Original Article

Comparison of caudal and intravenous dexamethasone as adjuvants for caudal epidural block: A double blinded randomised controlled trial

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ABSTRACT

Background and Aims: Dexamethasone has a powerful anti-inflammatory action with significant analgesic benefits. The aim of this study was to compare the efficacy of dexamethasone administered through intravenous (IV) and caudal route on post-operative analgesia in paediatric inguinal herniotomy patients. **Methods:** One hundred and five paediatric patients undergoing inguinal herniotomy were included and divided into three groups. Each patient received a single caudal dose of ropivacaine 0.15%, 1.5 mL/kg combined with either corresponding volume of normal saline (Group 1) or caudal dexamethasone 0.1 mg/kg (Group 2) or IV dexamethasone 0.5 mg/kg (Group 3). Baseline, intra- and post-operative haemodynamic parameters, pain scores, time to rescue analgesia, total analgesic consumption and adverse effects were evaluated for 24 h after surgery. Unpaired Student's *t*-test and analysis of variance were applied for quantitative data and Chi-square test for qualitative data. Time to first analgesic administration was analysed by Kaplan–Meier survival analysis and log-rank test. **Results:** Duration of analgesia was significantly longer ($P < 0.001$), and total consumption of analgesics was significantly lower ($P < 0.001$) in Group II and III compared to Group I. The incidence of nausea and vomiting was higher in Group I (31.4%) compared to Group II and III (8.6%). **Conclusions:** Addition of dexamethasone both caudally or intravenously as an adjuvant to caudal 0.15% ropivacaine significantly reduced the intensity of post-operative pain and prolonged the duration of post-operative analgesia with the significant advantage of caudal over IV route.

Key words: Caudal anaesthesia, dexamethasone, paediatric inguinal herniotomy, ropivacaine

INTRODUCTION

Paediatric anaesthesia has advanced enormously from the days when anaesthesiologists and surgeons adapted adult techniques and equipment to small children. Since then significant developments have occured including a better understanding regarding pain perception in neonates and advances in techniques of general anaesthesia, regional anaesthesia (RA) and perioperative pain management.[1]

By far the most commonly used RA technique in paediatric practice is the caudal epidural block. It is the easiest block to perform and to teach, with extensive safety record in children. However, it has the disadvantage of short duration of action after single injection.[2] Prolongation of single-shot caudal block has been achieved by the addition of various adjuvants such as opioids, ketamine, adrenaline and α2 agonists, but their utility has been challenged by unacceptable adverse effects in children.[3-6]

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Dexamethasone is a corticosteroid hormone with powerful anti-inflammatory as well as analgesic property. Its administration through epidural route has been shown to reduce the incidence and severity of post-operative pain in adults[7] and improved morbidity such as nausea, vomiting, fever and delayed oral intake, in children.[8]

Systemic administration of steroids suppresses tissue levels of bradykinin and the release of neuropeptides from nerve endings; it also inhibits synthesis of cyclooxygenase-2 in peripheral tissues and in the central nervous system resulting in a reduction in prostaglandin production which contribute to enhanced nociception in inflamed tissue.[9-11] Dexamethasone administration through intravenous (IV) route along with caudal block has been shown to significantly reduce severity of pain and rescue analgesic requirement in the post-operative period.[12]

The present study was aimed at comparing the effects of dexamethasone on the duration of first rescue analgesia when administered through IV or caudal route.

METHODS

The present prospective randomised double-blinded study was conducted after getting approval from hospital's ethical committee and informed/written parental consent. A total of 105 American Society of Anesthesiologists physical status I and II children, aged between 4 and 10 years, undergoing inguinal herniotomy were enrolled. Exclusion criteria exercised were children with contraindications to the caudal block such as allergy to local anaesthetic (LA) agents, coagulation disorders, pre-existing neurological disease, spine abnormalities or any infection at the local site.

During pre-operative visit, patient's age, weight and baseline vital parameters were recorded. Detailed history, general physical and systemic examinations were done. Routine laboratory investigations including haemoglobin level were carried out for all patients. All patients were kept fasting as per institutional protocol (2 h for clear liquid and 6 h for semi-solid and solid). Parents were taught to perform their role in the study and the use of visual analogue scale (VAS) for pain assessment.[13]

Computer randomisation with allocation concealment (sequentially numbered, opaque, sealed envelopes method) was carried out and all children were evenly assigned into three groups of equal numbers. A person not participating in the study kept the table of random numbers and prepared all medications. According to the weight, the volume to be injected was prepared in 1 mL syringes marked as IV test and caudal test.

