Original Research Article

A Hospital Based Comparative Study to Evaluate the Efficacy of 150 Mgs of Oral Pregabalin and 6 Mg Oral Melatonin Used as Premedication to Attenuate Stress Response and Haemodynamic Responses in Cholecystectomy for Laparoscopic Surgery

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Abstract

Background: Airway management is one of the core skills of the anesthetists. Various studies have been performed to study efficacy of drugs on attenuating haemodynamic responses to laryngoscopy. By far no study has been done to compare oral pregabalin & oral melatonin. This study was conducted to evaluate & compare efficacy of oral pregabalin & oral melatonin in attenuation of haemodynamic responses during laryngoscopy, intubation & extubation in laparoscopic cholecystectomy.**Materials & Methods:** This is a hospital based prospective study done on 50 Patients undergoing laparoscopic cholecystectomy in department of anaesthesiology in Dr. S. N. Medical College, Jodhpur. Patients were randomly divided into two groups of 25each with the help of achitbox method. Group P - (25 patients) oral pregabalin 150 mg, 120 min before surgery and group M-(25patients)oral melatonin tablets 6mg (two tablets of 3 mg), 120 min beforesurgery. Data are expressed as mean, intra group difference was evaluated by two-way analysis of variance(ANOVA),and intergroup usingt-test. P values of <0.05 were considered significant. **Results:** Our study showed that the mean age of patients was 37.34±10.78 years in group P and 35.38±12.45 years in group M, but statistically non-significant (P>0.05). The female to male ratio was 3:2 in both groups, female preponderance in our study. The SBP, DBP & MAP in group M was slightly lower as compare to group P, but statistically nonsignificant at baseline after 1 min., 3 min. & 30 after pneumoperitoneum in between groups. During laryngoscopy & intubation after pneumoperitoneum & after extubation the haemodynamic changes was statistically significant.**Conclusion:** We concluded that both the drugs can be used as an effective premedicant to attenuate the sympathetic response to laryngoscopy and tracheal intubation without more side effects.

Keywords: Cholecystectomy, Laparoscopy, Hemodynamic Changes, Premedication.

Introduction

Airway management is one of the core skills of the anaesthetist, either via facemask ventilation, insertion of a laryngeal mask airway, endotracheal intubation by direct or indirect (video-assisted) laryngoscopy or by use of a fibrescope. Laryngoscopic endotracheal intubation often requires the use of adjuncts such as a gum elastic bougie or stylet. Anaesthetists may also be required to perform a cricothyroidotomy or an emergency tracheostomy[1].Laryngoscopy is a term describing visualization or examination of the larynx by distraction of the upper airway structures, typically for the purpose of tracheal intubation and airway management in modern anesthesia and critical care practice as well as in many trauma scenarios. For nearly a century, direct laryngoscopy has been the standard technique for tracheal intubation. In this approach, a rigid laryngoscope is used to expose the laryngeal inlet under direct vision or line of sight to facilitate placement of a tracheal tube beyond the vocal cords. Alternatively, indirect techniques for tracheal intubation have been developed that do not require direct vocal cord visualization. These newer approaches include the design and use of malleable or rigid optical stylets, rigid indirect laryngoscopes such as the Bullard and TruView EVO2, fiberoptic technology, and video laryngoscopes, in which video camera systems provide a focused view of the laryngeal inlet [2]. Laparoscopic surgery involves the use of reusable metallic or disposable plastic trocars inserted through small skin incisions or ports made on the skin away from the site of surgery. These ports form the portal of entry to perform the surgical procedure by means of specially devised instruments and telescope. It has gained popularity due to better aesthesis, lesser pain, early ambulation, and discharge from the hospital with early return to work, minimizing the financial burden to the patient. Ever since Philips Mouret reported the first laparoscopic cholecystectomy in 1987, the approach has been adopted for many other surgical procedures including appendectomy, herniorrhaphy, colonic surgery, gastric surgery, urological and gynaecological surgery[3-7]. This is because of the combination of advancement in technology with the increasing acceptance of minimal access surgery (MAS) by patients, which has led to the expansion of the horizon of laparoscopic surgery.Pineal hormone melatonin(N-acetyl-5-methoxytryptamine) is an endo-genous sleep regulating hormone that can be used as pre-medication, regulation of circadian rhythms, as sedative,analgesic, anti-inflammatory,and antioxidant[8].

