

To Evaluate The Clinical Efficacy of Total Intravenous Anaesthesia in Paediatric Laparoscopic Surgery- Prospective, Randomized, Control Trial.

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ABSTRACT

Background: A prospective randomized study was carried out to compare the efficacy of epidural ropivacaine with ropivacaine plus dexmedetomidine for post-operative analgesia in thoracic surgeries. **Methods:** 60 patients of either sex, between 18-75yrs of age of ASA Grade 1&2 undergoing thoracic surgery under general anaesthesia with thoracic epidural were enrolled in this study. Patient in Group A received Drug A (Ropivacaine 0.2% 12 cc + 0.25 ml distilled water (n=30)). Patients in Group B received Drug B (Ropivacaine 0.2%12 cc + 0.5 µg/kg Dexmedetomidine (n=30)). Quality and duration of postoperative analgesia, sedation and hemodynamic changes in each group was studied. **Results:** Adding Dexmedetomidine as an adjuvant to Ropivacaine (as in group B) for epidural anesthesia increased the duration and quality of postoperative analgesia when compared with plain Ropivacaine (as in group A). **Conclusion:** The hemodynamic parameters were more stable and the patients were comfortable and moderately sedated in Group B as compared to Group A.

Keywords: Ropivacaine, Dexmedetomidine, Epidural route, Postoperative analgesia

INTRODUCTION

The development of minimally invasive surgery has revolutionized surgical procedures and in the process has influenced the practice of anesthesiology. The advantages of laparoscopic surgery include reduced overall adverse events, shorter hospital stay and rapid return to normal activities.

Paediatric laparoscopic surgery though, first described as early as 1973, was confined to mainly diagnostic procedures. It is only for the last 10-12 years that the role of laparoscopy for therapeutic purposes has gained momentum in paediatric patients.^[1] Laparoscopy in children requires special attention due to anatomical and physiological differences as compared to adults. The abdominal cavity to abdominal surface ratio in infants and children is lesser and the abdominal wall is more pliable as compared to that in adults.^[2] The increase

in intra-abdominal pressure (IAP) due to carbon dioxide insufflations decreases the venous return and increases the peripheral vascular resistance. Abdominal distension leads to a decrease in lung compliance and functional residual capacity, whereas airway pressure, pCO₂ and EtCO₂ increases and above all ventilation with nitrous oxide leads to bowel distension, further hampering visualization of the site and compromising the already decreased abdominal cavity of children.^[3] It is therefore desirable to avoid the use of N₂O and to look for an alternative technique. Total intravenous anesthesia can be defined as a technique of general anesthesia using a combination of agents given solely by the intravenous route and in the absence of all inhalation agents including nitrous oxide.

TIVA with propofol has several reported advantages specifically in laparoscopic surgery. Rapid onset and offset, better hemodynamic stability, smooth induction and high quality anaesthetic conditions. It avoids distension of air filled spaces in patient's body. Decreased incidence of nausea and vomiting is one of major advantage. It also eliminates occupational exposure to inhalational agents and operation theatre pollution. It has the potential to

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provide anaesthesia with equal and greater flexibility control that has not been possible with the use of inhalational agents.^[4,5]

Although the role of TIVA has been well described in adult patients but there remains the paucity of such data in paediatric patients and moreover the physiological implications of abdominal insufflation are not well documented in paediatric literature and cannot be simply extrapolated from adult data. Thus we conducted the present study in paediatric population

MATERIALS AND METHODS

This prospective randomised study was conducted in 50 ASA grade I/II patients of either sex in the age group of 1 to 12 years, who underwent elective laparoscopic surgery at Maulana Azad Medical College and associated Lok Nayak hospital. Sample size estimation of 25 patients in each group was based on considering the power of study as 80% with an alpha error of .05. Patients were randomly allocated by computer generated random number table to any of two study groups Patients who were excluded from the study were age less than 1 or more than 12 years, any associated respiratory, cardiac, metabolic disease bleeding diathesis, history suggestive of hypersensitivity to propofol injection or its compounds, history of previous laparotomy and surgery for more than two hours duration.

