Original Article

Comparative evaluation of i-gel® insertion conditions using dexmedetomidine-propofol versus fentanyl-propofol - A randomised double-blind study

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ABSTRACT

Background and Aims: i-gel® insertion necessitates adequate depth of anaesthesia to prevent laryngospasm, gagging or limb movements. We aimed to compare i-gel® insertion conditions with propofol induction after pre-treatment with dexmedetomidine or fentanyl. **Methods:** Eighty ASAI/II patients undergoing general anaesthesia were randomised into Groups D *(n* = 40) and F *(n* = 40). Group D received 1 μg/kg dexmedetomidine over 10 minutes followed by 5ml of 0.9%normal saline (NS) over 2 minutes. Group F received 10 ml of 0.9%NS over 10 minutes followed by fentanyl 1 μg/kg over 2 minutes. Thirty seconds after study drugs, propofol 2 mg/kg was given. Ninety seconds after propofol, i-gel® was inserted. Overall insertion conditions were assessed by Modified Scheme of Lund and Stovener. Heart-rate (HR) and mean arterial pressure (MAP) were noted at baseline, after study drug, propofol induction and 1,3,5,10 minutes after i-gel® insertion. Respiratory rate and apnoea times were recorded. **Results:** Insertion conditions were comparable between both groups. Moderately relaxed jaw, coughing and movement was observed in more patients of Group F. Incidence of apnoea was significantly higher ($P < 0.0001$) in group F (18/40) than group D (3/40).Mean duration of apnoea in group F (284.5 ± 11.19 sec) was significantly higher than group D (217.17 ± 16.48 sec). Percentage drop in MAP from baseline after propofol was more in group F (10.3%) than group D (5.6%). MAP after induction was significantly lower in group F compared to group D ($P = 0.002$), but similar after i-gel® insertion, 1,3,5 and 10 minutes after insertion. After propofol ($P = 0.003$) and i-gel® insertion ($P < 0.001$), HR was significantly lower with dexmedetomidine. **Conclusion:** Dexmedetomidine and fentanyl provide comparable conditions for i-gel® insertion with propofol.

Key words: Anaesthetics IV, dexmedetomidine, fentanyl, i-gel® insertion, premedication, propofol

INTRODUCTION

Amongst the second generation supraglottic airway devices[SGADs],i-gel®(IntersurgicalLtd,Wokingham,UK) not only has an easier insertion but has also reported to cause lesser airway morbidity over other SGADs with an inflatable cuff.[1]

Due to the difference in structural design and the pressure exerted over pharyngo-laryngeal area, the anaesthetic requirement for insertion of different SGADs varies.[2] i-gel® insertion in a non-paralyzed patient requires sufficient depth of anaesthesia to achieve adequate jaw relaxation and to prevent untoward effects like coughing, gagging, laryngospasm and head or limb movements. Although propofol is known to suppress pharyngo-laryngeal reflexes profoundly, when used as the sole induction agent

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for SGAD insertion, it may lead to dose-dependent cardio-respiratory depression.[3] Co-induction agents like opioids have been used with propofol to facilitate device insertion, to reduce the dose of propofol and associated adverse effects.[3] i-gel® insertion conditions may be improved by opioids but, they are associated with delayed anaesthetic recovery, muscle rigidity and post-operative apnoea, particularly after general anaesthesia.[4]

Dexmedetomidine is a highly selective, short-acting α_2-receptor agonist with dose-dependent analgesic, sedative, and anxiolytic effects, is a useful adjuvant to general anaesthesia. Dexmedetomidine when used as an adjuvant to propofol has shown to provide satisfactory insertion conditions and better attenuation of pressor response during SGAD insertion.[5,6]

It was hypothesised that dexmedetomidine and propofol provide better i-gel® insertion conditions as compared to fentanyl and propofol. Our primary aim was to compare jaw relaxation and overall i-gel® insertion conditions of dexmedetomidine versus fentanyl pre-treatment under propofol anaesthesia using the Modified Scheme of Lund and Stovener.[7] Changes in heart-rate (HR), mean arterial pressure (MAP), duration of apnoea and the total requirement of propofol were also studied as the secondary objectives.