Pregabalin,a gabapentinoid compound appears to produce an inhibitory modulation of neuronal excitability particularly in neocortex, amygdala and hippocampus of CNS [9,10].Various studies have been performed to study efficacy of drugs on attenuating haemodynamic responses to laryngoscopy. By far no study has been done to compare oral pregabalin & oral melatonin. This study was conducted to evaluate & compare efficacy of oral pregabalin & oral melatonin in attenuation of haemodynamic responses during laryngoscopy,intubation & extubation in laparoscopic chole-cystectomy.

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Materials & methods

This is a hospital based prospective study done on 50 Patients undergoing laparoscopic cholecystectomy in department of anaesthesiology in Dr. S. N. Medical College, Jodhpur.

Inclusion Criteria

Sixty ASA grade I and II patients,
Age between 18-65years,
Undergoing laparoscopic cholecystectomy

Exclusion Criteria

Patients having compromised renal, pulmonary and cardiac status (ASA grade III or above)
Patients with any systemic diseases.
Patients with anticipated difficult intubation (mallampati grade 3 and 4)
More than one attempts at intubation.
Patients in whom duration of laryngoscopy exceeds more than30secs.
Haemodynamically unstable patients
Previous History of allergy or contraindication to anaesthetics or any drugused.

Methods

Patients were randomly divided into two groups of 25 each with the help of achitbox method.All patients were explained about the anaesthesia technique and written informed consent taken.
Group P -(25 patients) oral pregabalin 150 mg, 120 min before surgery.
Group M- (25patients)oral melatonin tablets 6mg (two tablets of 3 mg), 120 min before surgery.
Pre-anaesthetic evaluation were done a day prior. On the day of surgery, patient received in OT, confirmation of patient's identity, fasting status, PAC and consent was done.
In the operating room standard 5 leads ECG, non-invasive blood pressure and pulse oximetry were attached, and base line parameters were noted. Venous access was secured using an 18 G cannula on the dorsum of the non-dominant hand. Injection midazolam1mg and fentanyl 1 µg/kg were given. Pre-oxygenation was done for 3 minutes, then induction with i.v propofol 2mg/kg. Succinylcholine were used intravenously 2 mg/kg to facilitate endotracheal intubation with proper sized well- lubricated cuffed endotracheal tube. Laryngoscopy and tracheal intubation was done with appropriate sized, cuffed endotracheal tube. Maintenance of anaesthesia with inhalation of isoflurane 1 minimum alveolar concentration; nitrous oxide:oxygen 40:60. Muscle relaxation were attained with Vecuronium bromide in the dose of 0.06–0.08 mg/kg intravenously as loading dose and one- fourth of the initial dose as maintenance doses. After completion of the surgery,neostigmine 50µg/kg and injection glycopyrrolate 10 µg/kg were administered intra-venously to reverse the residual neuromuscular blockade.

Statistical Analysis

Data are expressed as mean, intra group difference was evaluated by two-way analysis of variance(ANOVA),and intergroup using t-test. P values of <0.05 were considered significant.

Results

Our study showed that the mean age of patients was 37.34±10.78 years in group P and 35.38±12.45 years in group M, but statistically non-significant (P>0.05). The female to male ratio was 3:2 in both groups, female preponderance in our study (table 1).The SBP, DBP & MAP in group M was slightly lower as compare to group P, but statistically nonsignificant at baseline after 1 min., 3 min. & 30 after pneumoperitoneum in between groups. During laryngoscopy & intubation after pneumoperitoneum & after extubation the haemo-dyanamic changes was statistically significant in our study (figure 1-6).

