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Original Article

Anaesthesia Section

Evaluation of Efficacy and Safety of Age-Based Intrathecal Dosing of 0.5% Hyperbaric Bupivacaine in the Paediatric Age Group

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ABSTRACT

Introduction: Spinal anaesthesia in the paediatric population is a safe and reliable method of anaesthesia for infraumbilical surgical procedures. As there is greater variation in intrathecal dosing using a conventional weight-based schedule, a prospective cohort study was designed to administer an age-based intrathecal dosing schedule using 0.5% hyperbaric bupivacaine for infraumbilical surgeries in paediatric patients.

Aim: To find the efficacy of age-based intrathecal dosing in terms of level of sensory blockade, success rate and adequacy of blockade for infraumbilical surgery in the paediatric age group.

Materials and Methods: One hundred and thirty paediatric patients, aged between 2-12 years, posted for elective infraumbilical surgeries were given spinal anaesthesia at a dose of Age/5 (Partha formula) using 0.5% hyperbaric bupivacaine. Sedation during the procedure was provided using a combination of effective doses of pentazocine, midazolam, and atropine. The number of attempts, the success rate, the level of sensory blockade, the duration of anaesthesia and cardio-respiratory complications if any were noted.

Results: The mean age of the children was 8±2.55 years. The mean dose of 0.5% hyperbaric bupivacaine used in this study was 8±2.55 milligrams. The desired sensory level of T10 was achieved in the first attempt in all the cases (100%) within 10 minutes of the subarachnoid block. The mean duration of anaesthesia was 73.42±18.6 minutes. In all the patients, the surgical procedures were completed within this anaesthetic time and none of the cases had any conversion to general anaesthesia. No complications were found in any of the patients.

Conclusion: Administration of intrathecal dosing of 0.5% hyperbaric bupivacaine using Partha formula (Age/5) is a safe and successful method to provide subarachnoid blockade for infraumbilical surgeries in the Indian paediatric population.

Keywords: Anaesthesia, Dosage, Spinal

INTRODUCTION

Spinal anaesthesia in paediatric population is in vogue for several years since it was first described in 1909 [1]. However, its utility in paediatric patients came down due to the introduction of various muscle relaxants and inhalational agents. In the 1980s, the technique of spinal anaesthesia became popular especially in ex-premature neonates and infants due to its advantage of overcoming postoperative apnoea risk by avoiding general anaesthesia [2]. In recent years, the subarachnoid block is considered a safe option to general anaesthesia in many lower abdominal and lower limb surgeries outside of the neonatal period. But it is still underutilised due to the fallacies regarding its consistency, feasibility, and safety of the procedure [3-6].

The dosage of local anesthesia in paediatric population is primarily based on body weight [6]. However, the body weight varies among children of same age-group. Hence, calculating intrathecal dose of anesthesia using body weight may lead to complications causing over or under-dosing. Thus, we thought of a formula using the age of the patient to calculate the intrathecal dose in children. Besides, the length of the spinal cord varies with age. Therefore, a hypothesis was made that age could be an appropriate parameter for calculating the dose for spinal anaesthesia in paediatrics and designed this particular study. The aim was to determine the efficacy of spinal anaesthesia in paediatric patients using 0.5% hyperbaric bupivacaine at a local anaesthetic volume calculated by age (age/5) in terms of the level of sensory blockade and adequacy of blockade for infra-umbilical surgeries [7]. The objectives were to find the level of sensory blockade achieved after 10 minutes of subarachnoid blockade, the number of attempts, success rate, the incidence of perioperative complications, need for any supplemental form of anaesthesia and duration of anaesthesia.

MATERIALS AND METHODS

The study was conducted after obtaining the approval of the Institutional Ethical Committee (12/2017/32) and informed consent were obtained the parents. The study period was between February 2018 to October 2019. The sample size was calculated from a study by Verma D et al., where the mean sensory level of blockade for weight-based local anaesthetic dosing in spinal anaesthesia obtained was T6.35 with SD 3.2 (T4-T10) [6].

Sample Size Estimation

On hypothesising that age-based spinal anaesthetic dosing is effective and to find the difference in mean sensory level of 2 (T8.3) with a power of 0.9 (a=0.05), a sample size of 118 was obtained. Considering the dropouts and exclusions, a sample size of 130 was included.

Inclusion and Exclusion criteria: Children of both sexes aged between 2-12 years associated with the American Society of Anaesthesiologist (ASA) class I and II and scheduled for elective infraumbilical surgery were included in the study by continuous sampling. Those parents who were not willing and patients with local infection, coagulation abnormalities, and spinal anomalies were excluded from the study.

