Original Article

Post-Operative Outcomes of Intravenous Lidocaine Infusion on Major Abdominal Surgery in Pediatric Patients: A Randomized Control Trial in a Tertiary Care Hospital

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Conflict of Interest: None
Received: 14-11-2018
Accepted: 06-03-2018
www.banglajol.info/index.php/JSSMC

Abstract

Background: *Post-operative outcomes of a major abdominal surgery depend on careful & effective post-operative management. But it is a critical job especially in children. Obtaining adequate analgesia after major surgery is a problematic issue and postoperative pain still imposes a major burden of suffering in surgical patients.*

Objectives: *The principle objectives of the study is to evaluate the effects of intravenous lidocaine infusion in pain management of pediatric population undergone in major abdominal surgery; to reduce post-operative morbidity & enhance better surgical outcome in children.*

Methodology: *This is a randomized control trial carried out from January 2015-June2015,in a tertiary care hospital among 60 cases of 4 to 14 years children with major abdominal surgery without having any pulmonary, cardiac, hepatic or renal insufficiency. Grouping of patients that is lidocaine infusion group (Group A) and control group (Group B) was made among admitted cases for elective abdominal surgery by simple random technique by means of lottery. For assessment of postoperative pain FLACC Scale was used in both groups. Clinical examination findings & specifically designed data collection sheet with a set questionnaire were used as research instruments. Formulated data was analyzed by SPSS version 17, taking p value <0.05 as significant.*

Results: *It is noted that,after 24 hours of operation most of the patients 56.7% of group A had mild pain whereas 90% patients of group B had moderate pain (p<0.001)& during that time there was no patient with severe pain in group A whereas in group B 10% patients were with severe pain. At 48 hours, pain was absent in 13.3% children of group A and 6.7% in group B. In group A most of the children 76.7%had mild pain compared to moderate pain 18 (60%) in group B children at that hours (P<0.001). Again, regarding required amount of analgesics, patients received I/V lidocaine required less amount of analgesics than its counterpart. In present study, complications was noted only 3.3% patien in group A, where as in the opposite group it was found in 23.3% & p was <0.05. In group A, in 50% patients post operative bowel sound was returned within 72 hours, compared to 73.3% patients in group B. The p value was 0.001. About post-operative hospital stay, 83.3% children of the group A were released from hospital after 5th P.O.D whereas, in group B, only 50% children were released after 7th P.O.D of operation. The P value was 0.03 that is also significant.*

Conclusion: *Intravenous lidocaine could improve immediate and late post-operative pain with early recovery after major abdominal surgery in children & it can contribute to rapid post-operative rehabilitation programs.*

Key Words:
Post-operative pain, Intravenous lidocaine, major abdominal surgery, children.

[J Shaheed Suhrawardy Med Coll 2018; 10(1): 23-27]
DOI: http://dx.doi.org/10.3329/jssmc.v10i1.38899

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Introduction

Acute postoperative pain and postoperative ileus (POI) are common among patients who have undergone abdominal surgical procedures. Various analgesic agents have been the primary traditional method in treatment of postoperative pain[1,2] but,because of various undesirable side effects in surgical patients, like respiratory depression, nausea, vomiting, increased somnolence, and POI[3,4] it is a great problem and this may lead to increased patient and institutional costs, longer hospital length of stay, and an overall increase in patient dissatisfaction.[2,5] Anesthetists and surgeons must carefully consider postoperative

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analgesic regimens and seek methods of pain control that limit undesirable side effects.[6]

lidocaine has been used as an anesthetic and analgesic for more than half a century. A variety of intravenous, intramuscular, and topical methods for administering lidocaine have been developed.[7] Recent several clinical experiences suggest that lidocaine is useful for treatment of pediatric neuropathic condition and intravenous (IV) lidocaine, given as a single dose or as a continuous infusion, may be beneficial in the preservation of gastrointestinal motility and have influence in biochemical pain processes.[8,9] A number of studies have investigated the use of peri & post-operative intravenous lidocaine infusion for better post-operative outcome. The results found that, using intravenous lidocaine 2mg/kg over 30 minutes followed by 1mg/kg/hr compared to opeoids 0.05-0.1mg/kg/hr is associated with improve mobility & decrease supplementary analgesics in children. Use has expanded to other chronic pain syndromes and to the management of postoperative pain in children as well as adults.[9,10] The present study aims to explore effectiveness of continuous intravenous administration of lidocaine during and after abdominal surgery in pediatric age group that might improves patient rehabilitation and shortens hospital stay.

