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COMPARISON OF INJ. DEXMEDETOMIDINE AND PROPOFOL WITH INJ. FENTANYL AND PROPOFOL FOR SEDOANALGESIA IN COLONOSCOPY.

Anaesthesiology

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ABSTRACT

Background: Colonoscopy is one of the standard procedures for the diagnosis of the lower gastrointestinal system. The growing popularity and trends of day care anaesthesia has led to development of newer and efficient drug regimen. **Aims**: Our aim is to evaluate the efficacy of two drug regimens namely Dexmedetomidine and Propofol with Fentanyl and Propofol for sedo-analgesia in colonoscopy in terms of analgesia, intra-operative sedation, haemodynamic stability and side effects related. **Material and Methods:** 80 patients aged between 18-70 years with ASA physical status I-III undergoing elective colonoscopy were allocated in two groups. Group DP patients received 1 mcg/kg Dexmedetomidine over 10 minute, followed by 1 mg/kg Propofol iv. Group FP patients received 1 mcg/kg Fentanyl slow bolus, followed by 1 mg/kg Propofol. Propofol rescue doses 0.5mg/kg were administered if patient showed discomfort in both groups. The respiratory –haemodynamic data, pain and sedation score during the procedure evaluated by VAS and Ramsay sedation score. Recovery time in both groups were also compared. **Results:** Mean heart rate, systolic and diastolic blood pressure during procedure were lower in DP group as compared to FP group and difference was statistically significant (p value < 0.05). Differences in Mean sedation score (DP vs FP, 4.1 vs 4.25) and mean total rescue propofol dose(DP vs FP, 29.87 vs 24.25) were not statistically significant. There was significant difference in both groups in terms of VAS at 0 and 15 min. Mean recovery time was lesser in DP group as compared to FP group and difference was statistically significant (p value < 0.05). **Conclusion:** In our study, we found both groups suitable for safe sedation during colonoscopy procedures. Better pain control and early recovery in dexmedatomidine and propofol group is advantageous. However, it causes significant hypotension. Hence, the anesthesiologist must be aware to choose sedation regimen, respecting the patient's physical status and medical history.

KEYWORDS

sedoanalgesia, colonoscopy, dexmedetomidine

Colonoscopy is one of the standard procedures for the diagnosis, screening, treatment and follow up for many colorectal diseases. Anxiety of the patient is high and air insufflations into bowel causes pain during procedure(1). The purpose of sedation and analgesia is to relieve patient anxiety, discomfort and improve the outcome of endoscopic procedure(2). The air that remain in bowel after colonoscopy causes abdominal distension and abdominal pain. The achievement of safe and effective sedation for many endoscopic procedures remains a top priority for clinical gastro-enterologists and contribute to superior patient satisfaction, comfort and willingness to undergo repeat procedure(3). Although some studies recommend that the colonoscopy procedure can be performed without sedation, various other studies have reported this is not possible and that sedation administration before the procedure is safer for both patient and colonoscopist(4,5,6). Early recovery and mobilization of the patient is necessary to get rid of pain, therefore sedo-analgesics with short duration of action are also preferred for early mobilization(7). Doctors performing colonoscopy screenings through out the world tend to prefer sedo-analgesia. Midazolam, Propofol and/or Alfentanil or Pethidine combinations, alpha – agonists and neuroleptics are used for sedation-analgesia(8,9).

Propofol is a general anesthetic that is frequently used for sedation in colonoscopy with its rapid onset and termination of action. Propofol does not have pain relief effect and is recommended to be used with an adjuvant agent to reduce its side effects like respiratory depression, hypoxia and hypotension(10). Fentanyl is a synthetic opioid agonist being increasingly used for sedation and analgesia. Dexmedetomidine, a short acting alpha 2 agonist, has anxiolytic, anaesthetic, hypnotic and analgesic properties without causing respiratory depression and retains the response to verbal commands.

In our study, we aimed to evaluate and compare the clinical efficacy and safety of combination of Dexmedetomidine-propofol and Fentanyl-propofol on sedo-analgesics for colonoscopy on hemodynamics, visual analog scores (VAS), RSS and recovery of patients.

