Procedure for MLAST: - All the patients were taken to the operation theatre.

After adequate positioning and application of monitors operating area of the patient was prepared with antiseptic agents and draping was done. Lignocaine hydrochloride 2% or tumescent was then injected in operative area and patient was carefully watched till the onset of the anaesthetic effect has appeared which usually takes around 10 to 15 minutes. The dose of Lignocaine used was 2-5 mg/kg body weight with 1:100000 adrenaline. Tumescent solution was preferred in most of the cases which is prepared as follows: RL 300 ml, NaHCO₃ 20 ml, Xylocaine 2% 30 ml, Adrenaline (1: 100000) 2 ml, Hylase 2 ml. Sedation was provided by intra nasal or intravenous midazolam, 0.01-0.1 mg/kg.

Monitoring was done by clinical parameters, heart rate, respiratory rate SpO₂ and ECG when required. In general anaesthesia group: All the steps till draping were similar to MLAST group. The patients in this group were taken under general anaesthesia under strict monitoring. Surgeries were then performed depending upon the disease and indications.

Inhalational sevoflurane or halothane was used for induction and maintenance with atracurium as muscle relaxant. Postoperative pain was assessed with Neonatal and Infant Pain Score.³ Postoperative complications were assessed in terms of survival, wound complications, infection, hospital stay and cost of treatment. All observations and results were analysed and studied and statistical analysis was done.

The collected data were entered and analyzed using Epi Info 2000 (Center for Disease Control and Prevention, Atlanta, Georgia, USA) and SPSS version 16 (SPSS 16.0 for Windows, release 16.0.0. Chicago: SPSS Inc). Frequencies of all variables were taken to check frequencies. Mean and standard deviation (SD) were calculated for continuous variables. The risk factors were identified by univariate statistical tests.

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RESULTS: The present study included 237 neonates undergoing emergency surgery. Mean age of presentation was 4.54 ± 5.21 days. Mean weight of presentation was 2.5 ± 0.46 . Out of 237 cases, 189(79.74%) were males and 48(20.25%) were females. Distribution of cases according to the diagnosis is shown in Table 1. The most common condition presenting as neonatal surgical emergency in the present study is anorectal malformation (ARM) (68.35%). Overall mortality in the present study is 23.20%, the mortality in various diseases is shown in table 2. The commonest condition ARM has mortality of 16.04%. Maximum mortality was encountered in pure oesophageal Arteria (66.66%). 120 (50.63%) cases underwent the surgery under monitored local anaesthesia and sedation technique (MLAST) and 117(49.36%) cases were operated under general anaesthesia. None of the cases underwent any type of regional anaesthesia in the present study.

Distribution of cases in various diseases according to type of anaesthesia adopted is shown in table 3. In anorectal malformation group, 49.38% and 50.61% were operated under MLAST and GA, respectively. Overall mortality observed in MLAST group was 12 out of 120 cases (10%) and in GA group is 43 out of 117 cases (36.75%) [$p=0.0001$, significant]. In anorectal malformations, mortality in MLAST and GA group were 3.75% and 28.04%, [$p<0.001$, significant]. Distribution of mortality according to type of anaesthesia in various conditions is depicted in Table 4.

The mortality was higher in GA group in intestinal atresia [$p=0.0128$, significant] and were found statistically significant. In none of the diseases mortality was significantly higher in MLAST group as compared to GA group, except in esophageal atresia. Various factors which may be related with the risk of mortality were analyzed in the death and survivor groups as shown in Table 5. The factors associated with deaths, which were statistically significant, are clinical pneumonia, per operative fall of SpO_2 , and mechanical ventilation.

Presence of pneumonia clinically and radiologically were more in the survivor group as compared to death group [$p=0.042$, significant]. Out of 237 cases, 72(30.3%) needed mechanical ventilation. The need of ventilation in MLAST and GA groups were 22/120, 18.33% and 50/117, 42.73%, [$p<0.001$, significant]. The deaths were divided in to early and late deaths as per the criteria mentioned in material and methods. Out of total deaths (55), early deaths were seen in 26 cases (47.27%) and late deaths were seen in 29(52.72%) cases [$P=0.1078$, insignificant]. The MLAST group was associated with higher late deaths as compared to higher early deaths in GA group not significant.