Methodology:

The study design was a randomized controlled trial,comparing study group of continuous intravenous lidocaine infusion group after major abdominal surgery with a control group of using opioid analgesics in pediatric population. It was conducted for one year among patients admitted in the department of pediatric surgery for different intra-abdominal surgical conditions. After scrutinizing with thorough Clinical examination & relevant investigations, combined assessment of Department of pediatric Surgery & Department of Anesthesiology, Mymensingh Medical College Hospital was done. Patients for major elective abdominal surgery were prepared .Total 60 Sample from age group of 4years to 14 years without having allergy to lidocaine or any gross cardiac,renal, pulmonary or hepatic impairment were included & patients needed acute surgical or anesthetic measures or parents who disagreed to include their child was excluded from the study.The Study period was from January 2015-June2015. Grouping of the patients (Group-A for lidocaine infusion group & Group-B for Control group) was made by simple random sampling by means of lottery with sample size 60 (in each groups 30 respectively).Intravenous lidocaine (0.5%, 1mg/kg body weight) infusion was started just before skin closure & continued post operatively according to pain score that was measured by FLACC scale.[11]The study was done with the variables of Post-operative pain & requirement amount of analgesics, Post-operative complications (nausea & vomiting) duration of post-operative illeus, post-operative length of hospital stay as adjuvant analgesic with lidocaine or control group we considered pethidine (1-1.5mg/kg body weight) & NSAIDS accordingly. All analgesics including lidocainewas not allowed >72 hours of operation. Patients who required analgesics >72hours was excluded from the study. Data was collected in a specially designed data collection sheet &patient wasfollowed upto7thpost-operative day. With aSet of Questionnaire in a specifically designed data collection sheet was collected& collected data was analyzed statistically with SPSS version 17.

Results:

The total study population of 60 was equally distributed to lidocaine group and control group. 53% of children under I/V infusion of lidocaine were of 4-7 years of age, against 50% of children of the same age group under control group. The corresponding patients were 40% and 43% respectively from age group 8-11years. Equal number (7%) of patients in both groups was of more than 11 years age. Distribution of patients by Age Groups is shown in table-I.

Table-I

Distribution of patients by Age Group:

Age Groups	% of patients treated by	
	Group A	Group B
4 - 7 years	53	50
8 - 11 years	40	43
Above 11 years	7	7
Total	100	100

Regarding postoperative follow-up, of pain score of both groups of the children at 0- 6-hour most of the children of group A had moderate pain 24 (80%) Where as in group B 13 (43.3%) had moderate pain and 6 (20.0%) patients had severe pain in group A and 17 (56.7%) patients had severe pain in group B. At 7-24 hours most of the patient of group A had mild pain 17 (56.7%) whereas 27 (90%) patients of group B had moderate pain ($p<0.001$). At 7-24 hours there was no patient with severe pain in group A whereas in group B 3 patients were with severe pain. At 25-48 hours, pain was absent in 4 (13.3%) children of group A and 2 (6.7%) in group B. In group A most of the children 23(76.7%) had mild pain compared to moderate pain 18 (60%) in group B children ($P<0.001$) at that hours. At 49-72hours there was no patient in both groups with severe pain but 21 patients complained with moderate pain in group whereas only 4 patients in group had such complain. The distributed result was shown in Table II.

About analgesics use it was observed that Inj. pethidine was required in 1st 24 hrs of operation in both groups &

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Table-II

Post-Operative Pain Assessment

Severity Pain hours		Group A No		Group B No		P value (X^2 test)
0-6 hs	Moderate	24 (80%)		13 (45.3%)		
	Severe	6 (20.0%)	(n=30)	17 (56.7%)	(n=30)	0.001**
6-24 hs	Mild	17 (56.7%)	(n=30)	0		
	Moderate	13 (43.3%)		27 (90%)		
	Severe	0		3 (10%)	(n=30)	0.0001***
24-48 hs	Absent	4 (13.3%)	(n=30)	2(6.7%)		
	Mild	23 (76.7%)		10 (33.33%)		
	Moderate	3		18 (60%)	(n=30)	0.0001***
48-72 hs	Mild	4	(n=5)	21		
	Absent	1		7	(n=28)	

** = Highly Significant (P<0.001)

Table-III

Analgesics (total dose) other than lidocaine used as painkiller in the two groups:

