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TO COMPARE AND EVALUATE THE EFFECTIVENESS & SAFETY OF IV DEXMEDETOMIDINE AND IV DEXMEDETOMIDINE ALONG WITH EITHER FENTANYL OR BUTORPHANOL FOR MONITORED ANAESTHESIA CARE IN MICROSCOPIC MIDDLE EAR SURGERIES UNDER LOCAL ANAESTHESIA

Anaesthesiology

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ABSTRACT

Background: This study was designed to evaluate the comparative effectiveness and safety of dexmedetomidine and dexmedetomidine with Butorphanol or Fentanyl for sedation, analgesia, blood less surgical field, patients and surgeons satisfaction in patients undergoing middle ear surgery (MES) under local anaesthesia with Monitored Anaesthesia Care (MAC).

Material & Methods: 90 patients aged 12 to 50 years, ASA class I and II undergoing elective microscopic MES under Local Anaesthesia with MAC were randomized into three groups (n=30). All groups received inj. Dexmedetomidine 1µg.kg^{-1} in 100 ml NS as loading dose over 10 minutes and then 0.5 µg/kg/hr as infusion. In group D NS 10ml, group DF inj. Fentanyl 1µg.kg,$^{-1}$ in NS and in group DB inj.Butarphanol 1mg.kg^{-1} in NS was given after Dexmedetomidine bolus.

Results: Ramsay sedation score (RSS) remained higher in group DB and the VAS score remained at lower scale in group DB & group DF . Group DB patients required minimum rescue analgesia. Patients and surgeons were more satisfied in group DB.

Conclusion: We concluded that dexmedetomidine and butorphanol combination is better for intraoperative sedation, analgesia, patient comfort and surgeon satisfaction with bloodless surgical field.

KEYWORDS

Monitored Anaesthesia Care, Dexmedetomidine, Butorphanol, Fentanyl

Introduction:

MES (tympanoplasty and mastoidectomy) being performed under local anaesthesia owing of various advantages such as less surgical bleeding, feasibility to test hearing and facial nerve integrity during surgery, increase cost effectiveness & rapid recovery.[1]

Patient may feel discomfort due to pain, noisy suction, drilling, manipulation of instruments and frequent positioning of head & neck. Sympathetic stimulation in a restless patient may result in tachycardia and hypertention that leads to increase bleeding in the surgical field. Surgeons also worried of sudden head movement while performing crucial operative steps.

MAC is a planned procedure in which surgery is performed under local anaesthesia with parenteral drugs for adequate sedation and analgesia.[2] Safe sedation, anxiolysis & analgesia are the basis of conscious sedation during MAC.

MAC is preferably chosen for microscopic ENT surgeries where adequate sedation and analgesia without respiratory depression are desirable for the comfort of both patient and surgeon.[3] A bloodless surgical field is essential for better visibility and to minimize complications in microscopic surgery.

Dexmedetomidine is a highly selective α2-adrenoceptor agonist. It provides excellent sedation and analgesia with minimal respiratory depression.

Dexmedetomidine is considered a sedoanalgesic drug of choice for MAC[4] because of its short half-life, easy titration via intravenous infusion and rapid recovery without hangover effects. However, rescue analgesic doses are still required if it is used as a sole agent in surgery conducted under MAC. So we planned to add adjuvant like butorphanol tartarate and fentanyl citrate.

Butorphanol is an opioid agonist antagonist analgesic. It stimulates µ receptors in CNS & leads to hyperpolarization of cell membrane potential and suppresses transmission of ascending pain pathway.

Fentanyl is a potent, synthetic opioid analgesic with rapid onset and short duration of action and a strong agonist at the µ opioid receptor. It inhibits pain neurotransmitter release by decreasing intracellular calcium ions.

This study was designed to evaluate the comparative effectiveness and safety of dexmedetomidine alone and dexmedetomidine with Butorphanol or Fentanyl for sedation, analgesia, blood less surgical field as primary objective and hemodynamic stability, respiratory effects, patients and surgeons satisfaction as secondary objective in patients undergoing MES under MAC.

