Archives of Anesthesiology and Critical Care (Autumn 2023); 9(Supplement 1): 439-443.

Available online at http://aacc.tums.ac.ir

Research Article

The Comparison of Deep Sedation and Moderate Sedation in Pneumatic Balloon Dilation of Achalasia Patients

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ARTICLE INFO

Article history:
Received 07 November 2022
Revised 28 November 2022
Accepted 13 December 2022

Keywords:
Achalasia;
Deep sedation;
Moderate sedation

ABSTRACT

Background: Pneumatic Balloon Dilation (PBD) as an achalasia treatment is painful procedure because of tearing the lower esophageal sphincter (LES) muscle fibres. Recently, two sedation methods including the moderate sedation and deep sedation are used for increasing the convenience of the patients and gastroenterologist.
Methods: To compare the efficacy of moderate and deep sedation in PBD in treatment of Idiopathic Achalasia (IA).
Results: We prospectively assessed 200 IA patients. The first 100 patients (group A) underwent PBD by the moderate sedation using diazepam or midazolam and meperidine injections. The patients in the group B (100 patients) received midazolam, fentanyl and propofol as a deep sedation. The pulse rate (PR), systolic and diastolic blood pressure (SBP, DBP), respiratory rate (RR), and oxygen saturation were monitored before, during and after PBD and achalasia symptom scores (ASS) were collected before and 1.5 months after treatment.
The mean PR during and after procedures in the group B were significantly lower compared to the group A (p 0.001, 0.028). The patients in group B revealed less SBP and DBP after PBD versus group A (p 0.004, 0.002). The mean psi for 30 mm and 35 mm balloon dilators were significantly increased in group B compared to group (p 0.0001, 0.002).
Conclusion: We concluded that the deep sedation of achalasia patients in the PBD process can improved the efficacy of PBD and decreased the complications (transient chest pain) of the procedures. The patients with the deep sedation revealed less tachycardia and blood pressure rising and tolerated more pressure in balloon dilators.

Introduction

Achalasia as a primary motility disorder of the esophagus caused by defects in the lower esophageal sphincter (LES) relaxation and aperistalsis. Pneumatic balloon dilation (PBD) of the LES is one of the best treatments for achalasia patients [1]. With this method, some fibres of LES occurred gentle perforation and the pressure of LES is decreased. Patients usually experience severe chest pain during balloon dilation and immediately after the procedure because of esophageal tearing [2]. The complications of the pneumatic balloon dilation include transient chest pain, nausea, vomiting, hypertension after PBD, bleeding and esophageal perforation. Our experience revealed that by graded gradual pneumatic balloon dilation with

The authors declare no conflicts of interest.

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experienced gastroenterologist, the risk of esophageal perforation can be decreased until zero [3].

Although some patients tolerate dilation using only local anaesthesia, for many the procedure is unpleasant and increasing the inflation pressure of the balloon to until maximum pressure [15psi (pressure systems international) if is needed] is problematic. The result of the PBD is affected by some factors such as less pressure of the balloon [4]. Therefore, sedation allows patients to tolerate procedures by relieving anxiety, discomfort, or pain and makes stable patients without movement to decrease the risk of physical injury and esophageal bleeding or perforation [5-6].

Currently, four methods including minimal, moderate, deep sedation and general anaesthesia are introduced for patients 'sedation [7-8]. Two of them are used for the procedure of the pneumatic balloon dilation (PBD) in achalasia patients. One method is moderate sedation (conscious sedation) that patient able to obey verbal orders with or without physical motivation and patients have the spontaneous ventilation [7]. Pethedine (as a narcotic) and benzodiazepine such as diazepam and midazolam are usually used for this method. In the second method including deep sedation, patients only able to response to painful stimulation and spontaneous ventilation may be insufficient [7]. In these methods, the function of cardiovascular is preserved. Although the moderate sedation is tolerated by some patients in PBD procedures, many patients need deep sedation.