A detailed preanaesthetic checkup including appropriate investigations was conducted a day prior to surgery. In all patients, a eutectic mixture of local anaesthetic cream was applied on dorsum of both hands 1 hr before insertion of the IV cannula. All children were given IV atropine 0.01mg/kg followed by IV sufentanil 0.5µg/kg over 30 seconds as preanesthetic medications. Three minutes later, IV propofol in a dose of (2-2.5mg/kg) sufficient to abolish eyelash reflex was given over 1 minute. The trachea was intubated with appropriate size and type of endotracheal tube (ETT). Intraoperatively diclofenac suppository (1.5 mg/kg) per rectal was inserted in both groups. In group T, separate infusion of Propofol, 100µg/kg/min and sufentanil 0.5µg/kg/hr was started immediately after the intravenous induction of anaesthesia. The patients received controlled ventilation with air oxygen mixture. Infusion rates were titrated in steps of 10µg/kg/min for propofol and 0.1µg/kg/hour for sufentanil. The infusion of sufentanil was stopped at the end of surgical procedure and propofol infusion was stopped after the completion of last suture (just before dressing). In the group G, after IV induction, the anaesthesia was maintained by isoflurane (0.4-1%) and N2O & O2 (66% & 33%). Additional boluses of sufentanil 0.2µg/kg IV were at 20 min interval. Isoflurane was discontinued 5 minutes before last skin suture. The patients were shifted to post anaesthesia care unit (PACU). All patients were monitored for at least 1 hour in the PACU.

Perioperative complications, side effects for example airway problems, bradycardia, hypotension, hypoxemia, shivering, pain, nausea and vomiting were recorded for 1 hour. This study was done to evaluate clinical efficacy Total Intravenous Anaesthesia (TIVA) with Propofol & sufentanil VERSUS Conventional General Anesthesia using nitrous oxide (N₂O) and isoflurane in paediatric laparoscopic surgery. Variables studied were hemodynamic variables (Heart rate, systolic and diastolic blood pressure), Respiratory parameters (change in EtC-O₂, Peak inspiratory pressure), Postoperative recovery profile (Agitation, Postoperative nausea and vomiting, Pain), Surgeon’s satisfaction (visibility of operating field, ease of operation and surgeon’s satisfaction was graded as: Fully satisfied / Moderately satisfied/ Not satisfied) and Discharge criteria from PACU(Modified Aldrete’s score, time taken to get score ≥9 was recorded. Quantitative data was analysed by ANOVA with repeated measurements, unpaired T test/ non parametric Wilcoxon Mann Whitney test. Qualitative data was analysed by Chi Square / Fisher exact test. The data was analysed by SPSS statistical software. P value < 0.05 was considered significant.

RESULTS

Table 1: Demographic variables:

	Group T	Group G	p value
Mean Age(yrs)	3.61± (1.63)	3.64±1.63	0.949
Gender (M/F)	25/0	25/0	1.00

Table 2: Heart Rate (HR) in both groups at different reference time

	Group T	Group G
Basal HR	116.84±13.1	111.40±13.2
Mean AI	117.12±14.01	111.7±12.5
Mean PN	116±15.1	116.2±13.17
S1	115.48±14.16	116±12.9
S2	115.84±14.07	117.84±12
S3	115.39±13.1	118±11.5
S4	117.36±14.6	116.88±11.9
S5	116.40±14.2	115.48±12.09
S6	115.88±14.14	117±11.4
S7	117.60±14.1	119±11.5

B= baseline HR, AI- mean of after intubation every 1 min for 3 min, mean PN- mean HR during creation of pneumoperitoneum every 1 min for 5 min. S1- S7: Intraoperative at 5 min interval.

Both the groups were matched for demographic data [Table 1]. HR did not change much in group T (p=0.414) whereas there was a significant rise in HR in group G (p=0.001) during creation of pneumoperitoneum [Table 2]. In group T, SBP did not change much when compared to baseline value (p=0.89) whereas in Group G mean SBP rise was statistically significant (p=0.001). On comparing both the groups there occurred a significant change in SBP during pneumoperitoneum (p=0.001) [Table 3]. DBP followed the same trend as SBP [Table 4]. EtCO₂ and PIP, both groups were comparable at specific reference time [Table 5]. There were only 2

patients in group T with pain score ≥ 4 , whereas in group G, 6 pts had score ≥ 4 , although it was not statistically significant ($p=0.247$). In group T, 12% pts had agitation score ≥ 2 , whereas in group G 48% pts were having score ≥ 2 which was statistically significant ($p<0.05$) [Table 6]. In group T mean time taken to discharge from PACU was 37 ± 3.90 mins as compared to that of group G 46.8 ± 5.33 mins which

was statistically significant ($p<0.05$). In group T, surgeon was satisfied in 96% cases whereas in group G it was only seen in 60% cases which was statistically significant ($p=.003$). Only 1 patient in group T reported to have PONV whereas in group G it was recorded in 5 cases. But this data was statistically insignificant ($p=.083$).