METHODS

This prospective randomised controlled double-blinded study was conducted after the approval of institutional ethics committee (IEC/01/13) and registering the study with clinical trials registry of India (CTRI/2017/06/008928). The study was conducted between July 2017 and June 2018 in accordance with the priniciples of Declaration of Helsinki. Eighty eligible American Society of Anesthesiologists class I/II patients of either sex and aged between 18 and 60 years undergoing general anaesthesia for short surgical procedures were included and a written informed consent was obtained from all the participants [Figure 1]. Patients with a reduced mouth opening, neck and facial burns, Modified Mallampati class >3, Body Mass Index >30 kg/m^2, thyromental distance <6 cms, upper/lower airway obstruction, on beta blockers or bradycardia (heart rate <60/minute) and with known allergy to study drugs were excluded from trial. The

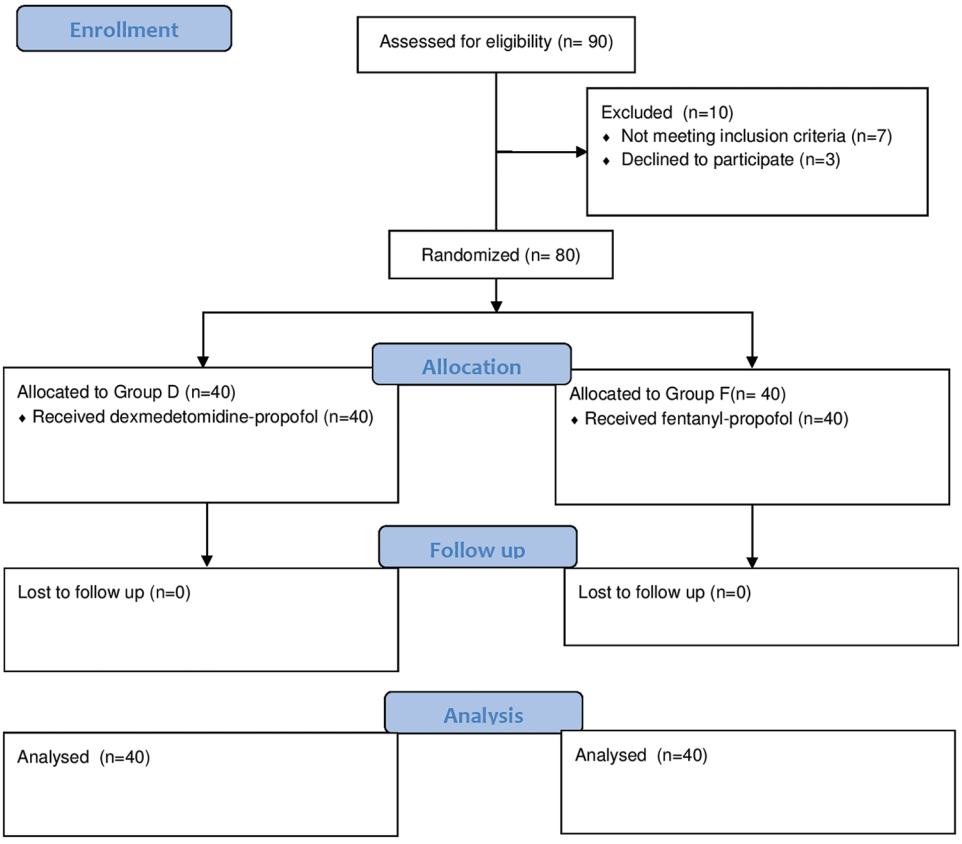

Figure 1: Consort flow diagram

anaesthesiologist A, who was not involved in the study, randomised the patients equally into two groups D and F based upon the computer-generated randomisation scheme. The random group allocations were concealed in a sealed envelope by anaesthesiologist A. An anaesthesiologist B, who did not participate in patient management or data collection, opened the sealed envelope and accordingly prepared the study drugs. The investigator introducing the i-gel®, the patients and the anaesthesiologist recording the data in the operation theatre were blinded to the allotment of groups.