On arrival of the patient to the operating room, all standard monitors were attached, and baseline heart rate [HR], mean arterial pressure (MAP) and oxygen saturation [SpO_2] were recorded by an investigator who was unaware of the group allocation. All patients were induced with sevoflurane 8% in oxygen and air (50/50) with spontaneous ventilation and IV line was secured with appropriate size cannula (22 and 24 gauge) and Ringer's lactate was started at the rate of 4 ml/kg/h. All the patients were premedicated with IV atropine 0.01 mg/Kg, IV midazolam 0.05 mg/Kg and IV fentanyl 1.5 μg/kg. An appropriate sized classic Laryngeal mask airway (cLMA) was inserted, and after insertion, sevoflurane concentration was reduced to 3% with fresh gas flow of 3–4 L/min. All the patients were placed in left lateral decubitus position, and under aseptic precautions, single-dose caudal block was performed using a 23-gauge short-bevelled hypodermic needle according to the group assigned.

Patients in Group I received caudal ropivacaine 0.15% (1.5 ml/kg) (ropivacaine hydrochloride ampoule, 0.75%, one ml diluted in 5 ml distilled water) along with caudal normal saline (NS) 0.025 ml/kg and NS 0.125 ml/kg, IV. Patients in group II received caudal ropivacaine 0.15% (1.5 ml/kg) with caudal dexamethasone 0.1 mg/Kg (0.025 ml/kg) and IV NS 0.125 ml/kg. Patients in Group III received caudal ropivacaine 0.15% (1.5 mL/kg) along with caudal NS 0.025 ml/kg and IV dexamethasone 0.5 mg/kg (maximum 10mg) (dexamethasone sodium phosphate vial 4mg/ml).

All the blocks were performed by the same anaesthesiologist throughout the study. The time of caudal block was recorded, and the surgery was allowed to start 10 min after caudal injection. Anaesthesia was maintained with sevoflurane in oxygen and air (50:50), and its concentration was adjusted to achieve haemodynamic changes within 20% of baseline value. No other, sedatives, and anti-emetics were used intraoperatively. Sevoflurane was discontinued at the beginning of skin closure, and during emergence from anaesthesia, LMA was removed, and the patient was transported to the post-anaesthesia care unit.

Vital parameters were recorded every 5 min till 30 min and every 15 min till the end of surgery. The maximum concentration of sevoflurane used was also recorded. Post-operative monitoring including vitals and pain (using VAS score) was recorded every hour till 3 h, every 3 h till 12 h and thereafter every 6 h till 24 h.

The primary outcome of this study i.e., the meantime to first rescue analgesic (time interval between a caudal block to the recording of VAS score ≥4) was recorded[14]. Rescue analgesia was provided with IV paracetamol (15 mg/kg). Secondary outcomes such as total doses of rescue analgesic and adverse effects such as post-operative nausea and vomiting, respiratory depression (fall in SpO_2 of <92% requiring supplementary O_2), urinary retention, hypotension (fall in the blood pressure >20% of the baseline value) and bradycardia (HR below 60 beats/min) were looked for and recorded. Incidence of bladder catheterisation, the initiation of clear liquid and time to discharge from hospital were also recorded.

We calculated that 35 patients in each group would be needed to detect an intergroup difference in the mean time to first rescue analgesic of at least 20% ($\alpha = 0.05$, ß = 0.2) based on previous study[15] demonstrating mean (standard deviation [SD]) time of 554.5 (114.6) min to first rescue analgesia in children who received caudal analgesia using 1.5 ml/kg of ropivacaine 0.15%. Based on the above study we assumed a prolongation of duration of analgesia by 20% using ropivacaine 0.15% 1.5ml/kg along with dexamethasone as an adjuvant, whose effect is to be assessed separately for caudal and IV route Summary data were tabulated and analysed using SPSS IBM software version 21 (IBM SPSS Advanced Statistics; Chicago, IL, USA). Results of the quantitative variables were represented as median (95% of confidence interval) or mean (SD), and results of categorical measurements were presented in numbers or ratio. Unpaired Student's *t*-test and analysis of variance using Bonferroni multiple comparisons' test were applied for comparing quantitative data, and Chi-square test was applied for qualitative data. Time to first analgesic administration was analysed by Kaplan–Meier survival analysis and log-rank test. The difference was considered significant if $P < 0.05$ was obtained.