Table 3: SBP in both the groups at different reference times

	SBP GR.-T	p value	SBP GR.-G	p value	DBP- GR.-T	p value	DBP GR.-G	p value
B- AI	-0.5±1.7	0.5	-1.8±0.7	0.243	-3±.4	0.5	-1.5±1.9	0.700
B- PN	-.06±2.2	0.89	-4.9±1.5	0.001	-.5±1.7	0.16	-5.3±2.7	0.001
B- S1	-.08±2.9	0.89	-3.8±2.1	0.001	-.28±2	0.50	-4.5±4.2	0.001
B-S2	-.24±3.3	0.72	-4.7±2.4	0.001	.12±2.4	0.81	-4.5±3.7	0.001
B-S3	-.2±4.1	0.81	-3.8±2.1	0.001	-.1±2.8	.78	-4.6±4.5	0.001
B-S4	-.24±4.3	0.78	-3.9±3.4	0.001	-.2±2.8	0.73	-4.4±5	0.001
B-S5	0.8±4.5	0.39	-4.3±3.1	0.001	-.1±3	0.79	-4.6±4.1	0.001
B-S6	0.8±4.9	0.42	-4±3.08	0.001	-.1±2.6	0.84	-4.5±4.0	0.001
B-S7	-.6±1.8	0.56	-4.8±2.4	0.001	-.3±1.9	0.933	-6.1±3.3	0.001

Mean \pm SD; BP expressed in mm Hg (SBP: Systolic BP, DBP: Diastolic BP)

B= Baseline BP, AI- Mean of after intubation every 1 min for 3 min, Mean PN- mean BP during creation of pneumoperitoneum every 1 min for 5 min. S1- S7: Intraoperative at 5 min interval.

Table 5: Comparison of ETCO2 between two groups

	Group T	Group G
AI	9.96±1.3	9.88±1.08
PN 1	12.92±0.86	12.93±1.4
PN 2	13.20±0.89	13.16±0.79
PN 3	13.40±0.69	13.36±0.89
PN4	13.25±1.07	13.20±0.74
PN5	13±1.07	12.90±1.15
S1	12.68±0.94	12.7±0.94
S2	12.32±1.18	12.42±1.1
S3	12.52±1.19	12.56±1.12
S4	12.40±1.268	12.36±1.18
S5	12.24±1.2	12.32±1.18
S6	12±1	12.1±0.9
S7	10.2±1.3	10.26±1.26

Table 5: Comparison of Peak Inspiratory Pressure (PIP) between two groups

	Group T	Group G
AI	9.96±1.3	9.88±1.08
PN 1	12.92±0.86	12.93±1.4
PN 2	13.20±0.89	13.16±0.79
PN 3	13.40±0.69	13.36±0.89
PN4	13.25±1.07	13.20±0.74
PN5	13±1.07	12.90±1.15
S1	12.68±0.94	12.7±0.94
S2	12.32±1.18	12.42±1.1
S3	12.52±1.19	12.56±1.12
S4	12.40±1.268	12.36±1.18
S5	12.24±1.2	12.32±1.18
S6	12±1	12.1±0.9
S7	10.2±1.3	10.26±1.26

AI- PIP after intubation, PN 1- PN 5: every one minute during creation of pneumoperitoneum. S1- S7: every five minute throughout the surgery.

