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The Effect of Inj. Dexmedetomidine Infusion in Cochlear Implant Surgery among Pediatric Patients

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Abstract

We have done our study with Dexmedetomidine infusion for 1 to 7 years old patients undergoing Cochlear implant surgery and observed for intra operative and post-operative hemodynamics, VAS Score, Modified Aldrete Score, Objective Pain Score, Pediatric Anesthesia Emergence Delirium Scale and Complications.Dexmedetomidine provides controlled hypotension, better surgical field and higher surgeon's satisfaction score leading to reduced surgery time.

Keywords: Dexmedetomidine Infusion, Cochlear Implant Surgery, Pediatric, Hypotensive Anesthesia.

Introduction

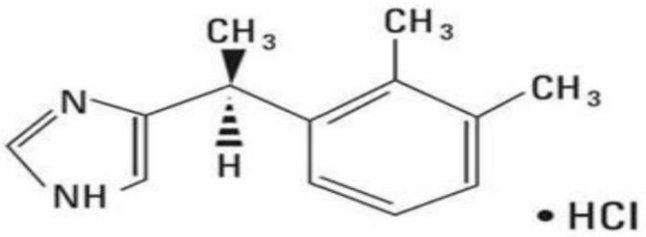
Cochlear implantation surgery is the one which is performed in paediatric patient of 1 to 7 years of age with congenital deafmutism at a rural tertiary care center. It is being performed since 5th September 2014 till now with government support without any mortality and morbidity. Good results in this surgery are obtained by providing bloodless surgical field with controlled hypotension and postoperative smooth outcome. To anaesthetize these patients, we are using Inj Propofol, Inj fentanyl,

Sevoflurane/isoflurane, Dexmedetomidine infusion and muscle relaxants. Dexmedetomidine is an active isomer of medetomidine and an agonist at α2 –adreno receptors. Medetomidine provides perioperative sedation and analgesia thus decreasing other general anaesthetic drug requirement, reduced postoperative pain score, postoperative delirium and other complications.

Dexmedetomidine

Dexmedetomidine is a stereoisomer of medetomidine, with chemical formula 4-[(1S)1-(2, 3-dimethylphenyl) ethyl]-1H-imidazole. Molecular weight of 236.7 and empirical formula is C13H16N2.HCl. It is a highly selective α2-adrenergic receptor agonist with a relatively high ratio of α2/ α1-activity.

Chemical structure



Pharmacokinetics

Dexmedetomidine hydrochloride is a white or almost white powder that is freely soluble in water and has pKa of 7.1. Its partition coefficient in- octanol: water at pH 7.4 is 2.89. It is a colorless, isotonic solution with pH of 4.5 to 7.0.

Pka 7.1

Protein binding 94%

Rapid distribution half- life 6 min

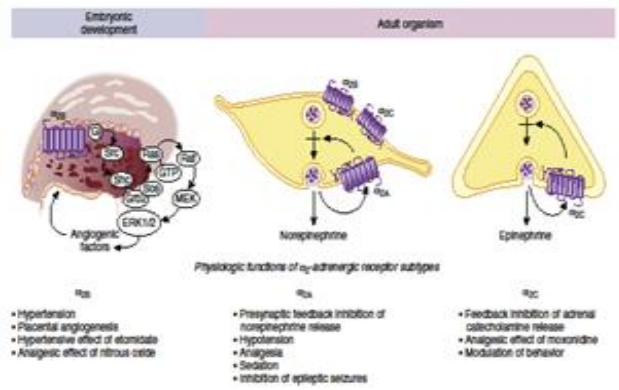
Terminal elimination half-life 2 hours

Volume of distribution 118 lts

Clearance 6 lt/hr

The solution is preservative-free and contains no additives or chemical stabilizers.

Dexmedetomidine undergoes almost complete hydroxylation through direct glucoronidation and cytochrome P450 metabolism in liver. Metabolites are excreted in the urine (about 95%) and feces (4%). The elimination half-life is approximately two hours. The average protein binding is 94%.