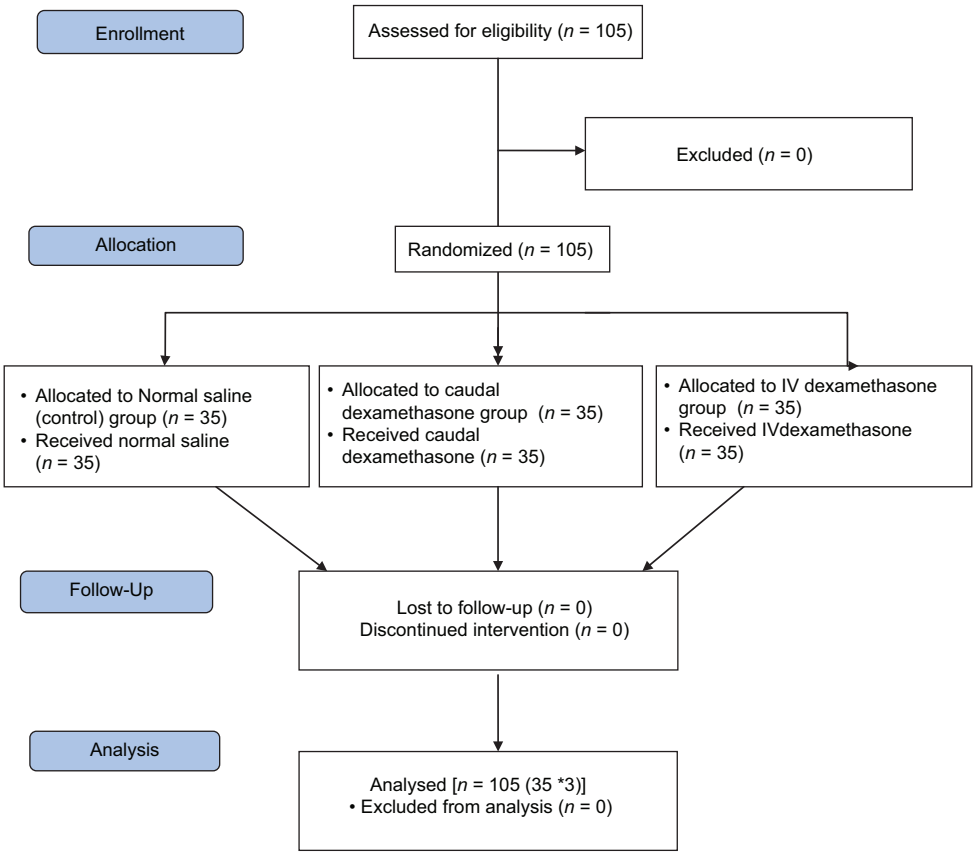

Figure 1: Consort flow chart of participants

RESULTS

All the patients screened were enrolled in the study [Figure 1]. All the groups of patients undergoing inguinal herniotomy were comparable regarding demographic profile, end-tidal sevoflurane concentration and duration of surgery ($P > 0.05$) [Table 1]. Failure of caudal block was not reported in any patient. The magnitude of haemodynamic (HR and MAP) changes between the groups was comparable [Figure 2], and therapeutic interventions were not required.

There was a significant difference between the groups in the VAS score measured 6 h after discharge from the PACU [Figure 3]. Group I patients achieved significantly higher VAS score compared with Groups II and III, where 54.29% of patients achieved a VAS score of >4 compared with 0% in Groups II and III [Figure 3]. The time to first rescue analgesia/duration of analgesia recorded as median (95% CI) was significantly longer in Group II 720.0 min (709.5–729.8 min) and Group III 620.0 (612.1–625.6 min) compared to Group I 220.0 min (210.4–239.2 min) ($P < 0.001$) [Table 2 and Figure 4]. Total rescue analgesic doses recorded as median (95% CI) were significantly more in Group I (2.0 [2.0–2.3]) compared to Group II (1.0 [0.9–1.1]) and Group III (1.0 [1.0–1.3]) ($P < 0.001$) [Table 2].

