http://doi.org/10.48165/ijabms.2021.23116

16

A comparison of dexmedetomidine versus midazolam - Fentanyl for sedoanalgesia and stable hemodynamic parameters, during colonoscopy under Monitored Anesthesia Care. (MAC)

Dr. Shweta Patel (Resident in Anesthesia, NHLM Medical college, Ahmedabad)
Dr. Manisha kapdi (Associate professor of anesthesia, NHLM Medical college, Ahmedabad, Gujarat)
manisha_kapdi@yahoo.com

Corresponding author: Dr. Manisha Kapdi
Correspondence: manisha_kapdi@yahoo.com

Abstract:

Background:
colonoscopy is routinely done under local anesthesia but it is stressful. Nowadays concept of conscious sedation or monitored Anesthesia care with mild sedoanalgesia is getting popular.

Aim& Objective:
The aim of our study was to compare the effects of dexmedetomidine versus midazolam Fentanyl combination on perioperative hemodynamics, sedation, pain, satisfaction and recovery scores during colonoscopy.

Study design: Randomized comparative observational study

Material and methods:
A total of 60 adult patients of ASA grade l/ll were included in the study. Patients were randomly allocated to two groups.
In Group A Midazolam 0.02 mg/ kg and fentanyl citrate 1 mcg/ kg were administered intravenously followed by 0.5 ml/ kg/ hr. of Normal saline.
In Group B An initial loading dose of 1 mcg/ kg dexmedetomidine was administered intravenously in 10 min to cases before the procedure and followed by continuous infusion dose of 0.5 mcg/ kg /hr.
Incremental dose of 1 mcg/ kg fentanyl citrate was administered intravenously immediately before the procedure. Peripheral oxygen saturation (SpO_2), mean arterial pressure (MAP), heart rate (HR), Ramsay Sedation Scale (RSS), Numeric Rating Scale (NRS) scores and colonoscopist satisfaction scores of the cases were recorded.

Results:
Although statistically significant values were not detected between the two groups with regard to mean arterial pressure.
In Group I heart rates were higher and Spo_2 scores were lower in a statistically significant manner. When the groups were compared with regard to RSS, the RSS scores of Group A at the 10th and 15th minutes were significantly lower than Group B. There was no statistically significant difference between the two groups when compared with regard to NRS scores. Satisfaction scores were significantly lower in Group B.

Conclusion:
Dexmedetomidine provides more efficient hemodynamic stability, higher Ramsay sedation scale scores, higher satisfaction scores and lower NRS score. So dexmedetomidine can be used safely as a sedoanalgesic agent.

Keyword: dexmedetomidine versus midazolam, Fentanyl for sedoanalgesia, stable hemodynamic parameters, colonoscopy, Anesthesia Care, Monitored Anesthesia Care. (MAC)

Introduction

Colonoscopy is done as diagnostic and therapeutic procedure. Although some patients can tolerate colonoscopy procedure without any sedoanalgesia, it is a distressful procedure for most patients. As a result, different techniques have been developed to increase patient comfort.
Conscious sedation is the one most frequently used. This method combines a suitable opioid analgesic and benzodiazepine and is one of the most efficient methods.[1,2]
Midazolam is most frequently used for agent for conscious sedation. It has a fast onset time for sedative effects and a fast recovery period. But the half-life of its active metabolite is long. With repeated dosages it results in prolonged sedation and a sleepy state;[3] also it can result in respiratory depression by decreasing respiratory response to carbon dioxide.[4] Thus pharmacological agents with minimal adverse effects should be investigated for this purpose.
Dexmedetomidine is a highly selective a_2-adrenoreceptor agonist with sedative and analgesic effects.[5,6] Its preferred potential effects are decrease in need for other anesthetics and analgesic drugs with which it is combined; decrease in stress-induced sympathetic response; and a cardiac protective effect against myocardial ischemia. It also has minimal adverse effects on respiratory functions.[7,8,9] Hsu et al.[10] have proved that dexmedeto-midine is well tolerated for respiratory functions even at high plasma dosages.

Because of these positive effects, it is a drug, which can be used in conscious sedation. Dexmedetomidine can also result in hypotension and bradycardia because of its sympatholytic effects.[11]
In our study, we compare the effects of dexmedetomidine and midazolam on perioperative hemodynamics, sedation, pain, satisfaction and recovery scores during colonoscopy.

Material and methods:

60 adult patients of ASA grade I/II were enrolled for elective colonoscopy procedure were included in this Retrospective, randomize observational study. After a detailed explanation of the colonoscopy procedure, an informed consent was obtained from all participants.

