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Comparative Study of Dexmedetomidine with Pethidine for Assessment of Intraoperative Sedation during Mastoid Surgery

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Abstract: ***ENT surgeries like mastoid surgeries are superficial, less invasive and can be done under local anaesthesia or local anaesthesia with sedation in co operative and well counseled patients. Local anaesthesia is cost effective but better preoperative counseling is needed and at times may cause patient discomfort if it is used as sole technique. Therefore MAC is an attractive option as it invokes less physiological disturbance, allow a more rapid recovery than general anaesthesia and cost effective. This study was conducted to compare level of sedation, degree of analgesia, haemodynamic changes, respiratory changes, intraoperative and postoperative side effects of dexmedetomidine with pethidine.***

Keywords: Mastoid surgery, monitored anaesthesia care, dexmedetomidine, pethidine

1. Introduction

With the advent of newer anaesthetic agents, anaesthetic adjuvants and equipments for precise drug delivery and monitoring vital parameters, the old concept of anaesthesia services on standby basis has gained new dimension of monitored anaesthesia care (MAC).

Monitored anaesthesia care (MAC) is nothing but the combination of local anaesthetic infiltration or peripheral nerve blocks with intravenous sedative and analgesic drugs given in more precise manner with equipments such as infusion pumps along with detailed monitoring of vital parameters.

ENT surgeries like mastoid surgeries are superficial, less invasive and can be done under local anaesthesia or local anaesthesia with sedation in co-operative and well counseled patients. Local anaesthesia is cost effective but better preoperative counseling is needed and at times may cause patient discomfort if it is used as sole technique. Therefore MAC is an attractive option as it invokes less physiological disturbance, allow a more rapid recovery than general anaesthesia and cost effective.

The choice of drugs which are administered under MAC must provide good and sustained level of sedation, analgesia and anxiolysis with the goal of providing rapid recovery without side effects.

Dexmedetomidine is the most selective central α_2-adrenoceptor agonist, providing dose-dependent sedation, analgesia, sympatholysis and anxiolysis without respiratory depression. The sedative effect is rapid, stable and maintains patient arousability.

Pethidine is a synthetic opioid analgesic. In addition to analgesia, the effect of pethidine on the central nervous system causes respiratory depression, drowsiness, sedation, change in mood, euphoria, dysphoria, mental clouding, nausea, vomiting, and electroencephalographic changes. Large doses of pethidine may induce excitation or convulsions.

This study was undertaken to compare dexmedetomidine and pethidine as sedative in mastoid surgery.

2. Literature Survey

- Jose Roberto Nociti et al (2003) did a comparative study aimed at evaluating the effects of dexmedetomidine on propofol requirements and cardiovascular/respiratory stability during sedation for plastic surgery under local anesthesia. MR Safavi,
- A Honarmand (2008) compared the effects of small doses of sufentanil or pethidine on cardiovascular changes induced by tracheal intubation.

3. Methodology

Institutional ethical committee approval was obtained and informed written consent was taken from all the patients. 60 patients posted for elective mastoid surgery were studied in a randomized prospective manner. The study population was divided into 2 groups of 30 each who fulfilled the inclusion-exclusion criteria.

Group D (Dexmedetomidine) : Received intravenous Inj. Dexmedetomidine 1 μgkg^{-1} bolus for 10 minutes followed by continuous infusion at the rate of 0.5 $\mu gkg^{-1}hr^{-1}$ till the end of surgery through infusion pump.

Group P (Pethidine) : Received intravenous pethidine 1mgkg-1

Inclusion criteria: Patients with ASA grade I and II, age between 20 - 55 years, either sex, history of no substance abuse or drug allergy.

Exclusion criteria: Patients of ASA grade III and VI, age < 20 years and > 55 years, pregnant or nursing mothers, morbid obesity (BMI > 40 kgm-2), allergy to local anaesthetic drugs, diabetes, hypertension, heart diseases, seizure disorders, neuropsychiatric disorders.