Table 6: post op agitation score

No. of patients with	Group T	Group G	p value
Score =1	22	13	0.006
Score =2	3	11	
Score =3	0	1	

DISCUSSION

In this era of minimal invasive surgeries, more and more procedures are being performed

laparoscopically not only in adults but also in pediatric population because of their varied advantages like better cosmetic result, less postoperative pain and early discharge from hospital. In the present study, the HR did not change much after intubation in both group T and group G. There was no episode of bradycardia or dysarrhythmias at any point of time in either of the groups. Heart Rate was also compared during creation of pneumoperitoneum. Mean HR did not change much in group T ($p=0.414$), whereas there was a significant rise in HR in group G ($p=0.001$). In group T difference in the mean values between HR at the start of the surgery and that of baseline value was 1.3 ± 4.329 ($p=0.129$) whereas in group G the difference was -4.6 ± 2.04 ($p=0.001$) and the same trend followed throughout the surgery in both the groups.

In both groups, SBP remained stable after intubation. In group G, SBP increased during creation of pneumoperitoneum ($p=0.001$) and remained increased throughout surgery ($p=0.001$). Whereas in group T, SBP remained stable during creation of pneumoperitoneum ($p=0.89$) and throughout the surgery ($p=0.72$). On comparing two groups, SBP was significantly higher in Group G throughout the surgery ($p=.001$)

As far as diastolic blood pressure is concerned, it showed exactly the same trends as the systolic blood pressures at a specific reference time. It suggests better haemodynamic stability both at creation of pneumoperitoneum and throughout the surgery with the use of TIVA as compared to inhalational anesthesia.

Our results were supported by the study done by Juckenhofel S et al,^[6] & Steinmetz J et al,^[7] who concluded that TIVA maintains better hemodynamic stability as compared to inhalational anesthesia in laparoscopic procedures.

In our study, we assessed the postoperative agitation on the basis of 3 point scoring system devised by Davis et al. The incidence of postoperative agitation in group G was 48% as compared with 12% of Group T ($p=0.006$) which was comparable to study done by U Grundmann et al[8] in which desflurane group noticed a higher incidence of agitation as compared to TIVA group (80% vs 44%). Post-operative agitation may be the consequence of hypoxemia, hypoglycemia, pain and effect of inhalational agents. Similar results were also observed by Shoichi Uezono et al,^[9] in 2000 when they compared emergence agitation in preschool children receiving either inhalational anesthesia with sevoflurane or propofol.

In this study, we used FLACC scale in children less than 7 years of age and VAS score in > 7 years to assess the postoperative pain. Patients were assessed post operatively for one hour and number of patients with the pain score ≥ 4 were noted. In Group T 8% of patients showed pain score ≥ 4 whereas in Group G 24% pt had score ≥ 4 ($p=0.247$). This may be attributed to the use of Diclofenac suppository preoperatively in both the groups. Also continuous infusion of sufentanil was used in group T and intermittent boluses of sufentanil were given in Group G. It was similar to study by Yang H et al,^[10] who compared propofol- fentanyl group with sevoflurane-remifentanyl group and they did not find any difference in post-operative pain and consumption of opioid between two groups.

Klinika et al conducted study on hemodynamic effects and recovery after total intravenous anesthesia in children.^[11] It showed that propofol provides satisfactory, stable anaesthesia for children with rapid and complete recovery, although children may need larger doses of propofol for induction and maintenance of anaesthesia.

Similar findings with respect to stable hemodynamics were revealed by the study conducted by Gozdemir M et al.^[12] But incidence of nausea and vomiting were more common in the desflurane group. In the TIVA group, a shorter recovery period was observed which is in accordance with our results.

Mean time taken to fulfill discharge criteria was 8.5 min less in Group T as compare to group G which was statistically significant ($p=0.001$). Propofol has a rapid and smooth onset of action and is as easy to titrate in children as in adults. There is lesser evidence of agitation or other behavioral disorders after TIVA with Propofol making it a very good option in day-care anaesthesia. In our study, surgeon was satisfied in 96% of cases in group T as compared to 60% in group G.

CONCLUSION

TIVA with propofol and sufentanil as compared to inhalational anesthesia with Isoflurane and N₂O in paediatric laparoscopic surgery provides better

haemodynamic stability, lesser incidence of emergence agitation, short recovery time in PACU, better surgeon satisfaction score. But, it doesn't have much influence on postoperative nausea vomiting and postoperative pain.

Limitation

Our study was not powered to detect difference in PONV in two groups. Larger randomized control trial may be required to generalize the findings of this study to general paediatric population.

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