MATERIALS AND METHODS

After obtaining the ethical committee's approval and the patient's written informed consents this prospective and randomized double blind study included total of 80 patients between 18 – 70 years of ASA I-III scheduled for elective colonoscopy screening. Exclusion criteria included gastrointestinal haemorrhage, known or predicted airway difficulty, pregnancy, alcohol or drug addiction, neuropsychiatric disease, sever heart or respiratory insufficiency and sedative drug allergy. Pre procedure evaluation of all patients were done. No sedative premedication was administered. Patients were kept fasting for atleast 8 hours. After patients were taken to the endoscopy ot, intravenous catheterization was performed with 20 G iv catheter and RL infusion was started. All patients were monitored with NIBP, ECGs and SPO2. Patients received 7L/min oxygen via face mask. Based on closed envelope method patients were divided into two groups of 40 patients each: The Group DP patients received inj. Dexmedetomidine 1 mcg/kg as an iv infusion over 10 min followed by 1 mg/kg propofol and Group FP patients received inj. Fentanyl 1 mcg/kg slow iv bolus followed by 1mg/kg propofol in lateral position. After the beginning of colonoscopy, patients' scores were limited to 4-5 values on the Ramsay Sedation Scale (RSS) by 0.5mg/kg bolus additional doses of propofol in sedation-analgesia maintenance. Parameters like heart rate (HR), Blood pressure (BP), oxygen saturation (SPO2) and RSS were recorded before the procedure (at baseline) then every 5 min after induction during procedure.

Colonoscopy duration is the time from induction to the end of colonoscopy procedure. The recovery time was the time from induction until the RSS scores progressed to value 2. Pain was assessed by VAS scores at 0 min, 15 min and 30 min in recovery unit(0: no pain, 10: intolerable pain). We recorded total propofol dosage and complications such as allergic reactions, bradycardia, tachycardia, hypotension, hypertension, respiratory depression, desaturation, nausea and vomiting. Desaturation was defined as the decrease of oxygen saturation to below < 90%. Apnea or desaturation was managed by Jaw thrust maneuver or manually ventilating the patient. Adverse events such as hypotension (defined as systolic BP <90

mmHg) were treated with fluid bolus and injection ephedrine 6 mg iv. bolus. Bradycardia (heart rate <40/min) was treated with injection atropine 0.6 mg iv. bolus.

RESULTS: The two groups were comparable in terms of age, sex distribution, weight, ASA status(Table 1). There was no significant difference between two groups in terms of duration of procedure. (Table 1)

Table 1: Demographic Data & clinical details

CHARACTERISTICS	GROUP DP (n=40)	GROUP FP (N=40)	P value
AGE (years) MEAN±S.D.	43.85±13.620	45.8±12.0	0.4989(NS)
WEIGHT (kg) MEAN±S.D.	60.4±8.3291	57.375±9.768	0.1402(NS)
SEX F/M	21/19	18/22	-
ASA(I/II/III)	21/18/1	18/20/2	-
PROCEDURE TIME (min)	23.28125±4.685	24.30556±5.497	0.3725(NS)

The mean baseline heart rate were comparable and statistically non-significant among both study groups(DP vs FP, 87.825±11.014 vs 85.225±15.185, P value 0.3834) The mean heart rate at 5, 10, 15 and 20 minutes respectively was less in DP group 75.125±13.437, 76.25±10.541, 74.125±8.231 and 72.425±9.015 respectively as compared to FP group 85.575±16.693, 84.225±17.433, 81.45±13.572 and 80±16.270 . The difference between mean heart rate of two groups was statistically significant at 5 min (P value- 0.0028), 10 min (P value – 0.0155), 15 min (P value – 0.0046) and at 20 min (P value – 0.0119) (Figure 1)

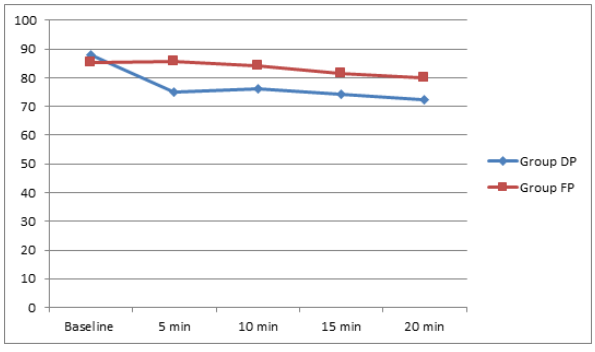

Figure 1 : comparision of heart rate between both groups.