The incidence of nausea and vomiting was higher in group I (31.4%) compared to Group II and III (8.6%). There was no incidence of other complications such as hypotension, bradycardia and urinary retention between the groups. Clear fluids were initiated at early stage in Group II (5.94 ± 0.76 h) and Group III (6.17 ± 0.56 h) compared to Group I (7.11 ± 1.937 h) ($P < 0.001$) [Table 2]. The times of discharge of the patients were comparable between the groups [Table 2].

DISCUSSION

Several studies suggested that the addition of dexamethasone through caudal route[16] or IV route[12,17-19] as an adjuvant to RA significantly reduced the post-operative pain by prolonging the duration of analgesia with significantly lesser analgesic consumption. Our study results are in line with this, in which we demonstrated that the addition

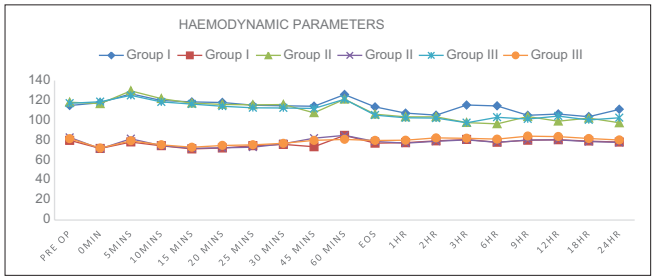

Figure 2: Comparison of haemodynamic parameters (heart rate in bpm and mean arterial pressure in mmHg in Y axis) among three groups over time (X axis)

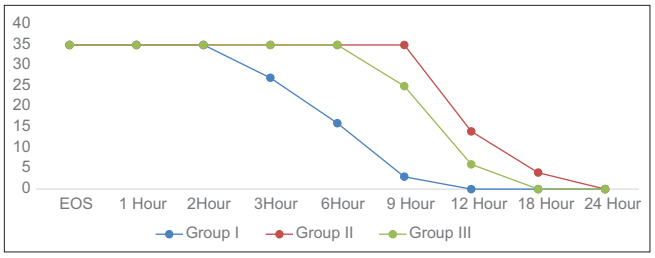

Figure 3: Number of patients having adequate caudal analgesia at different time interval in the post-operative period among three groups

Table 1: Comparison of demographic parameter, end-tidal sevoflurane and duration of surgery among three groups

Demographic parameter	Mean±SD			*P*
	Group I (*n*=35)	Group II (*n*=35)	Group III (*n*=35)	
Age (years)	3.7±2.0	3.6±2.1	4.2±2.1	
Weight (kg)	13.4±3.5	13.3±3.6	14.6±3.8	
Sex, male (%)	88.57	94.29	85.71	
End-tidal sevoflurane concentration (MAC)	3.3±0.3	3.2±0.2	3.3±0.4	0.111
Duration of surgery (min)	34.28±8.58	35.14±9.58	39±11.61	0.115

SD – Standard deviation; MAC – Minimum alveolar concentration

Table 2: Comparison of time to first rescue analgesia, total number of rescue analgesic consumption, initiation of clear liquid and time to discharge among three group

Parameters	Group I	Group II	Group III	*P*
Time to first rescue analgesia (median±95% CI) in min	220 (210.48-239.23)	720 (709.54-729.84)	620 (612.10-625.62)	<0.001*
Total number of rescue doses (median±95% CI)	2 (2.04-2.30)	1 (0.97-1.13)	1 (1.08-1.37)	<0.001*
Time to initiation of clear fluids (mean±SD) in h	7.1±1.9	5.9±0.7	6.1±0.5	0.001*
Time to discharge (median±95% CI) in days	1 (1.1-1.4)	1 (1.0-1.2)	1 (0.9-1.1)	0.95