Patients' baseline parameters such as heart rate, Electrocardiogram (ECG), mean arterial pressure, respiratory rate and oxygen saturation were noted upon arrival to the operation theatre and monitored continuously thereafter. Intravenous access was secured with 20G cannula and Ringer's lactate solution at 2 ml/kg/hr was started. Oxygen was administered via nasal cannula at 2 L/min to prevent de-saturation during study drug infusion over ten minutes. Premedication with IV Injection Glycopyrrolate 0.004 mg/kg was given. Group D received 1 μg/kg dexmedetomidine diluted to 10 ml with 0.9% normal saline (NS) over ten minutes by an infusion pump [Infusor 950, EMCO, India] followed by 5 ml of NS over 2 minutes. Group F received 10 ml of NS over 10 minutes by the same infusion pump followed by Injection fentanyl 1 μg/kg diluted to 5 ml with 0.9% NS over 2 minutes. Thirty seconds after the injection of study drugs, anaesthesia was induced with 2 mg/kg of Injection propofol given intravenously over 30 seconds. Ninety seconds after the completion of injection propofol, i-gel® (Intersurgical Ltd, Wokingham, UK) insertion was attempted. i-gel® was chosen in accordance with the manufacturer's recommendation based on patient's weight.[8] The blinded investigator with an experience of at least 50 i-gel® insertions inserted the i-gel® in the 'sniffing morning air' position. The square wave capnogram, bilateral symmetrical chest movement, auscultation of equal breath sounds and normal saturation confirmed an effective airway through i-gel®. Absence of any of the above clinical signs after i-gel® placement was defined as failed attempt.

Bradypnoea (respiratory rate <12/min) if occurred was recorded. Whenever apnoea (cessation of respiration >30 seconds) occurred, ventilation was assisted manually but allowing spontaneous respiration to occur, via facemask (before I –gel insertion) or via i-gel® until regular spontaneous respiration resumed. Anaesthesia was thereafter maintained on oxygen, nitrous oxide (50:50) and sevoflurane 1.5 to 2 volumes percent. No muscle relaxant was administered during the study.

Ease of insertion of i-gel® was evaluated by the degree of jaw relaxation achieved by using the "Young's Criteria'[9] [Absolutely relaxed jaw-I, Moderately relaxed jaw-II, Poorly relaxed jaw-III] While the overall i-gel® insertion conditions were assessed using the Modified Scheme of Lund and Stovener[7] [Excellent- No gagging or coughing, no laryngospasm, no patient movement, Good- Mild to moderate gagging or coughing, no laryngospasm, mild to moderate patient movement, Poor- Moderate to severe gagging or coughing, no laryngospasm, moderate to severe patient movement, Unacceptable- Severe gagging or coughing, laryngospasm, severe patient movement]. If any of the above were present during the first attempt of the i-gel® insertion then a further bolus of 0.5 mg/kg of propofol was administered. After three attempts of failed i-gel® insertion, it was decided to abandon the study and the case proceeded under general anaesthesia with endotracheal intubation. A 12 F gastric drain tube was inserted through the i-gel® and confirmed by auscultation of epigastric air which was injected through the proximal end of the drain tube. Number of attempts for i-gel® and drain tube insertion, number of additional propofol boluses and total dose of propofol were noted.

Besides i-gel® insertion conditions, the respiratory rate and apnoea time (time between last spontaneous breath after propofol and occurrence of first spontaneous breath) were recorded. Heart rate and blood pressure changes during i-gel® insertion were also recorded at intervals of baseline, after study drug infusion, after propofol induction, and at 1, 3, 5 and 10 minutes after the i-gel® insertion. No further data for haemodynamic parameters was recorded.

At the end of surgery, i-gel® was removed when the patient was able to open mouth on command and was inspected for bloodstains. Both the back and front of the i-gel® cuff were tested for regurgitation of gastric contents using litmus paper which would change its' colour in acidic pH.

Adverse events such as bradycardia, hypotension, coughing, laryngospasm, bronchospasm, or desaturation if occurred were recorded and treated appropriately.

A previous study reported a significant difference of 26.7% (*P*-0.019) in the incidence of absolutely relaxed jaw after pre-treatment with dexmedetomidine (96.7%) and fentanyl (70%) during propofol anaesthesia.[10] Assuming the same, at 2 sided type 1 error of 0.05% and power of 90%, sample size of 36 for each group was required to detect significant difference. Taking 10% drop out rate into consideration, 40 patients were studied in each group.