These children were kept nil per oral for 2 hours for clear fluids and 6 hours for milk. Promethazine 0.5 mg/kg per oral, a night before and in the morning 2 hours before surgery were given as premedication. Following the premedication, they were allowed to sleep in the preoperative holding room with parental support and shifted to the operating room. Inside the operating room they were premedicated with intravenous pentazocine (0.3 mg/kg), midazolam (0.05 mg/kg), and atropine (30 µ/kg) following intravenous

cannulation. This sedative drug combination was given to maintain immobility while performing the subarachnoid block. Heart rate, blood pressure and oxygen saturation were monitored throughout the process. Following sedation, a lumbar puncture was performed under strict aseptic precaution in lateral position with 25 gauge 9 cm Quincke's needle in the L4-L5 inter-space. Then 0.5% hyperbaric bupivacaine was administered at the volume calculated using age divided by 5 in ml. This formula was designed only for 0.5% hyperbaric bupivacaine due to its conventional use in spinal anaesthesia. The dosing hypothesis was based on the assumption that the dose of bupivacaine in milligrams corresponds to the age of the child in years [7]. The age in months after the completion of a year was noted and considered as the next age, if it is more than 6 months and the same age if it was was less than 6 months. To obtain the dose in volume (ml), age was divided by 5 to arrive at the age-based formula. The feasibility of using this formula was confirmed with adequate anaesthesia in a pilot study [7]. Also, the formula was successfully utilised in several other studies without any haemodynamic complications [7,8].

An additional dose of intravenous ketamine in 0.25 mg/kg was given if the child moved during the performance of the subarachnoid block. The haemodynamic parameters were monitored throughout the procedure and all the children received oxygen supplementation with face mask at 5 litres/min. The level of sensory and motor blockade was assessed at every two minutes interval for 10 minutes after making the child supine following the subarachnoid block. The sensory level was assessed by the loss of response to pin-prick to the dermatomal level or loss of movement of the lower limb. Motor blockade was assessed by the modified Bromage score [9] using the same pin-prick stimulus on the lower limb as follows:

0: Free movement of leg and feet with the ability to increase extended leg

1: Inability to increase extended leg and knee flexion decreased

2: Inability to increase or flex knees; flexion of ankle and feet present

3: Inability to increase leg, flex knee or ankle, move toes.

To identify the levels involving above L1, superficial abdominal reflexes were tested. The performance of surgery was allowed only after obtaining a sensory level of at least T10 and a Bromage score of 3 (complete motor block). The success of spinal anaesthesia was noted and it was defined as the absence of a response to surgical stimuli. In the presence of inadequate spinal sensory level, intraoperative pain or any complaint of the lack of relaxation from surgeons, further anaesthetic management was decided as per the attending anaesthesiologist. Demographic data, type and duration of anaesthesia were noted. The dose of local anaesthetic used, the number of spinal attempts and the need for intraoperative supplemental sedation were also noted. An attempt of spinal anaesthesia was defined as taking the needle out of the skin and reinserting. Complications related to anaesthesia such as vomiting, shivering, postdural puncture headache, and any manifestation suggestive of neurological injury were also recorded. The onset of pain or the movement of the legs was approximately taken as termination of action of intrathecal drug and this duration from the onset was calculated as the duration of anaesthesia.

STATISTICAL ANALYSIS

All the data were recorded in Microsoft Office-Excel and analysed using SPSS version 20.0 software. A simple descriptive analysis was performed.

RESULTS

The mean age of the children was 8±2.55 years. Out of 130 children, 89 (68.5%) were males and 41 (31.5%) were females. The mean weight of the children was 17.98±5.2 kg [Table/Fig-1]. The surgical procedures for which spinal anaesthesia given were lower limb orthopaedic procedures (46.2%), hernia repair (30.7%), orchiopexy (13.1%) and appendectomy (10%). In the operating room, 24 (18.5%) children received an additional dose of intravenous Ketamine (0.25 mg/kg) in addition to routine preprocedural sedation. The mean duration of anaesthesia was 73.42±18.6 minutes. In all the patients, the surgical procedures were completed within this anaesthetic time and none of the cases had any conversion to general anaesthesia. The mean dose and volume of 0.5% hyperbaric bupivacaine used in the study was 8±2.55 mg and 1.6 mL respectively.

Demographic parameters	Findings
Mean Age (Years)	8±2.55
Males (N)	89 (68.5%)
Females (N)	41 (31.5%)
Weight (Kg)	17.98±5.2

[Table/Fig-1]: Demographic characteristics of the patients.
Values expressed in Mean±SD; N=Number of cases

Spinal anaesthesia was performed in all the cases in the first attempt. All children achieved the desired sensory level of T10 within 10 minutes of the subarachnoid block. [Table/Fig-2] shows the number of cases with differing sensory level achieved. The highest sensory level achieved was T4 (n=2) and the lowest sensory level achieved was T10 (n=25). There was no incidence of shivering, vomiting or cardio-respiratory complications in any of the children.