After explaining the anaesthetic procedure to the patients, informed written consent was taken to include them in the study. All patients were prescribed 0.5 mg of alprazolam and ranitidine 150 mg orally the previous night.

On arrival of patients to operation theater the identity, NBM status, consent was confirmed. The procedure was once again explained to reduce anxiety. Intravenous access was secured with two 18 gauge venous cannula for fluid administration. Preloading was done with Ringer lactate solution 8 - 10 mlkg-1. The baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP), oxygen saturation (Sp02) and rate of respiration (RR) were recorded.

After completion of 10 minutes bolus dose of study drugs, Inj. Paracetamol 10 $mgkg^{-1}$ IV infusion was administered in both the groups. The vital parameters such as HR, SBP, DBP, MBP, RR, SpO_2, Ramsay sedation score (RSS) were recorded at 5 - minute intervals for first 20 mins & afterwards at 15 minute interval throughout the operation, and then in the recovery room at 0,10,20, 30,45 & 60 mins.

Ramsay Sedation Scale (RSS)

1) Patient is anxious and agitated or restless, or both
2) Patient is co-operative, oriented, and tranquil
3) Patient responds to commands only
4) Patient exhibits brisk response to light glabellar tap or loud auditory stimulus
5) Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
6) Patient exhibits no response

Local infiltration at surgical site was given with Inj. Lignocaine 2% plus Adrenaline 1:200000; 10 cc. If patients complained of pain with first infiltration intra operatively, additional local infiltration of Inj. Lignocaine 2% plus Adrenaline 1:200000 was given. The total dose Lignocaine 2% plus Adrenaline 1:200000 was not allowed to exceed $7mgkg^{-1}$.

The study was evaluated with respect to sedation and analgesia offered by both groups, haemodynamic stability, respiratory effects, postoperative analgesia, additional analgesic requirement, side effects like bradycardia, tachycardia, hypertension, hypotension, PONV (nausea, vomiting), dryness of mouth etc.

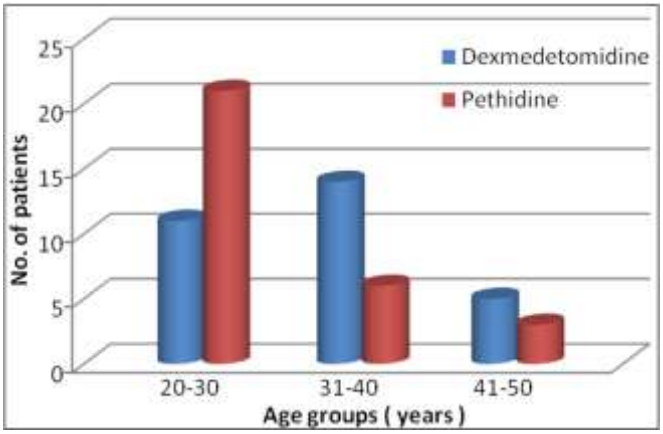
4. Statistical Analysis

Statistical methods applied are Descriptives, Independent-Samples Test, Crosstabs (Contingency table analysis).

5. Results

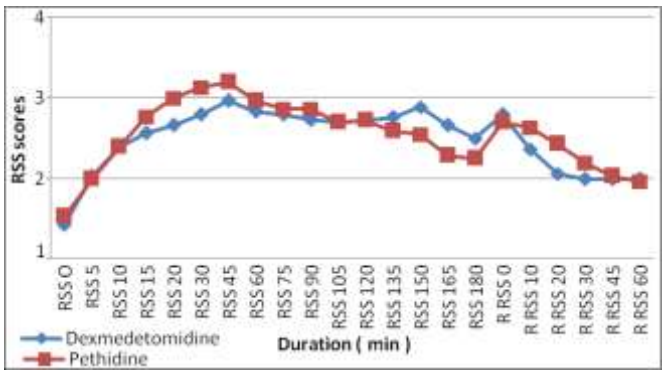
Data was collected and statistical analysis was performed as explained in the methodology of the study. The results and interpretations are as explained below.