DISCUSSION: The present study was conducted on 237 patients who were scheduled to undergo various surgical procedures according to diagnosis under monitored local anaesthesia and sedation technique [MLAST] and General anaesthesia [GA]. The patients selected randomly were in the age group of neonates. The most common condition presenting as neonatal surgical emergency in the present study is anorectal malformation (68.35%) In anorectal malformation group, 49.38% and 50.61% were operated under MLAST and GA respectively.

Overall mortality was 16.04%, 3/80 (3.75%) and 23/82 (28.04%) in MLAST and GA groups respectively. [$p<0.0001$, significant]. In this study the utility, results and complications associated with monitored local anaesthesia and sedation technique compared with general anaesthesia in neonatal emergencies surgeries. Neonatal surgical emergencies are very common presenting in developing country, incidence is about 1:2500 live births.⁴ Mean age of presentation was 4.45 ± 5.21 days, delay in diagnosis and late presentation is very common in our setup, which is similar in other

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studies of developing world by R Tenge-Kuremu et al in, which mean age of presentation was 3days.⁵ Mean weight of presentation was $2.5 \pm 0.46\text{kg}$ which shows that low birth weight is not a very common presentation in our setup, probably because of premature mortality before diagnosis and referral to the higher centres.

These results are in contrast to what one seen in other developing countries where neonatal surgical emergencies present very often in low birth weight babies.^{1,6} The most commonly presenting neonatal surgical emergency in our setup is anorectal malformation (68.35%). This data is supported by the fact that incidence of anorectal malformation is very high in Northern India, 1:1500-1:2000 live births.¹ Overall mortality in the present study was 23% in neonatal surgical emergency conditions, which is very high.

Mortality in neonatal surgical emergencies ranges from 11% to 40% in the developing world.^{1,6} We also fall in high mortality centres and there is definite need to analyse the risk factors associated. This study has equal distribution of cases amongst MLAST and GA group, which allowed us to analyse the data wisely. Mortality in MLAST/GA group were 10% and 36.75% [$p= 0.0001$, significant]. Decision to choose type of anaesthesia was arbitrary and adds the chances of selection bias, which is the limitation of present study. The point not to be ignored is that, other conditions which are operated under GA only, e.g. tracheoesophageal fistula are not considered in this distribution.

These results are similar to what one seen in developing countries where Anorectal malformation and intestinal atresia were the common neonatal surgical emergencies.^{5,7} In the study by Chirdan LB et al post operatively overwhelming infection developed in 58.3%, and 33.3% developed respiratory insufficiencies.⁶ In the study by Ameh et al postoperative infection observed in 55.9% of patients and respiratory tract insufficiencies in 27% of patients.⁷ This is in contrast to present study in which post operatively overwhelming infection was observed in 34.6% of patients and respiratory insufficiencies in 43.63%.

Thus it can be interpreted from the present study respiratory tract insufficiency is more common postoperative reason for mortality. The reasons for this discrepancy may be presentation with aspiration pneumonia due to late referral. In anorectal malformation (68.35%), the most commonly presenting neonatal surgical emergency in our setup, mortality observed in MLAST and GA group were 3.75% and 28.04% ($p<0.001$). Out of 162 cases, colostomy was performed in 87 cases, 53.70% and single stage pull-through was performed in 75 cases, 46.29%. The mortality is very high in colostomy (21, 24.13%) group as compared to pull-through group (5, 6.66%) [$p= 0.0027$, significant] Even though the pull-throughs are considered as more extensive procedure as compared to colostomy, the mortality was higher in colostomy group.