Data was analysed using SPSS ver. 16.0 software (SPSS Inc., Chicago, IL, USA). Continuous data was expressed as mean ± standard deviation. The unpaired *t*-test was used for intergroup comparisons between HR and MAP at each time point. Intra-group analyses were conducted using *t* tests with repeated measurements. Categorical data were expressed as percentage. The demographic data was analysed using Mann Whitney-test and Fisher-exact test. Ordinal categorical data such as i-gel® insertion conditions and number of attempts were analysed by Fisher-exact or Chi-square test. A *P* value <0.05 was accepted as statistically significant.

Table 1: Comparison of demographic variables and modified mallampatti test between groups D and F

Parameter	Group D (40)	Group F (40)	*P*
Age (yrs)	31.33±13.56	31.90±10.35	0.832
Sex M/F	7/33	6/34	0.762
Body mass index	23.75±2.67	23.25±1.817	0.39
Modified Mallampatti class I/II/III/IV	26/14/0/0	19/20/1/0	0.207

Data are expressed as mean±standard deviation or number (%). Group D – Dexmedetomidine group, Group F – Fentanyl group

Table 2: Comparison of overall insertion conditions by Modified Scheme of Lund and Stovener between groups D and F

Insertion conditions	Group D	Group F	Total	Chi-square test *P*
Excellent	25 (62.5%)	26 (65.0%)	51 (63.8%)	0.162
Good	15 (37.5%)	11 (27.5%)	26 (32.5%)	
Poor	0 (0%)	3 (7.5%)	3 (3.8%)	
Excellent	No gagging or coughing, no laryngospasm, no patient movement			
Good	Mild to moderate gagging or coughing, no laryngospasm, mild to moderate patient movement			
Poor	Moderate to severe gagging or coughing, no laryngospasm, moderate to severe patient movement			
Unacceptable	Severe gagging or coughing, laryngospasm, severe patient movement			

RESULTS

Airway assessment using MMT and demographic variables were comparable in both Groups D and F [Table 1]. Five out of forty patients in Group F and 1/40 in Group D ($P = 0.08$) had a moderately relaxed jaw during i-gel® insertion. None of the patients had a poorly relaxed jaw. However, group F had more episodes of coughing and movement during i-gel® insertion necessitating additional propofol boluses [Table 2]. No laryngospasm or bronchospasm was observed. Total dose of propofol was significantly ($P = 0.02$) higher with fentanyl (2.21 + 0.39 mg/kg) than with dexmedetomidine (2.07 + 0.21 mg/kg).

Baseline respiratory rates (RR) were comparable in both groups (*P* 0.363). Incidence of apnoea was significantly higher ($P < 0.001$) in group F (18/40) than group D (3/40).The mean duration of apnoea in group F (284.5 ± 11.19 sec.) was significantly higher ($P < 0.001$) as compared to group D (217.17 ± 16.48 sec). After propofol induction ($P = 0.003$) and i-gel® insertion ($P < 0.001$), HR was significantly lower with dexmedetomidine than fentanyl [Figure 2]. In group D, HR was significantly below the baseline after dexmedetomidine infusion ($P = 0.035$), propofol induction (13.7%, $P < 0.001$) and after i-gel® insertion ($P < 0.001$) [Figure 3]. As against this, in group F, a significant drop from the baseline HR was observed after bolus of fentanyl ($P = 0.010$) and propofol induction ($P = 0.02$) but, during i-gel® insertion HR increased above the immediate preceding values by 7.3% reaching nearly baseline values [Figure 3]. MAP was significantly lower in group F ($P = 0.002$) after induction while at 10 mins after i-gel® insertion it was lower in group D ($P = 0.019$) [Figure 4]. Percentage drop in MAP from baseline after propofol induction was more in group F (10.3%) than group D (5.6%) [Figure 5]. In this study, HR and MAP were within 15% from baseline in both groups and statistically significant bradycardia or hypotension did not occur throughout the study. No evidence of trauma or regurgitation during i-gel® insertion was found.