5.1 Age Distribution



The mean age of the patients in group D was 34.00 ± 9.135years and in group P was 30.37 ± 8.580years. The differences in the mean age between the two groups were statistically insignificant (p= 0.053) and both groups were comparable.

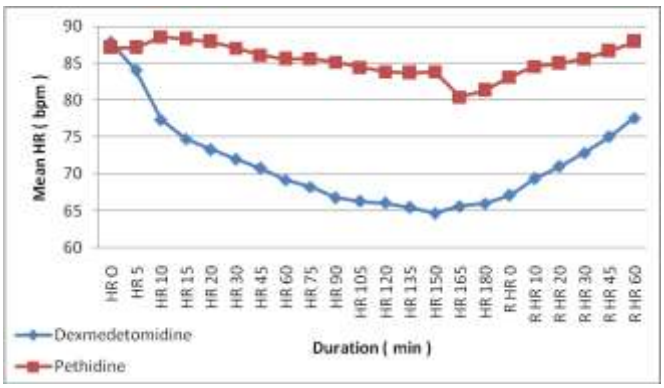
5.2 Level of Sedation Using Ramsay Sedation Scale



At initiation (0 min) of the drug infusion, the mean RSS was 1.43 ± 0.50 in group D and 1.53 ± 0.50 in group P. So the mean RSS values were comparable (p = 0.447).

At the end of 20 min of drug infusion, the mean RSS increased to 2.66 ± 0.47 in group D and at 3.00 ± 0.58 in group P. The difference between RSS was statistically significant (p = 0.019). The RSS showed statistical significance at 30min and at 150 min in intraoperative period. Intraoperatively, sedation was comparable in both groups except at 20min, 30min and 150min.

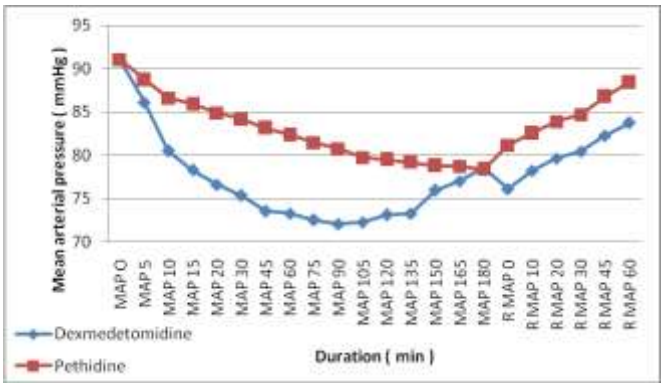
5.3 Heart Rate Changes



At initiation (0 min) of the drug infusion, the mean HR was 87.83 ± 7.16 bpm in group D and 87.10 ± 6.70 bpm in group P. Thus the mean HR was comparable in both groups (p = 0.684).

At 10 min of bolus, the mean HR was 77.36 ± 6.58 bpm in group D and 88.56 ± 6.42 bpm in group P. The difference between HR at 10 min of bolus in both groups was statistically significant (p= 0.000). This statistically significant decrease in HR lasted intraoperatively till end of surgery.

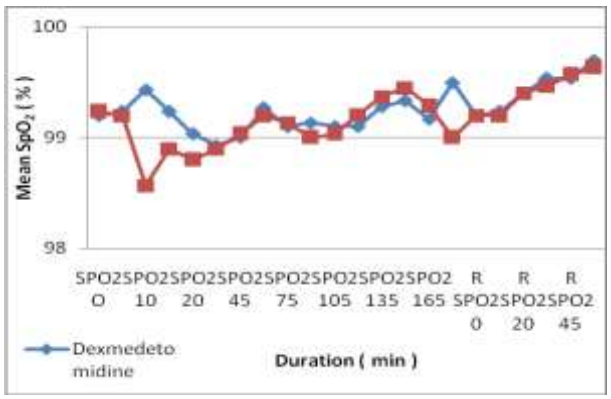
5.4 Mean Arterial Blood Pressure Changes



At initiation (0 min) of the drug infusion, the mean MAP was 91.00 ± 6.33mmHg in group D and 91.03 ± 5.37 mmHg in group P. The mean MAP was comparable in both groups (p = 0.983).