Method:

After approval from institutional ethical committee and written informed consent from the patients , 90 ASA class I & II patients , aged 12-50 yr of either sex who were planned for MES under LA with MAC were enrolled in this hospital based prospective double blind study conducted in year 2016 - 2017.

All the patients underwent preanaesthetic evaluation a day before surgery and were counseled with regard to sedation, local anaethesia and operative procedure. Visual Analogue Scale (VAS 0-10) was explained to patient.

Patients with preexisting co-morbidities, coagulation disorders, hypersensitivity to drug, pregnant and lactating women and patient with history of hypnosedatives were excluded from the study.

Patients were randomly selected and divided into three groups by Chit & Box method (n =30).

On the day of surgery after confirmation of fasting status patients were shifted to OT and multipara monitors were attached. Baseline SBP, DBP, SpO_2, Pulse Rate (PR) were recorded (T0). I.V. line was accessed with two 20G cannula and ringer lactate solution was started @ 2ml/kg/hr.

Inj. Glycopyrrolate 0.04mg.kg^{-1} and Inj. ondansetron 0.1mg.kg^{-1} were given as premedication in all patients. All three groups received inj. Dexmedetomidine 1µg.kg^{-1} in 100 ml Normal Saline (NS) over 10mins as loading dose followed by 10 ml NS in Group D, inj. Fentanyl 1µg.kg^{-1} diluted upto 10 ml in NS in Group DF and inj. Butorphanol 0.02mg.kg^{-1} diluted upto 10 ml in NS in Group DB. After that inj.

Dexmedetomidine 0.5µg/kg/hr was started in all patients and continued till the skin closure.

Once the patient achieve Ramsay Sedation Score (RSS) of 3, the surgeon was allowed for local anaesthetic infiltration 2% lignocaine with adrenaline [(1:2,00,000), (6-7 ml/kg)]. Patient's response to needle prick was evaluated by body movement and VAS score. Intra operatively if RSS <3 and patient felt pain inj fentanyl 1 mcg/kg was given as a rescue analgesic. All patients were given O_2 through nasal prongs @ 3L/min.

After completion of surgery all patients were shifted to PACU and observed for 2 hours.

Adverse effect like tachy/bradycardia, hyper/hypotension (deviation of PR, MAP 20% from baseline), bradypnea (RR <8 breath/min), desaturation (SpO_2 <90%), nausea, vomiting, dry mouth or any other event during and two hours after the procedure were noted.

Efficacy of technique was defined as the ability to complete the surgery without any rescue sedatives and analgesics. Safety of the technique was determined by analgesia/sedation related adverse events.

Vital parameter recorded at following time interval

T0	Preoperatively
T1	After loading dose
T2	After injection of local anaesthetic
T3	After skin incision
T4-Tx	Every 15 minutes till end of surgery

Visual Analogue Scale VAS (0-10)

- No pain
- 1 – 3 Mild pain
- 4 – 6 Moderate pain
- 7 – 9 Severe pain
- 10 – Worst pain

Ramsay sedation score

1	Anxious, agitated or restless
2	Cooperative, oriented and tranquil
3	Asleep, respond to command
4	Asleep but has a brisk response to light glabellar tap or loud auditory stimulus
5	Asleep has a sluggish response to a light glabellar tap or loud auditory stimulus
6	Asleep without response

Boezaart grading scale for scoring of surgical field bleeding

0	**No bleeding**
1	Slight bleeding, no suctioning of blood required
2	Slight bleeding, occasional suctioning required, surgical field not threatened
3	Slight bleeding, frequent suctioning required, bleeding threatened surgical field a few seconds after suction removed
4	Moderate bleeding, frequent suctioning required, bleeding threatened surgical field directly after suction was removed
5	Severe bleeding-constant suctioning required. Bleeding appear faster than can be removed by suction: surgical field severely threatened and surgery usually not possible.