Respiratory stability	
-Able to take deep breath and cough	2
-Dyspnea/shallow breathing	1
-Apnea	0
Oxygen saturation	
-Maintain value >92% on room air	2
-Needs o2 inhalation to maintain oxygen saturation >90%	1
-o2saturation <90% even with supplemental oxygen	0
Coniousiousness	
-Fully awake	2
-arousable on calling	1

Observations& Results:

The exclusion criteria were:

ASA physical status III-IV; age less than 20 years or more than 80 years; allergy to any of the drugs like midazolam, opioids and dexmedetomidine; history of chronic alcoholism, sedative and narcotic analgesic drug abuse; cardiovascular disease such as aortic and mitral stenosis, arrythmia or congestive heart failure; liver or renal insufficiency; uncooperative patient, serious illness or hipovolemia.

The cases were randomly assigned to two groups by picking arbitrary numbers from a bag as Group I for midazolam and Group II for dexme-detomidine. Standard monitorization (electrocardiogram, pulse oximetry and non-invasive blood pressure with 5-min intervals) and IV line secured.

In Group A continuous dose of 0.1 ml /kg /hr saline. infusion was started 10 min before the procedure and continued through the procedure. Immediately before the procedure 0.05 mg/ kg IV Midazolam and 1 mcg /kg IV fentanyl citrate were given.

In Group B a bolus dose of 1 mcg/ kg dexmedetomidine infused intravenously through syringe pump in 10 min starting 10 min before the procedure. And in the beginning of the procedure a continuous infusion dose of 0.5 mg/ kg /h was started. Also 1 mcg /kg fentanyl citrate was administered intravenously just before the procedure In both group.The cases were taken into the endoscopy room without any premedication and during the procedure they were monitored with electrocardiography, non-invasive blood pressure and pulse-oximetry After the procedure, all cases were observed until the Aldrete score reached 9 or over 9 (Table 1).[12]

During and after the procedure the patients were observed by anesthesiologists who were blinded to the treatment. oxygen saturation (SpO_2), mean arterial pressure (MAP) and heart rate (HR) were recorded both before and after completion of the study in consecutive 5-min intervals in both groups.

Both in the beginning and after completion of the colonoscopy procedure the 'Ramsay Sedation Scale'[13] (RSS) (Table 2) scores and 'Numeric Rating Scale' (NRS) (0 - no pain, 100 -worstpain imaginable)[14] scores that rate the pain were recorded in 5-min intervals consecutively. During the colonoscopy procedure, it was planned to administer an additional dosage of 0.01 mg kg^1 intravenous (i.v.) midazolam to patients with an RSS score of 1. It was also planned to administer0.01 mg/ kg intravenous (i.v.) fentanyl to cases who rated their NRS score 50 or over 50. The complications observed both during the colonoscopy procedure and after the procedure (apnea, cough and abnormal motions) were also recorded. Apnea was defined as not having a spontaneous breath for at least 20 s. The satisfaction level after the procedure was evaluated as good (1), intermediate (2) and worse (3) by Linkert scale.

Statistical analysis

All statistical analyses were performed with the SPSS software IBM Armonk NY USA version 16. qualitative data analysis by Student t-test; categorical data analysis by Mann -Whitney U test.

Table 1

Respiratory stability	
-Able to take deep breath and cough	2
-Dyspnea/shallow breathing	1
-Apnea	0
Oxygen saturation	
-Maintain value >92% on room air	2
-Needs o2 inhalation to maintain oxygen saturation >90%	1
-o2saturation <90% even with supplemental oxygen	0
Coniousiousness	
-Fully awake	2
-arousable on calling	1

Table 2 Ramsay Sedation Scale

Level 1 Patient anxious and agitated or restless or both

Level 2 Patient cooperative, orientated, and tranquil

Level 3 Patient responds to commands only

Level 4 Patient that demonstrates a brisk response to light glabellar tap or loud auditory stimulus

Level 5 Patient that demonstrates a sluggish response to a light glabellar tap or loud auditory stimulus Level 6 No response

Table 3 Demographics

Parameters	Group A	Group B	P value	Interference
Age(years)	59.6+/-8.5	57.6+/-7.2	>0.05	NS
Weight(kg)	68.2+/-11.2	67.4+/-12.3	>0.05	NS
Sex(M/F)	22/8	21/9	>0.05	NS
ASA grade(I/II)	15/15	16/14	>0.05	NS
Duration of procedure (mins)	20.7+/-1.4	19.2+/-2.6	>0.05	NS
Time to reach Alderte score 9	12.2+/-0.3	11.6 +/-0.7	>0.05	NS
Satisfaction score	2.2+/-0.2	1.5+/-0.3	<0.05	S

Results

Demographics were comparable in both groups. (Table 3).