Table 1: Distribution of mean age in between groups

Parameters	Group P (N=25)	Group M (N=25)	P- Value
Age (yrs)			
Mean±SD	37.34±10.78	35.38±12.45	>0.05
Gender			
Male	10	10	1.000
Female	15	15	

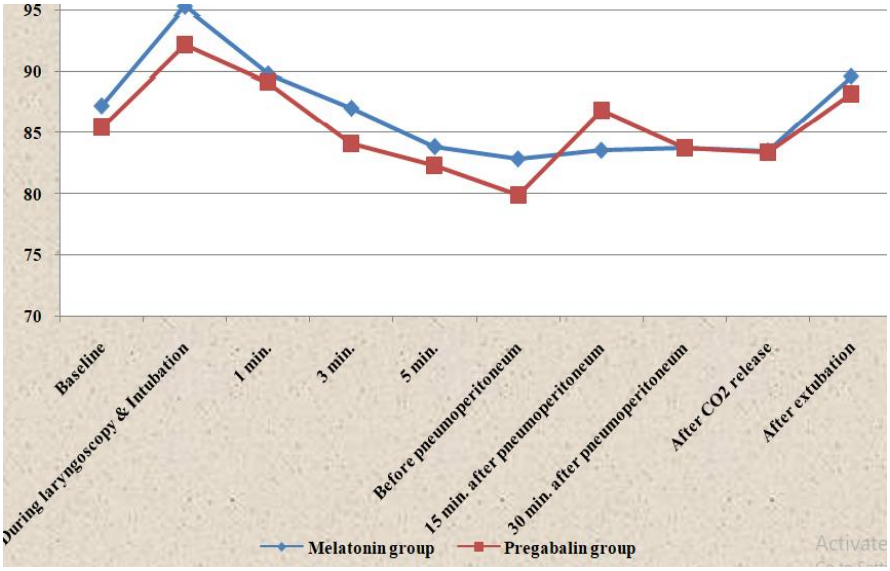

Fig1: Comparison of heart rate in different time interval in between groups

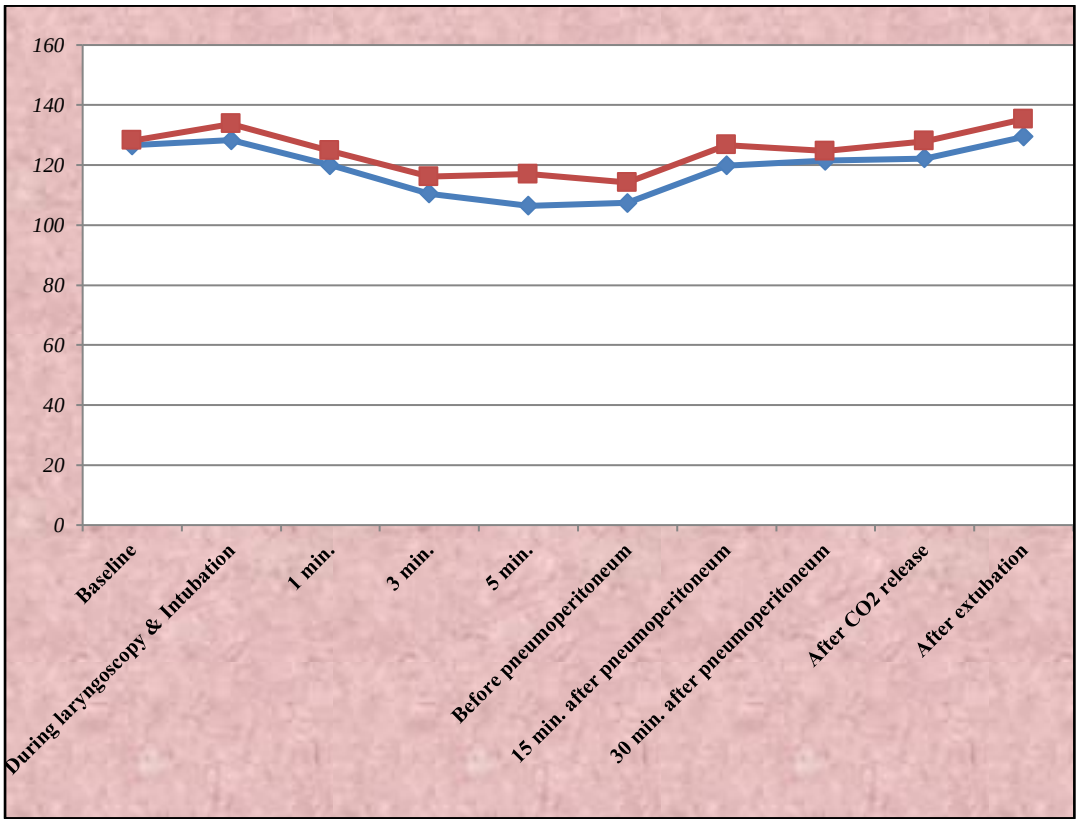

Fig 2: Comparison of SBP in different time interval in between groups

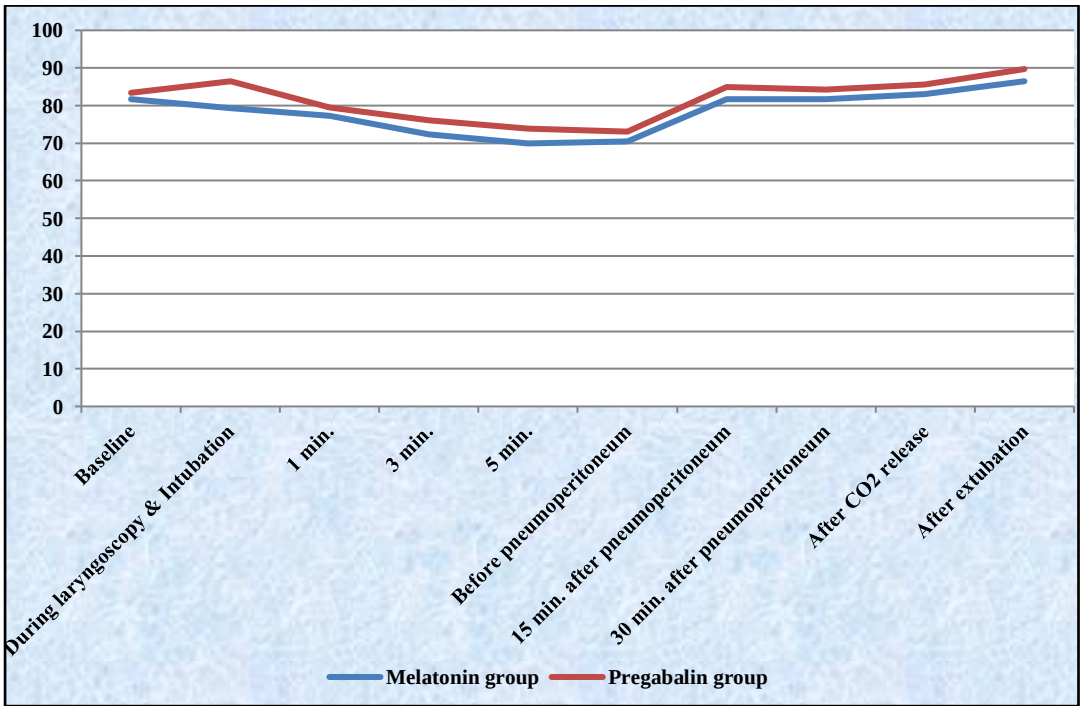

Fig 3: Comparison of DBP in different time interval in between groups

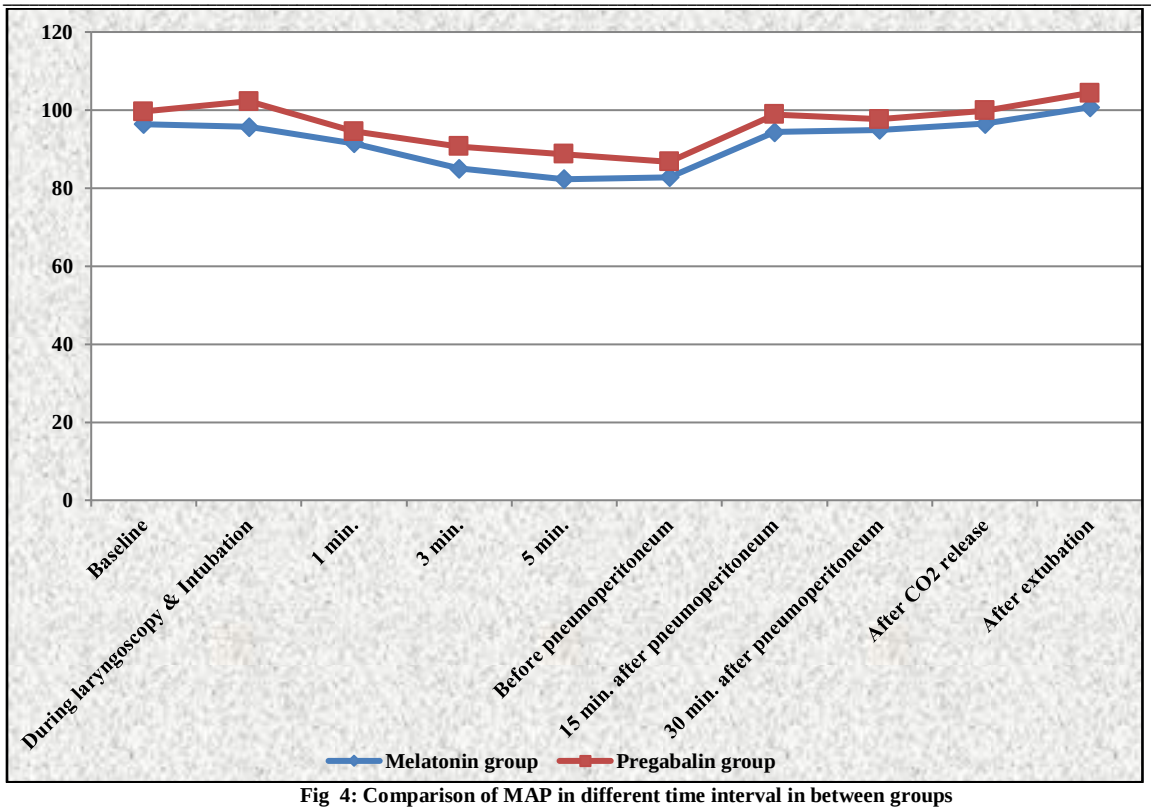

Fig 4: Comparison of MAP in different time interval in between groups

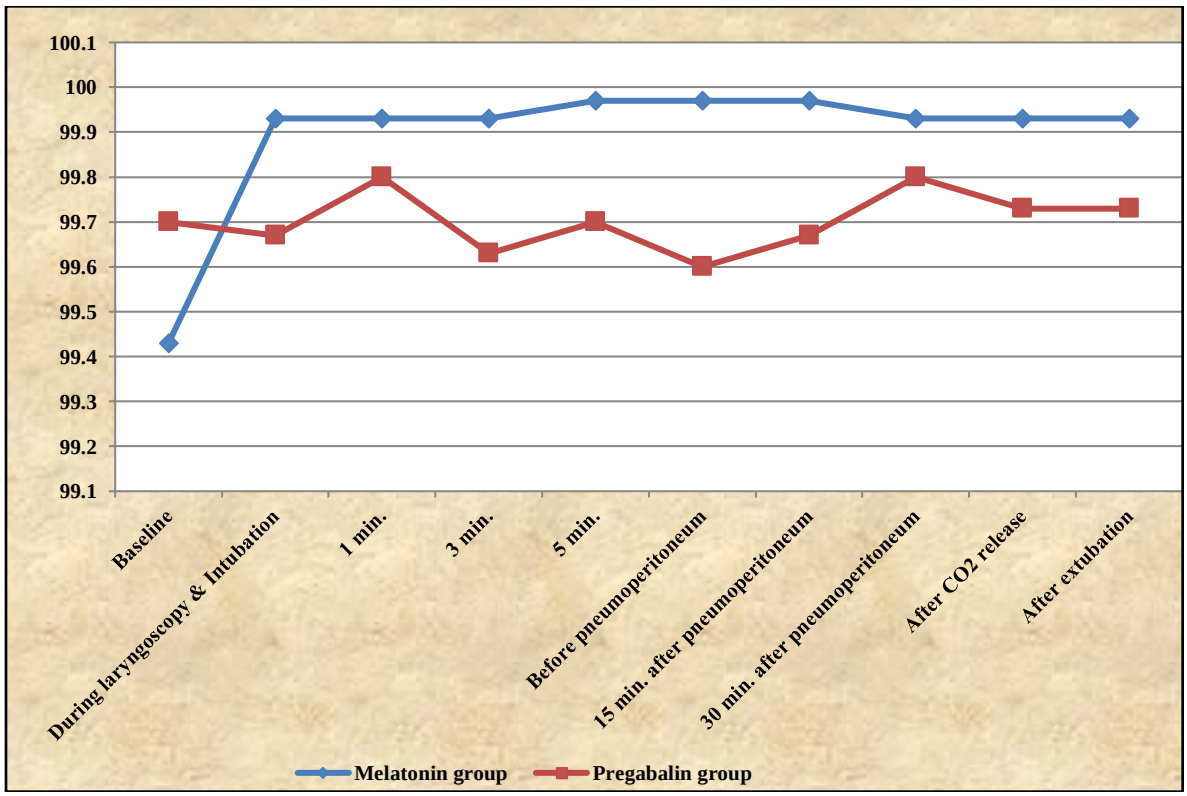

Fig 5: Comparison of SPO2 in different time interval in between groups

Discussion