Intravenous midazolam combined with morphine under heart rate and oxygen saturation monitoring in endoscopy procedures increased patients' obedience and cooperation compared to diazepam [5]. In the other hand, using fentanyl decreased the recovery time and help patients to tolerate the painful procedure [8].

Until now, there is no similar study to compare moderate and deep sedation methods in the PBD for achalasia patients and assess the complications and effect of sedation type in prognosis of PBD. This article is designed to compare two methods of sedation for PBD in achalasia patients and standardize the practice of pneumatic balloon dilation sedation.

Methods

We retrospectively evaluated all patients who underwent PBD from 2011 to 2017. Patients, who referred to our referral centre for achalasia symptoms, were evaluated by endoscopy, radiology and manometry and the diagnosis of achalasia was confirmed.

The standard questionnaire measuring achalasia symptom score (ASS) were used for the severity of symptoms and response to treatment similar to our previous studies [1, 9] (Table 1,2).

Table 1- Cardinal symptoms score

Symptom	Each meal	Daily	Weekly	None
Dysphagia to solids	3	2	1	0
Dysphagia to liquids	3	2	1	0
Active regurgitation	3	2	1	0
Symptom	Daily	Weekly	Monthly	None
Passive regurgitation	3	2	1	0
Chest pain	3	2	1	0

Table 2- Severity score of dysphagia for every swallow

Severity	Score	Description
No dysphagia	0	Normal passage of food from LES zone
Mild dysphagia	1	Sensation or short delay of passage of food from LES, without need of water
Modrate dysphagia	2	Need of water for passage of food from LES zone
Severe dysphagia	3	Accompanied with passive or active regurgitation

All patients were asked to fill the informed consent after a clarification of the risks, benefits, and replacement therapy.

A standard questionnaire was filled for all patients to record the medical history such as important cardiac or pulmonary disease, seizure or epilepsy or any neurological disease, stridor, snoring, or sleep apnea, any history of severe reaction to sedation or anesthesia, using any medications, drug and food allergies, alcohol or drug abuse.

All patients should have a clear liquid diet from 2days ago and have fasting from 12h ago. For the first,patients underwent topical pharyngeal lidocaine 2% sprays for the local sedation of pharynx,and then they were posited in the left lateral decubitus (LLD).

Anaesthesia method:

All the patients were separated to two groups according to the sedations. Group A was the patients who underwent the moderate sedation from March 2011 to March 2014.The deep sedation were done for the second group (group B) from March 2014 to March 2017. The group A received intravenous diazepam (5-10 mg) or midazolam (5mg) and pethedine (25-50mg). The group B underwent the deep sedation with midazolam (0.05 mg/kg), fentanyl (1-2 µg/kg), and propofol 20 mg at first and then 25-75 mic g/kg/min.

The pulse rate (PR), systolic and diastolic blood pressure (SBP, DBP), respiratory rate (RR), and oxygen saturation were monitored and recorded before, during and after PBD.

At the first the sedation was light. First, all patients underwent the upper gastrointestinal endoscopy, and then the balloon dilator was directed to the gastroesophageal junction (GEJ) under endoscope control.

At this stage, the sedation was done with a higher dose. This gradual sedation is necessary for preventing the probability of spiration of esophageal secretions during initial endoscopy and suction the remained secretion in the esophagus.

For the first time 30 mm balloon dilator (Rigiflex) was located on LES and gradually bloated from 3psi and then every 30 seconds increased the pressure to 15 psi and preserved for 60s. At the end, the balloon was emptied and pulled out from the esophagus, then; endoscopy was repeated for assessing the esophageal dilation. The patients were observed for the nausea, vomiting, chest pain, aspiration, pneumothorax and any evidence of the perforation such as continuous chest pain, tachycardia, emphysema, and fever. The patients underwent close observation for 6 hours and then they were discharged. The patients were discharged if they had not any vertigo, nausea, vomiting and they able to stand up and walk. At the end, the physician explained about the warning sign, complications, medication and follow up method and then the patients were discharged.

Ethical considerations:

The patients were alerted about the benefits and risks of the moderate and deep sedations. All patients were filled the informed consent and they voluntary participated in this study.