In Group A, a significant statistical decrease was found with regard to mean arterial pressure values at the onset of the study and at the 5th minute ($P < 0.05$). Changes in MAP were similar between the groups throughout the study (Fig. 1).

Heart rates at 5th and 10th minutes in Group B were significantly lower when compared with Group I ($P<0.05$) (Fig. 1).

There was a statistically significant difference between the Spo_2 scores at the 5th and 10th minutes. SpO_2 scores of Group A were lower (Fig. 1) ($P<0.05$).

RSS scores of Group A at 10th and 15th minutes were significantly lower compared with Group B ($P < 0.05$) (Fig. 2). The NRS scores in Group Awere lower than Group B. There was not a statistically significant difference regarding NRS scores between the two groups (Fig. 3).

In Group A seven cases needed an additional midazolam dosage. An additional fentanyl dosage was administered to four cases in Group I and also four cases in Group B. There were not any complications (). The, apnea, abnormal movements) in either case. No statistically significant difference was found between the two groups with regard to reaching the Aldrete 9 score. There was a statistically significant difference with regard to satisfaction scores of the groups; the scores of Group B were lower ($P < 0.05$).

Discussion

The most suitable agents for conscious sedation during endoscopic procedures are still being investigated. Studies investigating dexmedetomidine have also increased in number.

Demiraran et al.[15] in their study investigated and compared dexmedetomidine versus midazolam with regard to hemodynamics, sedation, and satisfaction scores in gastroscopies have found similar hemodynamic and sedation scores in both of the groups. They have evaluated sedation with a four-point somnolence score, which is different from our study. They have observed statistically significant high satisfaction levels in the midazolam group compared with the dexmedetomidine group (respectively 90, 1 3, 0 and 84, 9 4, 5). Although in our study, we did not observe a statistically significant difference between the two groups with regard to MAP and NRS scores; we did observe a statistically significant difference with regard to HR, SpO_2, Ramsay sedation and satisfaction scores.

In our study, we found higher RSS scores in the dexmedetomidine group compared with the midazolam group. Different from the study of Demiraran et al.,[15]

Regarding haemodynamics, we assumed that differences in our hemodynamic values had resulted from the higher dose dexmedetomidine infusion dosage (0,5 mg /kg /hr.) we had used compared with the dosage (0,2 mg /kg /hr) used in the study of Demiraran et al.[15]

Jalowiecki et al.[16] in their study comparing dexmedetomidine versus midazolam and fentanyl in colonoscopies observed a statistically significant decrease in the HR (in two cases 40 beats/minute) and MAP (in four cases a 50% decrease in initial scores) in the dexmedetomidine group. In the dexmedetomidine group, 47% of the cases required additional fentanyl; they reported vertigo in five cases, nausea and vomiting in five cases, and bigemini ventricular extrasystole in one case. In our study, we did not detect a significant clinical difference in hemodynamics in the dexmedetomidine group. Also, we did not find any complication in either of the groups. This difference would have resulted because of the higher number of ASA II cases (75%) in the study of Jalowiecki et al.[16] compared with our number of ASA II cases (50%).

Seybold et al.[17] had reported efficacious usage of propofol and dexmedetomidine combination during laryngoscopy and broncoscopy in two cases without leading to cardio respiratory depression and also providing adequate anesthesia. Uzumcugil et al.[18] compared propofol and fentanyl combination versus propofol and dexmedetomidine combination during laryngeal mask insertion and reported that MAP alteration and respiratory function alteration were lower in the dexmedetomidine group. They did not report any complication in any group. In our study, we have also reported less alteration in hemodynamic parameters in the dexmedetomidine group and have not reported any complications in either group.

Zeynologˇ lu et al.19 had compared the effects on recovery periods in cases treated with extracorporeal shock wave lithotripsy sedated with dexmedetomidine and midazolam and fentanyl combination and had observed prolonged recovery periods in the dexmedetomidine group.

We observed no difference between the dexmedetomidine group and the midazolam group with regard to recovery periods. This difference between these two studies may have resulted from the shorter mean duration of the colonoscopies in our study (20 min) compared with the mean duration (40 min) of extracorporeal shock wave lithotripsy. From this assumption, we can reach the hypothesis of a prolonged recovery time with increases in dexmedetomidine infusion. But this hypothesis should be validated and supported with prospective studies.