The reason may be the fact that more of the cases of colostomy (54, 62.06%) were done under GA as compared to pull-throughs (28, 37.33%). Hence one can interpret that mortality is not associated with procedure, rather it is associated with type of anaesthesia. Thus safety is compromised to a marked extent if GA is adopted. Similarly, intestinal atresia shows that mortality is higher in GA group and GA can be identified as high risk factor for neonatal surgical emergency. The pain score of neonatal surgical condition was taken preoperative (7.16 ± 0.73) and postoperative condition (7.09 ± 0.70) respectively which was not significant. [$p=0.69$, insignificant]. Risk factor of death: ventilation, preoperative fall of SpO_2 and clinical pneumonia are significant risk factor.

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The statistically insignificant of other risk factor like sepsis shows that sepsis is an equal risk factor for MLAST and GA and doesn't depend on the anaesthesia technique. As early deaths are due to anaesthesia and preoperative complications and often due to respiratory failure. It can be interpreted that GA carries high risk of early deaths. While MLAST causes more of late deaths which can be attributed to sepsis and MODS due to neonatal poor condition, delayed presentation and surgical complications, like leak.

So MLAST decreases the number of deaths due to respiratory complications and avoids complications carries on with GA. More deaths were identified due to respiratory complications if surgery was done under GA. In the MLAST group more deaths were due to overwhelming infection and sepsis. It reflects from this observation that respiratory complications and their threat to life are increased if GA is adopted. This invokes the thought that, GA adds the respiratory risks associated with outcome.

These results are in contrast to what seen in literature of developing countries where sepsis is major risk factor associated with mortality.^{5,6,7} The reasons which can be put forth are: unsafe GA, Poor anaesthesia techniques, and inappropriate immediate postoperative intensive care. In the presence of this scenario, MLAST appears to be safer than GA in the developing setup.

Surgical intervention under MLAST is not universally accepted in the area of advanced anaesthesia all over the world but the risk associated with GA and poor results should force the paediatric surgeons to adopt a safer technique of anaesthesia MLAST which full fills all the criteria of scientifically effective emergency surgical procedures like:

1. Safety of anaesthesia
2. Successful completion of appropriate procedure without any complications.
3. Pain less preoperative and rest of course.
4. Should be monitored

CONCLUSION: Anorectal malformation was the most common presenting neonatal surgical condition. Delayed diagnosis and presentation was common in neonatal surgical emergency condition. Mortality is higher if surgery is delayed and in respiratory insufficient neonate done under general anaesthesia. High risk factors for mortality are: General anaesthesia, preoperative fall of oxygen saturation level, Clinical pneumonia, and need of mechanical ventilation.

There is minimal risk, if surgery is performed under monitored local anaesthesia and sedation technique as compared to General anaesthesia. MLAST should be preferred over GA in setup of developed anaesthesia technique in neonatal surgical emergencies.

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| Study subjects (n= 237) | Number of cases (%) |
|--------------------------------|----------------------------|
| Anorectal malformation | 162(68.35%) |
| Intestinal atresia | 18(7.59%) |
| Gastroschisis | 11(4.64) |
| Perforation peritonitis | 11(4.64%) |
| Ruptured meningomyelocele | 11(4.64%) |
| Omphalocele | 8 (3.37%) |
| Esophageal atresia | 6 (2.53%) |
| Hirschsprung's disease | 5 (2.10%) |
| Malrotation | 5(2.10%) |

Table 1: Distribution of study subjects according to diagnosis

| Study subjects (n=237) | Deaths (n=55) (23.20%) |
|--------------------------------|-------------------------------|
| Anorectal malformation (162) | 26(16.04%) |
| Intestinal atresia (18) | 6(33.33%) |
| Gastroschisis (11) | 7(63.63%) |
| Perforation peritonitis (11) | 5(45.45%) |
| Ruptured meningomyelocele (11) | 1(9.09%) |
| Omphalocele (8) | 3(37.5%) |
| Esophageal atresia (6) | 4(66.66%) |
| Hirschsprung's disease (5) | 1(20%) |
| Malrotation (5) | 2(40%) |