DISCUSSION

This study of 80 patients receiving general anaesthesia with i-gel® insertion suggests that 1 μg/kg dexmedetomidine with 2mg/kg propofol provides satisfactory i-gel® insertion conditions comparable to that provided by 1μg/kg fentanyl with 2 mg/kg propofol. Similarly, comparable insertion conditions have been observed in the previous studies when effects of pre-treatment of dexmedetomidine and

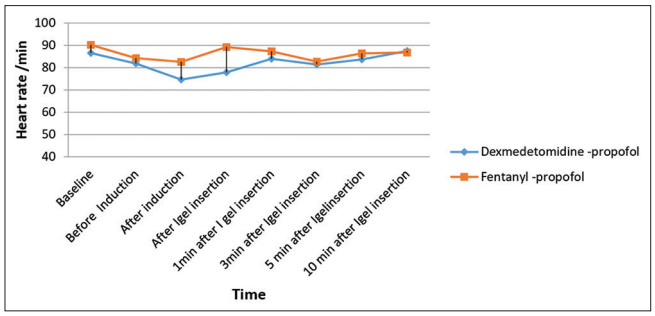

Figure 2: Comparison of heart rates between group D and Group F

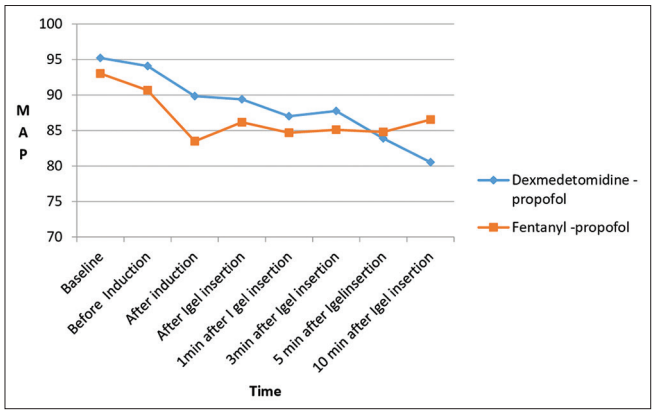

Figure 4: Comparison of mean arterial pressure between groups D and F

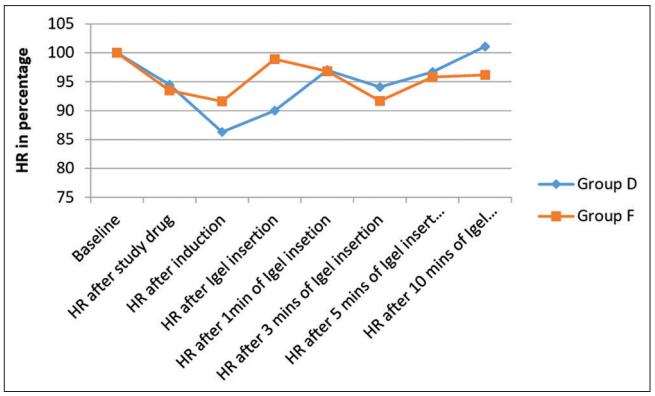

Figure 3: Comparison of percentage drop in heart rates from baseline in groups D and F

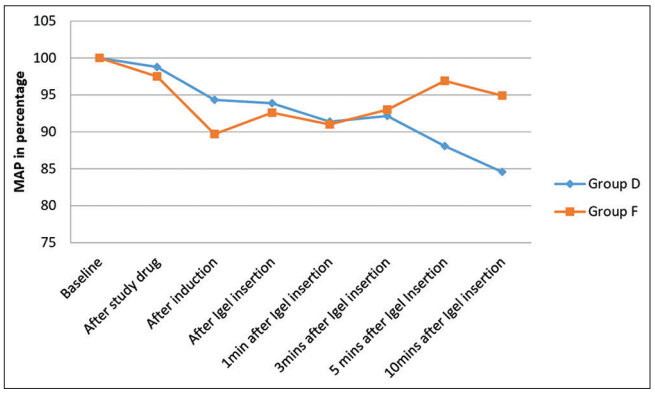

Figure 5: Comparison of percentage drop in mean arterial pressure from baseline in groups D and F

fentanyl on propofol anaesthesia for LMA insertion were assessed.[6,11,12]