Ethical Code: IR.TUMS.DDRI.REC.1395.14, Tehran University of Medical Sciences. Digestive Disease Research Institute.

Statistical Analysis

SPSS version 19.00 for Windows was used for analysing the data. Continuous variables were explained by the mean ± SD. For comparisons each group the paired T test for PR, BP, and symptom scores (ASS) were used. The differences between groups were tested by the Independent T test for PR, BP, and ASS. Crosstabs was used for comparing the nausea, vomiting and transit chest pain between two groups immediately after PBD.

Results

Two hundred achalasia patients were enrolled in this study. Patients were divided in two groups according to anaesthesia types in PBD procedures. The group A underwent moderate sedation, and the group B received deep sedation.

The mean age was 40.12 ± 13.89 (Min: 12, Max: 73) years and one hundred and seven patients were female (Table 3).

The patients were assessed by changes in pulse rate (PR), systolic and diastolic blood pressure (SBP, DBP) before, during and after procedure and achalasia symptom scores (ASS) before and 1.5 months after treatment. Moreover, side-effects of anaesthesia and PBD were recorded.

Balloon dilation:

In both groups, PBD were completed. A balloon size of 30 mm was used in 100 patients, and 35 mm in 94 and sizes 40 mm in 6 of patients (Table 4). The mean psi for balloon dilators were 8.77±2.54 for group A and 10.84±2.43 for group B (P value= 0.0001). In addition, the mean psi for balloon 3 and 3.5 cm in the group B were significantly higher than group A (Table 4).

Table 3- Baseline characteristic of the patients

Characteristic		Group A	Group B
Mean age		38.2(±14.05)	42.04(±13.53)
Sex	male	50	43
	female	50	57

Table 4- Number and psi of balloon

Psi/number	Group A	Group B	P value for psi
Size 3cm	8.29/56	10.89/45	0.0001
Size 3.5cm	9.21/40	10.91/53	0.002
Size 4cm	10.25/4	7.50/2	0.207

Symptoms score:

In the group A, the mean ASS before and at 1.5 months after treatment were 11.94 (±3.34) and 2.36 (±3.19), respectively (P. Value= 0.0001). In the group B, the mean symptom score reduced from 11.11(±3.33) before treatment to 2.36(±3.19) at 1.5 months after treatment (P value=0.0001) (Table 5).

All patients in the two groups showed a good response 1.5 months after treatment.

Vital signs:

The mean PR in the two groups had changed during the procedures. Comparing two groups, PR before procedure revealed no significant differences, however, the PR during and after procedures were significantly lower in the group B compared to the group A (Table 5).

The mean SBP and DBP before and during procedure were not significantly different between two groups, however, these values after PBD had significantly changes between two groups (Table 5).

The principal method for assessing the effective ventilation is oxygen saturation and any reducing the oxygen pressure of arterial makes change in oxygen saturation. No critical Oxygen desaturation occurred in both groups of our patients.

Complications

One of the complications of PBD is transient chest pain that significantly decreased in Group B compared to group A (P value=0.031) (Table 6). Also, Patients in group B suffered less nausea and vomiting in comparison to group A (P.value:0.046) (Table 6).

These minor complications were improved by conservative therapies. No severe complications (aspiration, pneumothorax and acute coronary syndrome) were seen. The mean recovery time in group A was 5.6±2.24h compared to 4.73±1.89h in the group B (P value 0.251).