Likert scale (for surgeon satisfaction)

1	Extremely dissatisfied
2	Dissatisfied
3	Somewhat dissatisfied
4	Undecided
5	Somewhat satisfied
6	Satisfied
7	Extremely satisfied

Results:

Patient's demographic data were comparable among the 3 groups. Mean PR(figure 1) and MAP (figure 2) showed a significant decrease from baseline in group DB as compare to group DF & D from 20min after administration of study drug till the end of sugery. Mean SpO_2 was comparable and within normal limits in all 3 groups.

All patients reached RSS of 3 within 10 minutes of administration of study drug. None of the patient required additional supplementation of sedation at that time. Mean RSS was significantly higher in group DB throughtout the procedure as compared to group DF and group D (figure 3).

VAS was decreased in all 3 groups 10min after Dexmedetomidine bolus. Group DB had significant lower scale (1-2) as compared to group DF (2-3) & group D (3-4) (figure 4).

Intra operatively 4 patients (13%) required rescue analgesia in group DB compared to 9 (30%) in group DF and 16 (54%) in group D.

Intra operative bleeding score was statistically insignificant (p value > 0.05). Maximum patients were in grade I and II in all groups. Surgeons were more satisfied with score of 6-7 i.e. excellent in Group DB (60%), in Group DF (40%) & in Group D (20%) which was statistically significant (p value < 0.05).

Post operative analgesia was required after 30 min in group D, after 1 hr in group DF and after 2 hr in group DB.

Bradycardia was seen in 2 patients in Group D and DF and 3 patients in group DB. It was treated with 0.6mg iv atropine. Dry mouth was seen in 1 patient in group D and group DB and in 2 patients in group DF.

Discussion:

MES commonly performed under LA even though LA effectively reduces pain, there is considerable amount of discomfort and anxiety associated with procedure.

Sympathetic stimulation and movement of an anxious patient result in increase bleeding and disturbs the fine microscopic nature of surgery and may even lead to graft failure. Proper patient selection, preoperative counselling about the procedure and use of appropriate sedative and analgesic are important for the success of surgery under LA. A tranquil, peaceful patient with bloodless surgical field hastens the procedure. Therefore MAC has become the common practice in microscopic surgeries.

The reason for choosing dexmedetomidine is that it has sedative, hypnotic, anxiolytic property with hemodynamic stability and minimum respiratory depression. Literature suggests that combining a sedative with an opioid provide effective moderate sedation.

We choose a loading dose of dexmedetomidine $1\mu g.kg^{-1}$ based on previous literature and because of its short distribution half life (5-6 min) it was given as maintenance infusion @ 0.5µg /kg/min. Decreased in Mean PR and MAP from baseline & subsequently maintained at significant lower level in group BD might be attributed to the sympatholytic, vagotonic and baroreflex sensitivity reducing effect of dexmedetomidine along with butorphanol which also cause small reduction in SBP & PR.

Our results correlate with the study conducted by Kewalramani et al (2016)[5] who found that Mean PR and MAP were significantly decrease from base line value in group BD as compare to group D.

The mean sedation score was found to be higher in group DB throughout the intraoperative period as compared to other two. Our results are consistent with Verma et al (2014)[6] & Kewalramani et al (2016)[5]. Mohamed et al (2013)[7] also found that the combination of dexmedetomidine/nalbuphine is a better alternative to midazolam/ nalbuphine in MAC since it provides analgesia, amnesia and sedation with better intraoperative and postoperative patient satisfaction and better surgical field exposure.

The sedation and analgesic property of dexmedetomidine is attributed to stimulation of α2 receptor in locus coruleus in brain and modulation of transmission of nociceptive in CNS and at spinal level. Butorphanol besides analgesia also leads to mild sedation so combination had increased sedation in the patients.

The mean VAS decreased in all the 3 groups after Dexmedetomidine loading infusion but this decrease was more profound in group DB. Similar results were found with Upendranath I et al (2016)[8]& Kewalramani et al (2016)[5].