Our study showed that the mean age of patients was 37.34±10.78 years in group P and 35.38±12.45 years in group M, but statistically non-significant (P>0.05). Various study done by Kumkum Gupta et al (2011) 11 aged 35 to 52 years, Shirin Parveen et al (2016)12 included aged between 20-60 years of both sexes, Bhawna Rastogi et al (2012) 13 aged 24-56 years. Another study done by Nadia M Bahgat et al (2016)14 aged 18-60 years. No significant difference was found in age, sex in our study.There was no significant difference in heart rate value among groups. During laryngoscopy & intubation the heart rate was increase in both groups as compare to baseline and before peritoneum the heart rate was decreases in both groups in our study. Bhawna Rastogi et al (2012)[13] found no significant decrease in heart rate was observed in different doses of pregabalin. Mohamed,Hosam M. et al (2013)[15] found no significant difference in heart rate between the different doses of melatonin.The SBP, DBP & MAP in group M was slightly lower as compare to group P, but statistically nonsignificant at baseline after 1 min., 3 min. & 30 after pneumoperitoneum in between groups. During laryngoscopy & intubation after pneumoperitoneum & after extubation the haemodyanamic changes was statistically significant in our study. Bhawna Rastogi et al (2012)[13] concluded that oral pregabalin premedication has adequately sedated the patients. The haemodynamic pressor response of airway instrumentation was attenuated in a dose-related fashion. The premedicated patients were haemodynamically stable perioperatively without prolongation of recovery time and side-effects.Mohamed, Hosam M. et al (2013) concluded that preoperative administration of melatonin one hour before surgery provided a significant decrease hemodynamic response of direct laryngoscopy and tracheal intubation as regard hemodynamic parameters and perfusion index[15]. Shirin Parveen et al (2016)[12] found that oral clonidine 0.3mg as well as oral pregabalin 150mg were effective in blunting haemodynamic stress response to laryngoscopy and tracheal intubation. Clonidine was found to be better than pregabalin in lowering of systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate changes associated with laryngoscopy. Bradycardia was common with both the drugs, more so in clonidine group. Another study done by Dhananjaya Bangalore Doddaiah et al (2017)[16]who founded significant reduction in SBP, DBP, and MAP, but not the tachycardia.

Conclusion

We concluded that both the drugs can be used as an effective premedicant to attenuate the sympathetic response to laryngoscopy and tracheal intubation without more side effects.

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