In conclusion, dexmedetomidine in colonoscopies, provide stable haemodynamics, higher Ramsay sedation and endoscopist satisfaction scores and lower NRS scores.

In nutshell dexmedetomidine is a good sedoanalgesic, which may come to be preferred and used efficiently in colonoscopies as compared to routine benzodiazepine opioid combination (Midazolam- Fentanyl)

References

1 Wong RCK. The menu of endoscopic sedation: all-you-can eat, combination set, a la carte, alternative cuisine, org o hungry. Endoscopy 2001; 54:122-126.

2 Ozel AM, Oncu K, Yazgan Y, et al. Comparison of the effects of intravenous midazolam alone and in combination with meperidine on hemodynamic and respiratory responses and on patient compliance during upper
gastrointestinal endoscopy: a randomized, double-blind trial. Turk J Gastroenterol 2008; 19:8-13.

3 Gan TJ. Pharmacokinetic and pharmacodynamic characteristics of medications used for moderate sedation. Clin Pharmacokinet 2006; 45:855-869.

4 Robin C, Trieger N. Paradoxical reactions to benzodiazepines in intravenous sedation: a report of 2 cases and review of the literature. Anesth Prog 2002; 49:128 -132.

5 Aantaa R, Scheinin M. Alpha -2- adrenergic agent in anaesthesia. Acta Anesthesiol Scand 1993; 37:1-16.

6 Venn M. Preliminary UK experience of dexmedetomidine, a novel agent for postoperative sedation in the intensive care unit. Anaesthesia 1999; 54:1136-1142.

7 Kamibayashi T, Maze M. Clinical uses of alfa2-adrenergic agonists Anesthesiology 2000; 93:1345-1349.
8 Taittonen MT, Kirvela OA, Aantaa R, Kanto JH. Effect of clonidine and dexmedetomidine premedication on perioperative oxygen consumption and haemodynamic state. Br J Anaesth 1997; 78:400 -406.
9 Wijeysundera DN, Naik JS, Beattie WS. Alpha-2 adrenergic agonists to prevent perioperative cardiovascular complications: a meta-analysis. Am J Med 2003; 114:742-752.
10 Hsu YW, Cortinez LI, Robertson KM, et al. Dexmedetomidine pharmacodynamics: Part I, Crossover comparison of the respiratory effects of dexmedetomidine and remifentanil in healthy volunteers. Anesthesiology 2004; 101:1066-1076.
11 Bloor BC, Ward DS, Belleville JP, Maze M. Effects of IV dexmedetomidine in humans: II. Hemodynamic changes. Anesthesiology 1992; 77:1134-1142.
12 Aldrete JA. The postanesthesia recovery score revisited. J Clin Anesth 1995; 7:89 -91.
13 Ramsay MAE, Savage TM, Simpson BRJ, Goodwin R. Controlled sedation with alfaxolone-alphadolone. BMJ 1974; 2:656-659.
14 Gould D. Examining the validity of pressure ulcer risk assessment scales: developing and using illustrated patient simulations to collect the data. J Clin Nurs 2001; 10:697-706.
15 Demiraran Y, Korkut E, Tamer A, et al. The comparison of dexmedetomidineand midazolam used for sedation of patients during upper endoscopy: a prospective, randomized study. Can J Gastroenterol 2007; 21:25-29.
16 Jalowiecki P, Rudner R, Gonciarz M, et al. Sole use of dexmedetomidinehas limited utility for conscious sedation during outpatient colonoscopy. Anesthesiology 2005; 103:269-273.
17 Seybold JL, Ramamurthi RJ, Hammer GB. The use of dexmedetomidine during laryngoscopy, bronchoscopy, and tracheal extubation following tracheal reconstruction. Paediatr Anaesth 2007; 17:1212-1214.
18 Uzumcugil F, Canbay O, Celebi N, et al. Comparison of dexmedetomidine-propofol vs. fentanyl-propofol for laryngeal mask insertion. Eur J Anaesthesiol 2008; 25:675-680.
19 Zeynelog˘ lu P, Pirat A, Candan S, et al. Dexmedetomidine causes prolonged recovery when compared with midazolam/fentanyl combination in outpatient shock wave lithotripsy. Eur J Anaesthesiol 2008; 25:961-967.

Conflict of Interest:

Nil

Funding:

Nil

Acknowledgement:

Nil