Gupta K. et al (2015)[9] also found that patients receiving dexmedetomidine infusion had statistically significant lesser bleeding at surgical field ($P < 0.05$) surgeon satisfaction score were significantly better with dexmedetomidine butorphanol combination as it provides bloodless surgical field along with calm and co-operative patient. Kewalramani et al (2016)[5] observed that the patient and surgeon satisfaction scores were significantly higher in group BD vs group D ($p<0.001$). Fazilet Sahin et al (2011)[10] conflict our results with no difference in the amount of bleeding, surgical view and surgeon satisfaction between dexmedetomidine and alfentanil.

Vikas Kuma et al (2015)[11] found one patient in Group D had significant bradycardia with hypotension and Parikh et al (2013)[12] observed 7 patients in group D had dry mouth vs. none in group MF (p value=0.006) which were consisted with our results.

Conclusion:

We concluded that dexmedetomidine and butorphanol combination is better in terms of perioperative analgesia, sedation, patient and surgeon satisfaction with bloodless surgical field and better haemodynamic stability as compared to dexmedetomidine alone and dexmedetomidine with fentanyl.

Limitations:

1) In our study, we observed sedation only by RSS because of unavailability of the Bispectral index.
2) The effect of dexmedetomidine on the cardiovascular system may be beneficial in high risk cardiac patients for which further studies to be carried out on cardiac patient.
3) The limited sample size in our study was mostly due to surgeon preference to general anaesthesia for middle ear surgery.

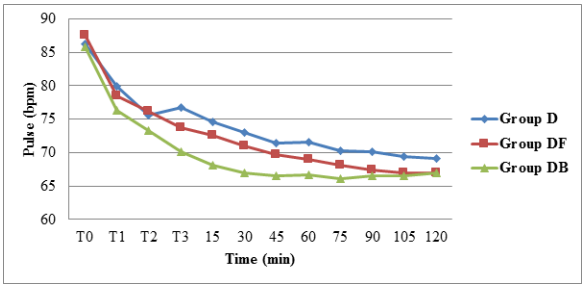

Figure 1: Comparison of intraoperative mean pulse rate among three groups

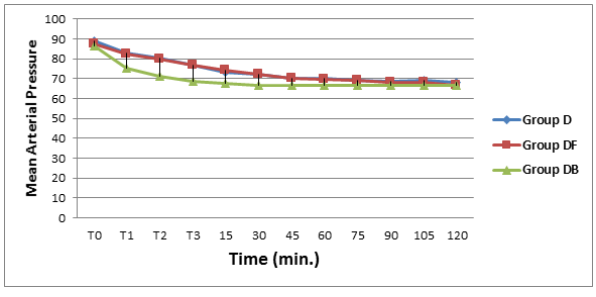

Figure. 2: Comparison of Mean MAP among three groups

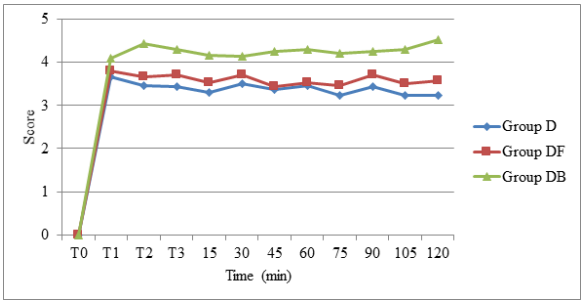

Figure 3: Comparison of Sedation score in three groups at various specified timings

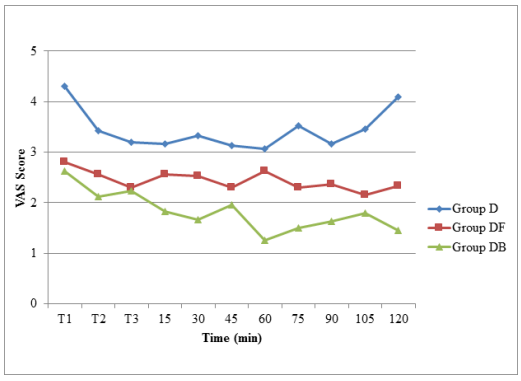

Figure 4: comparison of VAS among three groups

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