*Significant value. CI – Confidence interval; SD – Standard deviation

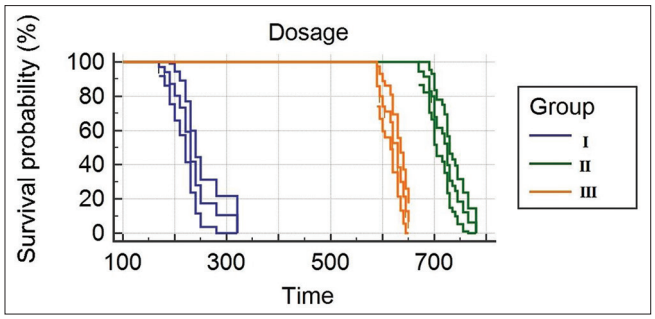

Figure 4: Kaplan–Meier survival curve for time to first rescue analgesic administration

of dexamethasone through caudal or IV route could significantly prolong the mean time to first rescue analgesic with the significant advantage of caudal over IV route in children undergoing inguinal hernia repair.

Various literatures support the analgesic effects of dexamethasone when administered as an adjuvant to RA for post-operative pain in adults and children.[16,20] Even the systemic administration of steroids has to be effective for reducing post-operative pain, but the results are inconclusive.[8,21-23]

As for all additives in RA, the true question is to compare the potential local effects to a systemic administration, particularly when additives were used off-label. Lack of control group with IV dexamethasone did not allow researcher of previous studies to comment on the potential local effect of dexamethasone. Hence, to study the local effects of dexamethasone as a caudal adjuvant in detail, we included group with IV dexamethasone.

Hong JY *et al*. [12, 15] demonstrated that a single dose of i.v. dexamethasone (0.5 mg/kg) in combination with a larger volume (1.5 ml kg) of diluted ropivacaine 0.15% prolongs analgesic duration, reduces postoperative pain, decreases rescue analgesic requirements compared with a caudal block alone. Similarly Yousef GT *et al*.[16] found that addition of either magnesium sulphate (50mg) or dexamethasone (0.1mg/kg) to 0.15% caudal ropivacaine significantly prolonged the duration of analgesia with reduced analgesic consumption. Based on the above studies we used 0.15% ropivacaine along with dexamethasone IV (0.5mg/kg) or caudal route (0.1mg/kg) according to group allocation.

The mechanism of the analgesia induced by corticosteroids is not fully understood. However, this effect is suspected to be mediated by their anti-inflammatory or immunosuppressive effects.[24,25] Adjuvants such as epinephrine produce prolongation of RA by its vasoconstrictive property, but this is not responsible for block prolongation by dexamethasone because of its relatively rapid effect.[26] Corticosteroids may have a local effect on the nerve, and the dexamethasone effect may be related to this action. Some authors believe that analgesic properties of corticosteroids are the result of their systemic effect.[27]

The antiemetic property of dexamethasone is well known through direct central action at the tract nucleus, interaction with the neurotransmitter serotonin and receptor proteins tachykinin NK1 and NK2, alpha-adrenaline, etc.[28] Results of our studies are in line with this, we found that the incidence of nausea/vomiting was comparatively low in group receiving dexamethasone 8.6% (3/35) than control group 31.4% (11/35). It is advisable to use, therefore, prophylactic antiemetics to all patients administered caudal epidural with local anaesthetics alone. Other studies[12,16] found no difference in the incidence of nausea and vomiting when dexamethasone was used as an adjuvant to caudal block.

Adverse effects with a single dose of dexamethasone are probably extremely rare and minor in nature, and previous studies[12,16] have demonstrated that short-term use of dexamethasone was safe.[29] Similarly, in our studies, there were no incidences of systemic complications such as hypotension, bradycardia and urinary retention or local complications such as neurotoxicity, respiratory depression and pruritus, postoperatively when dexamethasone was given intravenously or caudally along with ropivacaine.

In children with limited understanding and communication skills, reliable assessment of pain is challenging and assessments made by their parents are often used as a proxy measure. The paediatric pain assessment tools are based on either self-report or observation of behaviour. Self-report is the only truly direct measure of pain, and hence it is considered the 'gold standard' of measurement. We used visual analogue scale (VAS) for assessing the post-operative pain because of its ease to perform and simplicity to teach parents and nurses; in addition, all observer-rated scales, except the simple VAS, are likely to require raters to be trained in their use. Although pain cannot be necessarily quantified based on parents' report as VAS is subject to bias, there is

a lack of sufficient literature to prove this pitfall and hence VAS was preferred.