The mean baseline and at 5 min Systolic blood pressure were comparable and statistically non-significant among both study groups (DP vs FP, 131.95±10.122 vs 133.925±15.794, P value 0.9064 and at 5 min 122.075±11.067 vs 124.625±13.073, P value 0.1335) The mean systolic blood pressure at 10, 15 and 20 minutes was respectively less in DP group 111.975±10.044, 117.1±11.801 and 116.425±8.199 respectively as compared to FP group 117.625±14.001, 123.825±12.516, 121.875±12.461. The difference between mean systolic blood pressure of two groups was statistically significant at 10 min (P value – 0.0414), 15 min (P value – 0.0224) and 20 min (P value – 0.0235) (Figure 2)

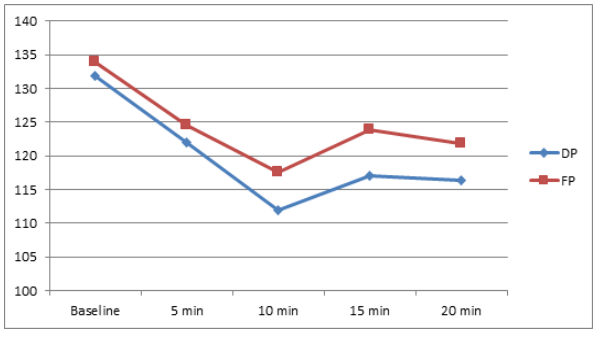

Figure 2: comparision of systolic blood pressure between both groups.

The mean baseline and at 5 min Diastolic blood pressure were comparable and statistically non-significant among both study groups (DP vs FP, 79.425±8.533 vs 82.1±9.156, P value 0.1804 and at 5 min 76.95±8.301 vs 79.075±9.474,P value 0.1157). The mean diastolic blood pressure at 10, 15 and 20 minutes was respectively less in DP group 71.875±7.122, 76.725±9.128 and 76.775±8.100 respectively as compared to FP group 75.925±10.356, 82.8±10.203, 82±11.293. The difference between mean diastolic blood pressure of two groups was statistically significant at 10 min (P value – 0.045), 15 min (P value – 0.0104) and 20 min (P value – 0.0199) (Figure 3)

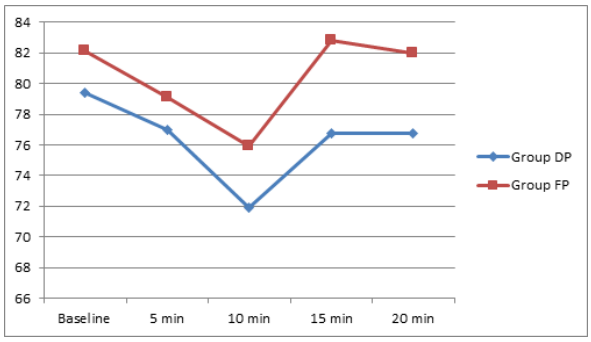

Figure 3: comparision of diastolic blood pressure between both groups.

Spo2 < 90% was observed in both groups following administration of the drugs (Group DP= 27.5%, Group FP= 35%), but the difference between the groups was not significant (P value - 0.25). Mean RamSay Sedation Score in DP group was 4.1±0.841 vs in FP group was 4.25±0.926 which was statistically not significant. (P value 0.450). Mean total rescue propofol dose of group DP was 29.875±13.130 while in group FP it was 24.25±17.414. Difference was not statistically significant (P value – 0.1069). Regarding VAS, it was significantly less in DP group compared to FP group at 0 min and 15 min post procedure. However after 30 min, it was comparable between both groups(Table 2)

Table 2: Visual Analog Scale for post procedural pain

VAS	GROUP DP	GROUP FP	P VALUE
0 min	1.675±0.7298	2±0.3922	0.0153 (S)
15 min	2.55±0.5523	2.8±0.4640	0.0314(S)
30 min	3.3±0.6076	3.55±0.6385	0.0767(not quite significant)

Mean recovery time was lesser in DP group 7.875±1.963 as compared to FP group 8.7±1.488 and difference was statistically significant. (P value- 0.0374)

DISCUSSION:

In our clinical study, we compared the efficacy of Dexmedetomidine and Fentanyl, used as an adjuvant agent together with propofol during colonoscopy, on hemodynamic, sedation, and recovery time. We compared total rescue propofol dose and VAS also in 80 patients.