At 10 min of bolus, the mean MAP decreased to 80.50 ± 5.77 mmHg in group D and 86.60 ± 5.58 mmHg in group P. The difference between mean MAP at 10 min of bolus in both groups was statistically significant (p= 0.000).This statistically significant decrease in MAP lasted intraoperatively till 150min of surgery (mean duration of surgery 145min).

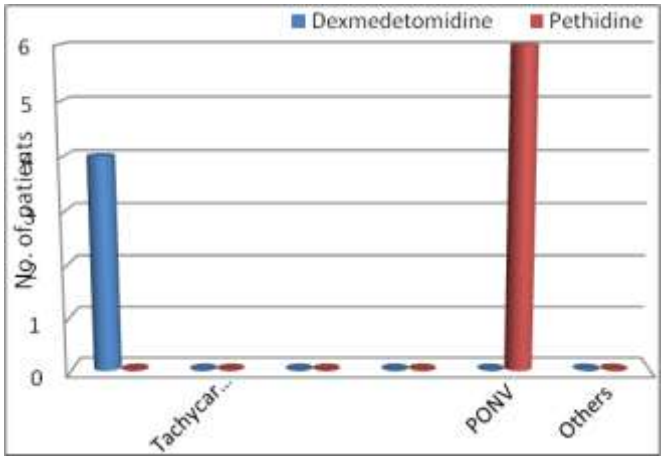
5.5 Oxygen Saturation Changes



At initiation (0 min) of the drug infusion, the mean SpO_2 was 99.20 ± 0.84 % in group D and 99.23 ± 0.85 % in group P. The mean SpO_2 were comparable in both groups (p = 0.880).

At 10 min of bolus, the mean SpO_2 was 99.43 ± 0.56 % in group D and 98.56 ± 0.62 in group P. The difference between mean SpO_2 at 10 min of bolus in both groups was statistically significant (p= 0.000). At 15min intraoperatively, there was statistically significant difference (p = 0.041) in mean SpO_2 was observed in group D compared to group P.

5.6 Side Effects



The occurrence of side effects in group D were – Bradycardia 4 (13.3 %), Tachycardia 0 (0%), Hypotension 0 (0%), Hypertension 0 (0 %), PONV 0 (0 %), Others 0 (0%) and in group P – Bradycardia 0 (0 %), Tachycardia 0 (0%), Hypotension 0 (0%), Hypertension 0 (0 %), PONV 6 (20 %), others 0 (0%).

6. Discussion

ENT surgeries like mastoid surgeries are superficial, less invasive and can be done under local anaesthesia or local anaesthesia with sedation in co-operative and well counseled patients. Local anaesthesia is cost effective but better preoperative counseling is needed and at times may cause patient discomfort, if it is used as sole technique. Therefore MAC is an attractive option as it invokes less physiological disturbance, allow a more rapid recovery than general anaesthesia and cost effective. Thus the primary objective in

providing MAC is to ensure patient comfort, safety and satisfaction during surgery.

The standard of care for patients receiving MAC should be the same as for patients undergoing general or regional anaesthesia including standard preoperative assessment, intraoperative monitoring and postoperative recovery care. Vigilant monitoring is required because patients may rapidly progress from a 'light' level of sedation to 'deep' sedation (or unconsciousness) and thus may be at risk for airway obstruction, oxygen desaturation and even aspiration.

The choice of drugs which are administered under MAC must provide good and sustained level of sedation, analgesia and anxiolysis with the goal of providing rapid recovery without side effects.

Dexmedetomidine when used for sedation during mastoid surgery under local anaesthesia, provided reliable and titratable sedation with faster recovery. It has a better hemodynamic stability, providing analgesia without adverse respiratory events. During mastoid surgery, induced hypotension helps in controlling perioperative bleeding and provides good exposure of surgical field. These characteristics are desirable in patients undergoing mastoid surgery.Dexmedetomidine is a better alternative to pethidine for sedation.

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