The main limitation of our study is that motor block could not be evaluated as it is unlikely at the 0.15% concentration of ropivacaine we used. Although we used VAS as a pain assessment tool, the use of Faces Pain Scale-Revised would have been more appropriate. Moreover, we looked for immediate local complications of dexamethasone, but the delayed local complications could not be ruled out.

Several studies tried to investigate the analgesic effect of dexamethasone as an adjuvant to RA.[12,18,19] In line with this, our study is able to demonstrate the use of dexamethasone either caudally or intravenously as an adjuvant to caudal block could be a superior alternative to LA alone. Although dexamethasone is a safe drug with minimum side effects,[16,17] there is a need for further multicentric RCT to confirm the findings of our study. So that dexamethasone can become adjuvant of choice in paediatric caudal block.

CONCLUSION

We conclude that the addition of dexamethasone either caudally or intravenously as an adjuvant to caudal 0.15% ropivacaine may significantly prolong the mean time to first rescue analgesic with the significant advantage of caudal over IV route in children undergoing inguinal hernia repair. In addition to this, dexamethasone can be considered as a safe adjuvant to caudal block with no potential side effects.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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Announcement

Conference Calender - 2016

Name of Conference: 37th Annual Conference of ISA West Bengal State Branch, ISACON WEST BENGAL 2016
Date: 16th to 18th Dec 2016
Organizing Secretary: Dr Subhendu Sarkar
Mobile: 09831171162
E mail: subhendusarkar757@gmail.com
Website: www.isawb.in

Name of Conference: 29th Annual Conference of ISA Assam State Chapter, ISACON Assam 2017 (ABISACON 2017)
Date: 21st to 22nd Jan.2017
Preconference Workshop: 20th Jan. 2017
Venue: Alumni Hall, Silchar Medical College Silchar, Cachar, Assam
Org. President: Dr A K Laha
Org. Secretary: Dr.Abhijit Das
Mobile: 9401000010
E mail: adasdr14@gmail.com

Name of the Conference: 3rd ISACON TELANGANA 2017
Date: 28th to 30th July 2017
Venue: Prathima Medical College, Karimnagar
Org Chairman: Dr. Raja Reddy
Organizing Secretary: Dr. I. Rathnakar
Mobile No. : +919849059955
Email: rinjamuri@hotmail.com
Website : www.isatelangana.org

Name of the Conference: 33rd Annual Conference of the Indian Society of Anaesthesiologists, Karnataka State (ISACON Karnataka 2017)
Date: 11th to 13th August 2017
Preconference workshop: 10th August 2017
Venue: Vijayanagar Institute of Medical Sciences (VIMS), Ballari
Organizing Chairman: Dr D Srinivasalu
Organizing Secretary: Dr. S Bala Bhaskar
Mobile No.: +91 98800 12349
Email: sbalabhaskar@gmail.com
Website: www.isakarnataka.in

Name of the Conference: 18th Annual Conference of Indian Society of Neuro Anesthesiology and Critical Care (ISNACC 2017)
Date: 24th- 26th February 2017
Venue: Post Graduate Institute of Medical Education And Research (PGIMER) Chandigarh
Org Secretary: Dr Nidhi Panda
Email: isnacc2017@gmail.com

Name of Conference: 7th National Conference of Academy of Regional Anaesthesia of India
Date: 8th and 9th Sep. 2017
Workshops: 10th Sep.2017
Venue: Brilliant Convention Centre, Indore
Org. Chairman: K K Arora
Org. Secretary: Dr Javed Khan
Mobile: 9826955065
E mail: javed1964khan@gmail.com, secretaryaora2017@gmail.com
Website: www.aora2017.com

Name of Conference: Combined 12th Congress of SAARC AA and the 33rd Annual Academic Congress of the College of Anaesthesiologists and Intensivists of Sri Lanka (SAARC AA Congress)
Dates: Feb. 24 to 26, 2017
Venue / Place: Colombo, Srilanka

Name of the Conference: 14th International Conference of Asian Society of Paediatric Anaesthesiologists" (ASPA 2017)
Date: 3rd & 4th June 2017
Preconference workshops: 2nd June (Surya Children Hospital, Mumbai)
Venue: Grand Hyatt, Mumbai, India
Org.Secretary: Dr Vrushali Ponde
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Website: www.aspa2017.com