Sensory level	Number of cases, N (%)
T4	2 (1.5)
T6	20 (15.4)
T8	83 (63.9)
T10	25 (19.2)

[Table/Fig-2]: Number of cases with differing sensory levels.

DISCUSSION

Spinal anaesthesia in children is a safe and cost-effective procedure that provides optimal surgical conditions in several day-care surgeries [4,7,10]. So far, paediatric spinal dosing is conventionally done based on weight {0.5 mg/kg (for child <5 kg), 0.4 mg/kg (for 5-15 kg), 0.3 mg/kg (for >15 kg)} [6]. This dose range involves a wide variation to obtain a particular dosage for children. Drug dosing is predominantly based on weight and rarely other clinical parameters such as age, height and body surface area are used [11,12]. Calculations involving anatomical length are predominantly calculated based on age. For example, the Endotracheal tube length calculation. The length of the spinal column is one of the determinants for intrathecal spread of local anaesthetic drug and its length varies with age. Therefore, it was decided to utilise age as a parameter to determine spinal dosing in the paediatric population. Thus, this study was undertaken to study the efficacy and safety of spinal anaesthesia using an age-based formula in the paediatric population.

Sedation is essential for the performance of paediatric spinal anaesthesia as it prevents any untoward movements during the procedure. This measure forbids complications such as failure of spinal anaesthesia and conversion to general anaesthesia. In this study, 24 out of 130 cases received an additional dose of intravenous Ketamine (0.25 mg/kg) in addition to routine preprocedural sedation to facilitate the performance of the subarachnoid block. The importance of sedation for the performance of the subarachnoid block in paediatric patients is well established in several studies [13,14]. In this study successful spinal anaesthesia was achieved in all the cases without the requirement for any other supplemental form of anaesthesia. The desired sensory level of T10 was achieved in all the cases within 10 minutes of spinal anaesthesia. The highest sensory level achieved was T4 (n=2) and the lowest sensory level achieved was T10 (n=25). T8 sensory level was achieved in 63.8%

of the cases (n=83). All the patients had adequate sensory level till the end of surgery. In a pilot study conducted using this age-based formula, successful first attempt spinal anaesthesia was achieved in 88 % of cases [7]. Similarly, in a study conducted by Frumiento C et al., among 262 neonates, successful first attempt spinal anaesthesia was achieved in 97.3% of cases [15]. In a one-year prospective audit conducted by Verma D et al., successful spinal anaesthesia was achieved in 58.8% of cases in the first attempt and in 41.2% of cases in the second attempt with a median peak sensory level of T6. Also, they demonstrated a mean time to two-segment regression of 45 minutes while in the present study, the mean spinal anaesthetic duration was of 73 minutes [6]. The possible difference in findings could be due to variation in the method of assessment. The above findings suggest that spinal anaesthesia in the paediatric population is a feasible option with a remarkable outcome.

The mean local anaesthetic drug volume obtained in this study was 1.6 ml of 0.5 % hyperbaric bupivacaine and the mean local anaesthetic volume obtained using conventional weight-based formula was 1.16 ml. The local anaesthetic volume obtained using conventional weight-based formula is less when compared to the local anaesthetic volume obtained using age-based formula. This finding suggests that there is a higher probability of inadequate spinal blockade secondary to the use of conventional weight-based dosing especially in the Indian population. This might lead to the use of some supplemental form of anaesthesia or conversion to general anaesthesia. In the study by Frumiento C et al., 21.4% cases required some form of supplemental anaesthesia [15]. In the findings of the study by Verma D et al., 3.4% cases were regarded as a failure and general anaesthesia given. Also, Authors reported complications such as shivering (2.9%) and hypotension (2%) [6]. In a similar study conducted by Ahmed M et al., shivering was noted in 6.5% and hypotension was noted in 2.5% of cases [16]. However, no such complications were noted in the present study.

Limitation(s)

The study did not have a control group involving conventional dosing technique to identify comparative findings. Therefore, further comparative studies with conventional weight-based dosing are required to further substantiate the above results. The study did not evaluate the effect of varying height in the same age group paediatric population on the sensory level attained. The study involved Indian paediatric population; therefore, the application of this age-based dosing in children with different races may not be possible due to variable length of spine.

CONCLUSION(S)

This age-based spinal dosing in paediatric population has demonstrated adequate spinal blockade with an optimal surgical condition for infraumbilical surgeries consistently. Also, the safety and recovery profile obtained without any haemodynamic or respiratory complications makes this technique a preferred one for paediatric spinal anaesthesia.

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