Uses

- Sedation of mechanically ventilated patients in ICU settings.
- Dexmedetomidine possesses anxiolytic, sedative, analgesic, anti-sialagogue and sympatholytic properties, which render it suitable as premedication agent.
- Adjunct to local anaesthetics for prolongation of effect.
- For procedural sedation in non-intubated patients.
- Used in monitored anaesthesia care (MAC) or as a sole agent for total intravenous anaesthesia (TIVA).

Advantage

- Minimal respiratory depression
- Cardioprotective.
- Reno-protective.
- Cerebro-protective.

Adverse effects

1. Reduces heart rate and blood pressure
2. Dry mouth.
3. Diuresis.
4. Nausea and Vomiting.
5. Irregular heart rate.
6. Potentiates effects of opioids, sedatives and anaesthetics.

Aims and objectives

1. To determine that inj. Dexmedetomidine infusion is a suitable agent for hypotensive anaesthesia in cochlear implant surgery.
2. To determine that Inj. Dexmedetomidine infusion is a suitable drug to stabilize intraoperative hemodynamics.
3. To find out post-operative outcome in pediatric patient after intraoperative Inj. Dexmedetomidine infusion.

Material & Methods

This study is going to be conducted at rural tertiary care center, which will include total 60 samples of pediatric patients (1-7 years of age group) who were undergone through cochlear implant surgeries in last 3 years. The data regarding these patients were collected from ENT department and Anaesthesia department which includes the effects of bolus dose of dexmedetomidine for quality of hypotensive anaesthesia with hemodynamic stability, other general anaesthetic drug requirements intra operatively ,post-operative pain score and incidence of postoperative complications in paediatric age group particularly emergence delirium with sevoflurane.

Patients were given premedication with inj Ondensatron 100mcg/kg and InjGlycopyrrolate 4 mcg/kg &inj. Midazolam 0.5 mg. In induction , inj Propofol 2 mg/kg , Fentanyl 2mcg/kg and Scholine 1.5mg/kg were given. Intubation done with appropriate sized cuffed ET tube.

Total dose of injDexmedetomidine infusion(solution of 4mcg/ml made by adding 200mcg of Dexmedetomidine in 48ml of 0.9% Nacl) 1mcg/kg i.v in 10 min. followed by Dexmedetomidine infusion 0.5 mcg/kg/hr in maintenance. For maintenance, O2, N2O, Sevoflurane and in muscle relaxation, Atracurium (induction with 0.5mg/kg and maintenance with 0.1 mg/kg) were given. Patients received intra operative fluids according to 4-2-1 formula. InjDexmedetomidine infusion was stopped before reversal. Reversal was done with InjMyopyrolate (Glycopyrrolate 8mcg/kg and Neostigmine 30-70mcg/kg). Extubation was done when patient started breathing spontaneously with adequate muscle power tone. Diclofenac suppository was given for post-operative analgesia. Data regarding intra operative monitoring of heart rate, non-invasive blood pressure (both systolic and diastolic), SPO2 done. Post-operative pain score and post-operative delirium emergence will be studied.

In the PACU modified Aldrete or agitation using Pediatric Anesthesia Emergence score, OPS and PAED score immediately on arrival, Delirium (PAED) scoring system at 30, 60, 90 and 120 min after extubation were recorded. Any episodes of shivering, PONV, hypotension, bradycardia or other complication were recorded.

The patients were randomly assigned into 2 groups:

Group D: patients who were started on intravenous infusion of Dexmedetomidine 1mcg/kg for 10min followed by 0.5mcg/kg/hr.

Group P: patients who were given Normal saline infusion as a placebo 100 ml for 10 min. followed by 2ml/hr.

Place of study: Department of ENT and Anaesthesiology and PSM, C U shah medical Collage and hospital, Surendranagar.

Inclusion criteria: Patients of ASA grade I or II with congenital or acquired deafness.

Exclusion Criteria

- Children with cardiac anomalies
- Children on drugs for any chronic ailment.
- Severe milestone delay

Statistical Analysis: Descriptive and qualitative Analysis will be done by using SPSS statistical software.