Post-operative day (P.O.D)	Required Analgesics(mg/kg)	Group A (n=30) (Mean ±SD)	Group B (n=30) (Mean ±SD)	P value (t- test)
1st	Pethedine	28.25± 40.29	39.25 ±46.59	
	NSAIDs	-	78.65 ±25.36	
2nd	Pethedine	-	-	0.001**
	NSAIDs	80.62±20.24	221.52±40.33	
3rd	Pethedine	-	-	
	NSAIDs	20.12±31	175.55±67.77	

** = Highly Significant (P<0.001)

NSAIDS for rest of the follow up period's group according to severity of pain. The mean requirement of analgesics in mg/kg body weight, patients of group B required higher doses of analgesics than group A. In group A at 1st P.O.D the, mean (±SD) doses of Inj. Lidocaine required was 56.62±25.25 mg/kg & inj. Pethedine was 18.25± 10.29 but no NSAIDS was required. On the contrary, the amount of injpethidine& NSAIDS used in group B,45.25 ±46.59&78.65 ±25.36 respectively. Again in the following 2nd& 3rd P.O.D required dose of NSAIDS in Group B is more than Group A & p value was also significant (<0.001). The findings were shown in table III.

Table IV

Status of postoperative Complication: (Nausea & Vomiting)

Complication	Group A (Lidocaine Group) (n=30)	Group B (Control Group) (n=30)	P value (X^2 test)
Yes	1 (3.3%)	7 (23.3%)	<0.05*
No	29 (96.7%)	23 (76.7%)	

*= Significant (p<0.05)

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Regarding post-operative complications only one patient (3.3%) in group A had developed nausea & vomiting which was managed accordingly whereas 23(76.7%) patients in group B complained nausea & vomiting. The p value was <0.05, that B was significant. The table IV shows the status of postoperative Complications of the study.The Post-operative bowel sound was returned in15 (50%) patients within 72 hours in group A, whereas in 22 (73.3%) patients bowel sound was found in after 72 hours. The t- test was 0.0017 it was significant. The result is shown in table V.

Table V

Total Duration of post-operativeillus

Hours	Lidocaine Group (Group A) (n=30)	Control Group Group B (n=30)	P value (X^2 test)
<48 hrs	7 (23.3%)	2(6.6%)	
48-72 hrs	15(50%)	8 (26.6%)	
>72hrs	8(26.6%)	22 (73.3%)	0 .001
t-test Mean±SD	53.21±12.11	75.31±13.11	0.001

About the status of post-operative hospital stay most of the group A children were released from hospital after 5th P.O.D 21 (83.3%), 7 (23.3%) after 7th and 2 (6.6%) were discharged after 7th P.O.D of operation, however, in group B, most of the children were released after 7th P.O.D of operation 15 (50%), 8 (26.6%) after 5th -6th P.O.D and 7 (23.3%) after 7th P.O.D. The P value was (0.03) that is also significant. Table VI demonstrates the result.

Table VI

Total Duration Hospital stay

Post-operative days(P.O.D)	Lidocaine Group (Group A) (n=30)	Control Group (Group B) (n=30) (Mean±SD)	P value (X^2 test)
5th -6th (P.O.D)	21(88.3%)	8((26.6%)	0.03
6th- 7th (P.O.D)	7 (23.3%)	15(50%)	
>7th (P.O.D)	2 (6.6%)	7 (23.3%)	

** =Highly Significant (P<0.001)

Discussion

In the era of modern enhanced recovery programs aiming at decrease the length of hospital stay, the issue of pain control is of outmost importance.[12]

In current study, the total studypopulation of 60 was equally distributed to lidocainegroup(group A) and control interventionsgroups (group B). 53% of children under I/V infusion of lidocaine were of 4-7 years of age, against 50% of of the same age group under control group. The corresponding patients were 40% and 43% respectively from age group 8-11years. More or less with similar age group(2-5 years) such a study was done.[10]