The two groups were thus comparable in terms of age, weight, sex distribution, ASA status and mean baseline hemodynamic and respiratory parameters.

Propofol has limited analgesic effect and higher doses are often required, when it is used as a single agent for colonoscopy, resulting in higher sedation levels. Thus, the use of propofol in combination with other agents may be preferable to propofol alone(11). Chiung-Dan et al. detected a significant difference between the two groups in terms of hemodynamic and propofol consumption in their study in which they used propofol alone and in combination with fentanyl-midazolam in colonoscopy sedation. They concluded that, using the combination drugs in lower doses as 25-50 mcg of fentanyl and 1-2 mg of midazolam, significantly decreases the consumption of propofol while increasing patient safety. In this study, propofol was given by infusion as different from our study(12,13).

The mean heart rate, systolic blood pressure and diastolic blood pressure during the procedure was less in DP group as compared to FP group. Hypotension and bradycardia have been reported in dexmedetomidine infusion, particulary with high bolus dosing regimens, on patient with pre-existing cardiac problems and a loading dose infusion given over 10 min (14,15,16). Our results also correlate

well with the study of Ragab A et al (17), who compared the effects of dexmedetomidine/morphine/propofol with benzodiazepines/ morphine/propofol as adjuncts to local anaesthesia during rhinoplasty – on analgesia, sedation, respiratory and hemodynamics variables and surgeon and patient satisfaction. Intraoperative mean arterial blood pressure and heart rate in dexmedetomidine group were lower than their baseline values and corresponding values in midazolam group.

Dexmedetomidine is also associated with decrease in heart rate because of its sympatholytic effect which is similar to the other sedatives and baroreflex effect after vasoconstricton(18). Kaygusuz compared the sedation with dexmedetomidine 1mcg/kg followed by 0.2mcg/kg/hr or propofol 1 mg/kg followed by 2.4mg/kg/hr during shockwave lithotripsy combined with fentanyl 1 mcg/kg and reported no significant difference in heart rate values during sedation and recovery but the heart rates in each group decreased from baseline(19). In our study, decrease in heart rate was significantly different between both groups.

Decrease in blood pressure following dexmedetomidine therapy than the baseline values and corresponding values in Midazolam-Fentanyl therapy($p<0.05$) during tympanoplasty was noticed by Parikh DA et al (20)

Dexmedetomidine is unique in that it does not cause respiratory depression because its effects are not mediated by the gamma –amino butyric acid system. The percentage of fall in spo2 were statistically insignificant in both the groups similarly in accordance with studies conducted in past where respiratory endpoints were unchanged in both groups throughout the entire study period(20,21).

In present study, Ramsay Sedation Scores were equal in the both groups during the procedure and the differences was statistically insignificant(p 0.4508). Study done by Dere Ket al(22), who concluded that RSS in dexmedetomidine group were significantly higher than the midazolam/Fentanyl group at 10 and 15 min in patients undergoing colonoscopy under conscious sedation.

All patients were arousable on command in group DP. Shorter recovery time was observed in group DP than group FP (p value 0.0374) in our study. Similar result was observed by T.Nisar, S.A. Zahoor et al(2). They have reported recovery time was lesser in DP group as compared to FP group (DP vs FP 8.7±1.4 min vs 10.56±1.6 min). Ryu JH et al(23) recorded a recovery time of 18.4 min in the dexmedetomidine propofol group. Unlike our study they have used maintenance dose of dexmedetomidine after a loading dose of dexmedetomidine.

Need for rescue mean propofol dose was lower in FP group in our study but difference was not statistically significant. (p value 0.1069). In contrast, Ali AR et al(24) in their study reported that propofol/ dexmedetomidine combination was accompanied with less propofol consumption, prolonged analgesia and lower incidence of intraprocedural and postprocedural complications compared to propofol/fentanyl group.

CONCLUSION:

Dexmedetomidine is better adjuvant then fentanyl when combine with propofol as it provides moderate sedation better post procedure analgesia and also enhance early recovery post colonoscopy.

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