Review of literature

Inj Dexmedetomidine was approved in 1999 by the US Food and Drug Administration (FDA) as a short-term sedative and analgesic for critically ill or injured people on mechanical ventilation in the intensive care unit. In 2008, FDA expanded its indication to include non-

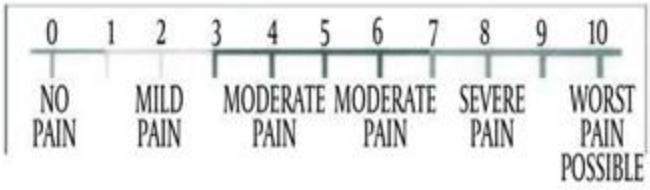
intubated people requiring sedation for surgical or non-surgical procedures, such as colonoscopy.

Afonso J1, Reis F concluded in his study that Dexmedetomidine offers a unique ability of providing both sedation and analgesia without respiratory depression.

Gurbet A2, Basagan-Mogol E, Turker G, Ugun F,

Kaya FN, Ozcan B concluded in his study that Continuous iv dexmedetomidine during abdominal surgery provides effective postoperative analgesia, and reduces postoperative morphine requirements without increasing the incidence of side effects. Patel A3, Davidson M, Tran MC, Quraishi H, Schoenberg C, Sant M, Lin A, Sun X. concluded in his study that. Postoperative opioid requirements were significantly reduced, and the incidence and duration of severe emergence agitation was lower with fewer patients having desaturation episodes.

Visual Analogue scale (VAS)



Modified Aldrete Score

Parameter	Description of patient	Score
Activity level	Moves all extremities voluntarily/on command	2
	Moves 2 extremities	1
	Cannot move extremities	0
Respirations	Breathes deeply and coughs freely	2
	Is dyspneic, with shallow, limited breathing	1
	Is apneic	0
Circulation (blood pressure)	Is 20 mm Hg > preanesthetic level	2
	Is 20 to 50 mm Hg > preanesthetic level	1
	Is 50 mm Hg > preanesthetic level	0
Consciousness	Is fully awake	2
	Is arousable on calling	1
	Is not responding	0
Oxygen saturation as determined by pulse oximetry	Has level >90% when breathing room air	2
	Requires supplemental oxygen to maintain level >90%	1
	Has level <90% with oxygen supplementation	0

Maximum total score is 10; a score of ≥9 is required for discharge.

Objective Pain Score (OPS) for Post-operative Pain Assessment

Pain Scale Item	Score
Blood pressure*	
10% Higher	0
10%-20% Higher	1
20%-30% Higher	2
Crying	
Not crying	0
Crying, but respond to comforting	1
Crying, no response to comforting	2
Moving	
None	0
Restless	1
Thrashing	2
Agitation	
Asleep or calm	0
Mild	1
Hysterical	2
Verbal	
Asleep or state no pain	0
Mild pain (cannot localize)	1
Moderate pain (can localize)	2

*Compared with preoperative blood pressure.

Pediatric Anesthesia Emergence Delirium Scale (PAED)

Behavior	Not at all	Just a little	Quite a bit	Very much	Extremely
The child makes eye contact with the caregiver	4	3	2	1	0
The child's actions are purposeful	4	3	2	1	0
The child is aware of his/her surroundings	4	3	2	1	0
The child is restless	0	1	2	3	4
The child is inconsolable	0	1	2	3	4

Comparison of demographic profile and baseline variables expressed as mean ± standard deviation.

Variable	Group D(n=30)	Group P(n=30)	P-value
Age (in years)	3.18 ± 0.72	3.22 ± 0.86	0.55
Sex (M:F)	16:14	15:15	0.76
Weight (kg)	12.96 ± 1.88	13.39 ± 1.68	0.95
Fentanyl consumption	40.81 ± 7.34	58.12 ± 7.27	0.02
propofol consumption	24.68 ± 6.34	42.24 ± 6.22	0.01
heart rate (beats/min)	121.5 ± 3.38	120.94 ± 3.99	0.65
MAP(mmHg)	75.88 ± 2.87	76.44 ± 1.75	0.35
Duration of surgery	112 ± 0.27	130 ± 4.95	0.00