In present study, pain assessment was done by FLACC Scale[11] in both groups of the children. At 0- 6-hour most of the children of group A had moderate pain 24 (80%) where as in group B 13 (43.3%) had suffered from moderate pain and 6 (20.0%) patients of group A and 17 (56.7%) patients of group B complained severe pain. At 7-24 hours mild pain was observed 17 (56.7%) patient of group A whereas 27 (90%) patients of group B had moderate pain (p<0.001). At 7-24 hours there was no patient with severe pain in group A whereas in group B 3 (10%) patients were with severe pain. At 25-48 hours, pain was absent in 4 (13.3%) children of group A and 2 (6.7%) in group B. In group A most of the children 23(76.7%) had mild pain compared to moderate pain 18 (60%) in group B children (P<0.001) at that hours. The results denote that use of postoperative I/V lidocaine decrease the pain severity in earlier period than the control group. This result is consistent with study results of several researchers.[1,10]

In this study, Analgesics were used in each group according to mg/kg body weight after pain scoring pain level with FLACC Scale. Inj. pethidine was required for 1st 24 hrs of operation in both groups & NSAIDS for rest of the follow up periods according to severity of pain. In patients of group B he means requirement of analgesicswas higher in doses than group A. In group A at 1stPost-operative day(P.O.D) the, mean (±SD) doses of Inj. Lidocaine required was 56.62±25.25 mg/kg & inj. Pethidine was 18.25± 10.29 but no NSAIDS was required. On the contrary, the amount of injpethidine& NSAIDS was used in group B,45.25 ±46.59&78.65 ±25.36 respectively. Again in the following 2nd& 3rd P.O.D required dose of NSAIDS in Group B was more than Group A & p value was also significant (<0.001). This indicates that patients received I/V lidocaine required less amount of analgesics than who did not receive lidocaine. More or less almost similar result was noted in different other studies where lidocaine infusion decreases posto-perative fentanyl requirement in patients undergoing laparoscopic cholecystectomy & patients receiving lidocaine infusion showedmarked decrease in opiate requirement (14.4± 2.5,12.6 ±3.3 vs. 5.4± 2.9, 4.1 ± 2.6 lg/kg/d on 1st and 2nd postoperative day, P = 0.03, 0.04 respectively), with no difference in sedation score between the groups.[13]

In this study, post-operative bowel sound was returned in15 (50%) patients within 72 hours in group A, whereas

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in 22 (73.3%) patients bowel sound was found in after 72 hours. The t- test was 0.0017 it was significant. Similar result was also found in another study where recovery of intestinal transit assessed by time to first flatus was faster in the Lidocaine group ($P< 0.001$).

In present study, post-operative complications (nausea & vomiting) was noted only one patient(3.3%) in group A had which was managed accordingly whereas 23(76.7%) patients in group B complained nausea & vomiting. The p value was <0.05, that B was significant. Almost same result was noted in[14] where gastrointestinal discomfort was present in 3 and 15 patients in the Lidocaine and Reference groups respectively ($P< 0.05$). Recovery of intestinal transit assessed by time to first flatus was faster in the Lidocaine group ($P< 0.001$).

About post-operative hospital stay, the current study showed that, most of the group A children were released from hospital after 5th P.O.D 21 (83.3%), whereas, in group B, most of the children were released after 7th P.O.D of operation 15 (50%). On the other hand 7 (23.3%) after 7th and 2 (6.6%) of patients were discharged after 7th P.O.D of operation in group A & 8 (26.6%) after 5th -6th P.O.D and 7 (23.3%) after 7th P.O.D. The P value was (0.03) that is also significant. This result has similarity with[10] wherethe length of hospital stay was also significantly less in the lidocaine group than control group(7± 2 vs. 5 ± 2; P = 0.03).Hence ,both study results demonstrate that use of I/V lidocaine as post-operative analgesics can shorten the hospital stay of pediatric population.

Conclusion:

Postoperative intravenous lidocaine infusion attenuates the stress response to elective major abdominal surgery in pediatrics. It is also associated with earlier return of bowel function, decrease in analgesics requirements, and lessen the length of hospital stay. Based on the findings and some critical statistics, it can be recommended that, intravenous lidocaine can be used as an effective analgesic agent in pediatric patients with major abdominal surgery to reduce post-operative morbidity.

Limitations:

Small sample size & single centre study are significant limitation of the study. Besides that, as we do not have any study before so, power calculation of lidocainethat was mainlybased on side effects gained from similar studied in adult population was a great limitation

Acknowledgement

The study authors are kind acknowledge to the head of the department of Pediatric surgery, Mymensingh Medical College and authority of Bangladesh Medical Research Council (BMRC) for financial support as well as cordial support to carry out the study smoothly. We are indebted and owe many thanks to our patients & their parents who were the heart of the study for their willing participation & cooperation in this research.

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