Table 2: Distribution according to disease specific mortality

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| Study Subject (n=237) | MLAST n=120 (50.63%) | General anaesthesia n=117(49.36%) |
|------------------------------|---------------------------------|--|
| Anorectal malformation (162) | 80(49.38%) | 82(50.61%) |
| Intestinal atresia (18) | 11(61.11%) | 7(38.88%) |
| Gastroschisis (11) | 7(63.63%) | 4(36.36%) |
| Perforation peritonitis (11) | 5(45.45%) | 6(54.54%) |
| Ruptured meningocele (11) | 4(36.36%) | 7(63.63%) |
| Esophageal atresia (6) | 5(83.33%) | 1(16.66%) |
| Omphalocele (8) | 3(37.5%) | 5(62.5%) |
| Hirschsprung's disease (5) | 3(60%) | 2(40%) |
| Malrotation (5) | 2(40%) | 3(60%) |

Table 3: Distribution of cases according to anesthesia

| Study Subject (n=237) | MLAST mortality 12/120(10%) | GA mortality 43/117 (36.75%) | P value |
|-----------------------------------|--|---|--|
| Anorectal malformation (n=162) | 3/80(3.75%) | 23/82, (28.04%) | <0.001, chi-square- 15.987, highly significant |
| Intestinal atresia (n=18) | 1/11, (9.09%) | 5/7, (71.42%) | 0.0128, significant |
| Gastroschisis (n=11) | 3/7, (42.85%) | 4/4, (100%) | 0.1939 |
| Perforation peritonitis (n=11) | 1/5, (20%) | 4/6, (66.66%) | 0.2424 |
| Ruptured meningocele (n=11) | 0/4, (0%) | 1/7, (14.28%) | 1.0 |
| Esophageal atresia (n=6) | 4/5, (80%) | 0/1, (0%) | 0.3333 |
| Omphalocele (n=8) | 0/3, (0%) | 3/5, (60%) | 0.1964 |
| Hirschsprung's disease (n=5) | 0/3, (0%) | 1/2, (50%) | 0.4 |
| Malrotation (n=5) | 0/2, (0%) | 2/3, (66.66%) | 0.4 |

Table 4: Mortality in various diseases according to type of anesthesia

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| Factor | Survivors (n=182) | Deaths (n=55) | P value | Logistic regression coefficient |
|----------------------------|----------------------|------------------|--|---------------------------------------|
| Mean weight (kg) ± SD | 2.53 (±0.45) | 2.55 (±0.53) | 0.7675 | 0.099 |
| Clinical sepsis ± SD | 63 (34.61%) | 24 (43.63%) | 0.224, chi-square=1.479 | 0.380 |
| Laboratory sepsis | 79 (43.40%) | 26 (47.27%) | 0.613, chi-square= 0.256 | 0.156 |
| Clinical pneumonia | 47 (25.82%) | 7 (12.72%) | 0.042, chi-square=4.118 significant | -0.869 |
| Laboratory pneumonia | 50 (27.47%) | 9 (16.36%) | 0.095, chi-square= 2.788 | -0.66 |
| Per operative fall of SpO2 | 22 (12.08%) | 24 (43.63%) | <0.0001, chi-square= 26.875, highly significant | 1.728 |
| Mechanical Ventilation | 17 (9.34%) | 55 (100%) | <0.0001, chi-square= 164.131, highly significant | 12.377 |

Table 5: Various factors associated with deaths and survivors

AUTHORS:

1. Roshan Chanchlani
2. Rakesh Mishra
3. Vikesh Agarwal
4. Nagendra Singh

PARTICULARS OF CONTRIBUTORS:

1. Associate Professor, Department of Surgery, CMCH, Bhopal.
2. Associate Professor, Department of Pediatrics, CMCH, Bhopal.
3. Associate Professor, Department of Pediatrics and Surgery, NSCB, Jabalpur.
4. Senior Resident, Department of Surgery, NSCB, Jabalpur.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Roshan Chanchlani,
#1/6-Idgah Kothi,
Doctors Enclave,
Near Filter Plant,
Idgah Hills,
Bhopal-462001, M. P.
Email: roshanchanchlani@gmail.com

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