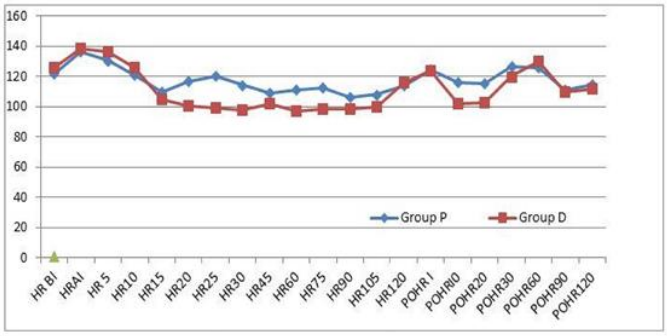
Group D, Dexmedetomidine group; Group P, placebo group. Data is expressed as Mean ±SD. P values calculated using Student's t-test and $p<0.05$ is shown in bold.

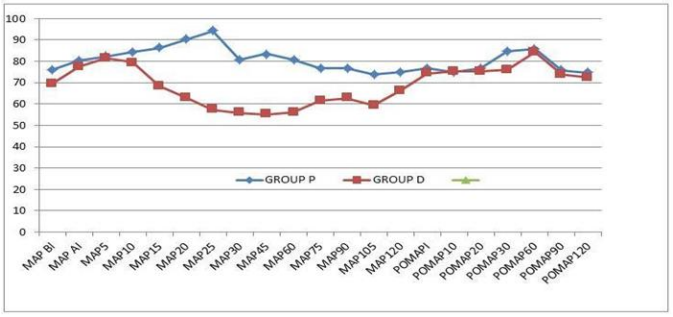
Comparison of surgical score (SS), objective pain score (OPS), emergence agitation score (EAS) and Aldrete Score (AS) at various times interval.

Parameter	Group D (n=30)	Group P (n=30)	P-value
SS at 15 min	1.25 ±0.45	1.94 ±0.25	0.00
SS at 30 min	1.62 ±0.50	2.06 ±0.57	0.02
SS at 45 min	1.72 ±0.34	2.87 ±0.34	0.30
SS at 60 min	2.10 ±0.42	3.26 ±0.44	0.01
SS at 75 min	1.31 ±0.61	2.87 ±0.50	0.03
SS at 90 min	1.84 ±0.57	1.87 ±0.52	0.50
SS at 105 min	1.26 ±0.51	1.25 ±0.45	0.63
OPS on arrival	4.2 ±0.7	7.9 ±0.3	0.01
OPS at 30 min	2.0 ±0.3	5.4 ±0.8	0.03
OPS at 60 min	2.4 ±0.6	4.9 ±0.6	0.01
OPS at 90 min	6.2 ±0.9	6.7 ±0.9	0.78
OPS at 120 min	2.4 ±0.6	2.1 ±0.6	0.54
PAED on arrival	7.1 ±0.3	13.4 ±0.7	0.00
PAED at 30 min	10.6 ±0.4	16.6 ±0.8	0.01
PAED at 60 min	8 ±0.2	14.8 ±0.4	0.00
PAED at 90 min	13.9 ±0.4	14.6 ±0.2	0.56
PAED at 120 min	5.0 ±0.5	8.3 ±0.6	0.66

Incidence of complications [n]

Complication	Group D	Group P
Shivering	2	6
PONV	1	8
Hypotension	1	1
Bradycardia	5	2
Emergence agitation (PAED Score >16)	1	12
Dry mouth	5	2





Limitations

The limitation of our study was that the monitoring of quality of the surgical field visualization was done with a subjective scoring system and we depended upon the assessment by the operating surgeon for this. Further, we did not use laser Doppler flowery to evaluate blood supply to the implant site that would have added to the authenticity of the observation in a measurable method.

Conclusion

The main findings of our study are:

Intraoperative dexmedetomidine provides controlled hypotension, better surgical field and higher surgeon's satisfaction score leading to reduced surgery time. Dexmedetomidine significantly reduces consumption of propofol and fentanyl to achieve hemodynamic stability. Compared to placebo, dexmedetomidine provides better recovery profile and lower incidence of postoperative complications like emergence agitation, postoperative pain and nausea/vomiting.

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