Although the overall insertion conditions as summed up by the modified scheme of Lund and Stovener[7] were comparable in both groups, dexmedetomidine provided better jaw relaxation as assessed by Young's criteria with 97.5% patients having absolutely relaxed jaw as compared to 87.5% with fentanyl. In the fentanyl group, 12.5% patients had moderately relaxed jaw and required additional boluses of propofol to facilitate i-gel® insertion. Though not statistically significant, this was a clinically significant finding as added increments of propofol in group F led to episodes of hypotension (<15% of baseline MAP), which were treated with crystalloids. Our findings are in accordance with study by Lande SA *et al.*[5] who compared dexmedetomidine and fentanyl for LMA insertion and reported 96.6% patients having absolutely relaxed jaw with dexmedetomidine. The superiority of dexmedetomidine over fentanyl in providing better jaw relaxation for insertion of the SGAD has been reported by other studies as well.[5,6,10,12]

Regurgitation or aspiration during i-gel® insertion can occur due to inadequate depth of anaesthesia, multiple insertion attemptsand patient movement or with use of opioids. However, we found no signs of regurgitation or trauma during i-gel® insertion in any of the cases.[13,14]

Dose of dexmedetomidine as 1 μg/kg infusion over 10 min was given as suggested by previous studies.[10] The rapid injection of a loading dose of dexmedetomidine can have biphasic effects on blood pressure, with temporary increases in blood pressure by a direct α_2-adrenoceptor-induced vasoconstrictive response in the peripheral vasculature and bradycardia followed by a low mean arterial pressure due to decreased sympathetic outflow.[15] Slow infusion of drug over 10 minutes or more causes long-lasting stabilisation of heart rate and blood pressure at values slightly below the baseline most likely the result of activation of central presynaptic α-2A adrenergic receptors resulting in sympatholysis.[15,16]

Fentanyl 1 μg/kg has been reported to provide optimal SGAD insertion conditions along with significantly better haemodynamic stability. Prolonged apnoea was observed when higher doses of fentanyl were used.[17,18]

The predetermined dose of propofol induction (2 mg/kg) along with the timing of administering propofol injection and i-gel® insertion after pre-treatment with fentanyl or dexmedetomidine, were as suggested by previous researchers.[6,19-22] The aim was to achieve effective synergistic levels of the drug combinations used before I gel insertion.

Both fentanyl and dexmedetomidine are known to reduce propofol requirement for SGAD insertion.[11,21] However, in our study, patients in fentanyl group required more additional boluses of propofol due to inadequate jaw relaxation, coughing and movement. Hence mean total dose of propofol was significantly more with fentanyl (*P*-0.02). Similarly, higher doses of propofol for induction (2.03+/-0.41 mg/kg, *P*: 0.01) with fentanyl than dexmedetomidine (1.40+/-0.48 mg/kg) have been observed for lumbar laminectomy cases.[23] Moreover, dexmedetomidine pre-treatment also reduces the half-maximal effective concentration (EC50) of propofol for SGAD insertion without muscle relaxants thereby decreasing the total requirement of propofol.[11,24]

Both the study drugs resulted in reduction of MAP. However, in both groups this reduction from baseline was not statistically significant. This was in contrast to findings by Uzumcugil *et al*. who reported significant fall after loading infusion of drugs over 2 minutes, which could be due to more rapid rate of drug administration in their study.[6]

MAP after propofol induction was significantly lower in group F than group D. Similar findings of greater fall of MAP with fentanyl than with dexmedetomidine have been published in literature.[6,10] Propofol when used for induction in a dose of 2.0–2.5 mg/kg decreases mean blood pressure due to its vasodilatory and myocardial depressing effects[25] which can be further potentiated by co-induction with fentanyl.[26,27] The reduction in MAP after fentanyl-propofol was well tolerated by prehydrated, ASA I-II patients in this study however precaution is needed in elderly/debilitated patients. With dexmedetomidine –propofol there was 5.6% decrease from baseline in present study which is akin to 6.3% decrease in MAP after dexmedetomidine-propofol for LMA insertion.[11] Although dexmedetomidine can cause dose dependent decrease in arterial BP due to decrease in serum norepinephrine concentrations and inhibition of sympathetic outflow from the brainstem- the locus coeruleus, pre-treatment with dexmedetomidine is reported to attenuate the decrease in blood pressure during propofol induction.[11] Pre-administration of dexmedetomidine in the dose of 1 μg/kg also reduces the frequency of hypotensive episodes before and after i-gel® insertion.[24]