Table 5- The comparison of vital sign before, during and after PBD

		Mean (±SD) Group A	*P value	Mean (±SD) Group B	*P value	**P value of Comparison of A and B
PR	Before PBD	77.22±18.67	-	81.30±17.93	-	0.117
	During PBD	98.±27.48	0.0001	90.60±18.80	0.0001	0.028
	After PBD	96.54±23.46	0.002	86.88±17.24	0.0001	0.001
SBP	Before PBD	120.95±20.21	-	125.55±18.17	-	0.092
	During PBD	152.18±14.83	0.067	127.62±23.30	0.004	0.088
	After PBD	123.54±19.40	0.003	131.81±20.93	0.210	0.004
DBP	Before PBD	80.46±10.67	-	81.03±13.30	-	0.739
	During PBD	81.04±9.90	0.045	84.53±16.31	0.610	0.070
	After PBD	79.55±12.45	0.002	86.56±18.23	0.519	0.002
ASS	Before PBD	11.94±3.34	-	11.11±3.33	-	0.080
	1.5 months after PBD	2.36±3.19	0.0001	2.40±2.81	0.0001	0.931

*Paired sample T test, in comparison with before PBD

**Independent T test

Table 6- The complication of anesthesia and PBD between two groups

Complication	Group A	Group B	P value
Transit chest pain	36	21	0.031
Nausea and Vomiting	27	17	0.046

Discussion

In this study, we compared the moderate and deep sedation regime in two groups of achalasia patients during pneumatic balloon dilation procedures. No similar study was found comparing these two regimes.

In the Eckardt's study, fifty-four achalasia patients underwent PBD with topical anaesthesia of the pharynx. The balloon was inflated from 6 to 12 psi depending on the patient's tolerance in approximately two minutes. Nine patients established severe pain and the procedure had to be ended prematurely [10]. Therefore, by this premature treatment, the need for sedation is highlighted.

Katsinelos et al experienced using intravenous pethidine (25-50 mg), diazepam (5-10 mg) and midazolam (2-5 mg) in seventy-four balloon dilation procedures. The 30, 35 and 40 mm balloons were done in 26, 39 and 9 procedures. Four patients (5.4%) presented esophageal perforation with initial 30-mm balloon despite of our study. The median hospital stay was 1.9 days [11]. However, the time of hospital stay in our patients was 4-6 hours.

In the kostic's study, Patients for pneumatic balloon dilation were sedated with midazolam combined with morphine. Balloon with size 30, 35 and 40mm were used for patients and were inflated to 10 psi for 60 s. All procedures were done successfully without any complications [12]. Tanaka et al treated Fifty-five patients with three times balloon inflations. They inflated balloon in each session according to this method: 3–4 psi in first dilation, 4-5 psi in a second dilatation and 5-7 psi in the third dilatation. They determined the balloon pressure by the patient's tolerance of pain. Patients were sedated with intravenous injections of pentazocine (7.5-15 mg) and hydroxyzine (12.5–25 mg) [4]. In another study, fifty-six achalasia patients underwent conscious sedation with 0.05 mg/kg midazolam under pulse rate and oxygen saturation monitoring.35 mm balloon dilator with maximum 10 psi was done under good patients' obedience and cooperation. They had no serious complications during and after procedures like ours [5]. In our study, the mean psi for balloon 30 and 35 mm were 10.89 and 10.91 mmHg in the deep sedation group.

One study assessed the efficacy of fentanyl and diazepam in 200 patients who referred for endoscopy. The endoscopy was tolerated better in patients who underwent fentanyl injections compare to diazepam injection and also, the patients needed less time for recovery with the fentanyl similar to our patients in the deep sedation group [13].

This study has some limitations. Achalasia is a rare disease and the sample size is small. Therefore, the study can be continued with more sample size. Some results,

such as chest pain after treatment, may have been partially due to a patient's tolerance.

Conclusion

In our study, we used moderate and deep sedation in pneumatic balloon dilation in achalasia patients. Patients, who underwent deep sedation, revealed less tachycardia and blood pressure rising (especially in Diastolic blood pressure). They tolerated more pressure in balloon dilators and also, they had less nausea and vomiting, and transit chest pain after procedures. In addition, we had no sever complications of anaesthesia such as aspiration, pneumothorax, cardiac arrest and also no PBD complications such as perforations and severe bleeding. The fluctuation of O2 saturation in the monitoring was tolerable and no moderate to severe desaturation was seen in both moderate and deep sedation patients.

In the other sides, the recovery time for the patients in the deep sedation regime was less than the moderate sedations. However, this difference was not significant.

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