We recorded a greater percentage decrease from baseline in heart rate with dexmedetomidine. The sympatholytic and preserved baroreflex effects of dexmedetomidine cause dose dependent decrease in heart rate during anaesthesia.[17] In a previous study, a loading dose of 1 μg/kg dexmedetomidine was closely associated with bradycardia from 5 min after dexmedetomidine administration to the peri-insertion period of i-gel®.[24] In this study clinically significant bradyacardia necessitating pharmacological intervention did not occur in any patients. Even in the laparoscopic surgeries, when haemodynamic response of dexmedetomidine and fentanyl was compared, the difference of heart rate from baseline was not statistically significant after ten minutes of either drug.[25]

Dexmedetomidine in a dose of 1 μg/kg is previously reported to blunt the sympatho-adrenal responses to i-gel® insertion[24] while fentanyl 1 μg/kg did not suppress sympatho-adrenal response to LMA insertion adequately.[3,6] Even 0.5 μg/kg Dexmedetomidine may be more effective than 1 μg/kg Fentanyl in maintaining haemodynamic stability during extubation.[27] This study found more effective attenuation of pressor response to I gel insertion following 1 μg/kg of dexmedetomidine as compared to fentanyl.

In the present study, the incidence and mean duration of apnoea was significantly more with fentanyl ($P < 0.01$) than with dexmedetomidine. Higher incidence of apnoea could also be due to more additional boluses of propofol required in fentanyl group.Incidence and duration of apnoea after induction with propofol is dependent upon the dose, speed of injection, and concomitant premedication and is known to be potentiated by opioids.[23] Apnoea with dexmedetomidine was recorded in our patients who required additional supplements of propofol for i-gel® insertion. The mechanism of sedation by dexmedetomidine is similar to natural sleep with minimal effects on respiration and ventilation.[15] Dexmedetomidine does not potentiate respiratory depression caused by propofol. This could be the reason for shorter mean duration of apnoea observed with dexmedetomidine as compared to fentanyl. However, a few authors have reported statistically

significant increased respiratory rates and apnoeic episodes after dexmedetomidine infusion of 1 μg/kg over two minutes.[6,15] Such rapid infusion of dexmedetomidine in human volunteers increased plasma concentrations of the drug to levels that caused irregular breathing with mild hypercapnia,[15] which may be the possible explanation of increased respiratory rate found in these studies. We did not experience any significant change in respiratory rates with 1μg/kg dexmedetomidine when infused over ten minutes. Though the respiratory rate decreased after fentanyl infusion, it was not clinically significant, and no patient developed bradypnoea or desaturation.

Various studies in the previous literature have used varied doses and rates of dexmedetomidine and fentanyl as a pre-treatment for propofol induction for SGAD insertion. In this study we found that pre-treatment with dexmedetomidine at 1 μg/kg intravenously infused over ten minutes prevented overt bradycardia and hypotension, decreased the number and duration of apnoeic episodes and provided satisfactory i-gel® insertion conditions with decreased consumption of propofol. Hence, dexmedetomidine may be a suitable co-induction agent with propofol for i-gel® insertion without neuromuscular blockade.

This study has certain limitations. A control group with propofol alone was not included. Since propofol has several times been reported to be inadequate for SGAD insertion when used alone and higher doses can be unsafe for respiration and haemodynamics, propofol control group was thought to be unethical. Another limitation is that the depth of anaesthesia at the time of i-gel® insertion was only assessed clinically and no specific monitor was used due to non-availability. BIS/Entropy would have been more clinically suitable to assess the level of awareness during airway manipulation. This study was conducted in patients with MMT I and II. Further studies are required to assess the effect of pre-treatment of these drugs on i-gel® insertion condition in patients with higher MMT or difficult airway.

CONCLUSION

Pre-treatment with 1 μg/kg of dexmedetomidine or fentanyl along with propofol provided satisfactory and comparable insertion conditions for i-gel®.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Ethics committee approval

Yes.

Institute

Clinical trial registry number

CTRI/2017/06/008928.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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