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CLINICAL EFFICACY OF NEBULIZED DEXMEDETOMIDINE IN CONSCIOUS SEDATION IN DAY CARE FLEXIBLE BRONCHOSCOPE

Dr Sumit Kumar Verma,[1] Dr Smriti Bandhu,[2] Dr. Avanish Vinayak Deshmukh[3*]

[1] PG Student, Department of Anaesthesia, Narayan Medical college, Jamuhar, Sasaram, Bihar

[2]Associate Professor, Department of Anaesthesia, Bharat Ratna Late Shri Atal Bihari Vajpayi Memorial Medical College, Rajnandgaon, Chhattisgarh

[3*]Assistant Professor, Department of General Surgery, Government Medical College, Akola, Maharashtra

Corresponding Author

Dr. Avanish Vinayak Deshmukh

Email id: avanish.deshmukh@gmail.com

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ABSTRACT

Background: Sedative agents used in bronchoscopy procedures need trained professional personnel for administration and monitor the subjects. The increase in the cost of procedure, inpatient stay, and duration. Inhalational use of sedative agents can be a practical solution to the issue. Dexmedetomidine in the inhalational form can be given results similar to the intravenous form with no significant adverse events.

Aim: The present study aimed to assess the clinical efficacy of nebulized dexmedetomidine in conscious sedation in daycare flexible bronchoscopy.

Methods: The present study prospectively assessed subjects that needed bronchoscopy and these subjects were randomized to attain the nebulized form of either 0.9% saline or dexmedetomidine before bronchoscopy. The study parameters were recorded and assessed before, during, and following bronchoscopy. Data gathered were analysed statistically for results formulation.

Results: The study results showed that side effects are minimized using commonly given sedation agents in bronchoscopy including dexmedetomidine, fentanyl, and midazolam. The nebulized dexmedetomidine is a safe and efficacious agent for sedation compared to a placebo. Conscious sedation administration decreases inpatient stay and cost. Exhaustion of hemodynamic parameters by dexmedetomidine can be advantageous in reducing unwanted effects.

Conclusions: The present study concludes that dexmedetomidine in a nebulized form improves the comfort of subjects during the procedure. It decreases the pressure response during bronchoscopy and can be a cost-effective and safer agent in nebulized form for conscious sedation in bronchoscopy.

Keywords: Bronchoscopy, Conscious sedation, nebulized dexmedetomidine, flexible bronchoscopy

INTRODUCTION

Conscious sedation has now formed a vital part of the flexible bronchoscopy (FB) procedure. Proceduralist-administered sedation is presently the need of the time concerning the areas with limited resources, in procedures of shorter duration, and concerning the cost-effectiveness of the procedure. However, considering proceduralist-administered sedation, it needs the sedative agent to be preferably locally acting, easy to administer, effective, and safe.[1]

Dexmedetomidine is an agent that is preferred during respiratory procedures considering it to be devoid of the attenuation of the hemodynamic parameters and not causing respiratory depression. In hospitals that are devoid of the resources and limited advanced technologies use, healthcare personnel are not trained well in providing intravenous sedation, nebulized dexmedetomidine can be an agent of choice. It can be used in tertiary healthcare centres because its efficacy is similar to its intravenous counterpart, it is safe, easy to administer, and is a non-invasive agent. Hence, it can be administered easily by the operating personnel without any need for anesthetists. This can help cut down the cost and overall duration of the procedure significantly.[2]

However, the evidence of the clinical use of nebulized dexmedetomidine in flexible bronchoscopy is limited, existing literature data depicts a positive response concerning the discomfort of the subject and the shorter recovery time in comparison to standard premedication agents. An added benefit of using locally acting dexmedetomidine is its action on bronchial smooth muscles in relieving bronchospasm which allows making the procedure smooth.[3] Hence, the present study aimed to assess the clinical efficacy of nebulized dexmedetomidine in conscious sedation in daycare flexible bronchoscopy.

MATERIALS AND METHODS

The present prospective randomized clinical study aimed to assess the clinical efficacy of nebulized dexmedetomidine in conscious sedation in daycare flexible bronchoscopy. The study subjects were from the Outpatient Department of Pharmacology of the Institute. Verbal and written informed consent were taken from all the subjects before participation.

The present study assessed subjects aged 18 years to 70 years depicted for flexible bronchoscopy. The exclusion criteria for the study were subjects that were not willing to participate in the study, hemodynamically unstable subjects, lactating mothers, pregnant females, active infections or nasal anomalies interfering with nebulization administration, and subjects with known allergies to the study drugs. In sample collection, subjects were screened in the study using randomization to two groups where Group I subjects were nebulized with dexmedetomidine and Group II subjects using the placebo drug.

After the final inclusion of the study subjects, demographic data were recorded in a preformed structured proforma. Group I subjects were managed with dexmedetomidine nebulization and Group II subjects with 0.9% w/v saline nebulization. The subjects were given nebulization 15 minutes before starting the procedure.[4] Before insertion of the bronchoscope, 2ml of 2% lignocaine jelly was applied to the nostrils of the subjects and 2ml of 1% lignocaine spray to the oropharynx. Further lignocaine spray administration was done by advancing the scope at the level of vocal cords over the trachea and each bronchus using the spray-as-you-go technique.

The bronchoscope was moved further to assess bronchial segments and collect the needed samples. From bronchoscope insertion to the nostrils of the subjects to completion of sampling, the tolerance and comfort of subjects were assessed using a validated composite score. The score was assessed separately in two stages, first before and second after crossing the vocal cord. Additively, vital parameters were recorded as pulse oximetry saturation, non-invasive blood pressure, and heart rate assessment before initiating the procedure and were continuously monitored for the complete procedure and recorded at specific intervals. Subjective assessment of the subjects was done using a proforma after 2 hours of bronchoscopy. The perspective of the subjects was assessed concerning discomfort during the procedure, cough occurrence, and quality of sedation.

The data gathered were analysed statistically using SPSS (Statistical Package for the Social Sciences) software version 24.0 (IBM Corp., Armonk. NY, USA) for assessment of descriptive measures, Student t-test, ANOVA (analysis of variance), Fisher's exact test, Mann-Whitney U test, and Chi-square test. The results were expressed as mean and standard deviation and frequency and percentages. The p-value of <0.05 was considered.

RESULTS

The present prospective randomized clinical study aimed to assess the clinical efficacy of nebulized dexmedetomidine in conscious sedation in daycare flexible bronchoscopy. The study assessed 120 subjects who had to undergo conscious sedation in daycare flexible bronchoscopy. The mean age of the study subjects was 48.91±11.63 and 52.41±12.67 years in

Group I and II subjects. There were 26 males and 34 females in Group I and 32 males and 28 females in Group II. The mean BMI in Groups I and II was 21.81±3.05 and 21.88±2.99 kg/m2 respectively. Indications of bronchoscopy were infection, malignancy, and others in 46, 8, and 6 subjects from Group I and 34, 22, and 4 subjects from Group II. The mean bronchoscopy duration was 10.61±3.3.5 and 10.08±2.81 minutes in Groups I and II. Bronchoscopy route was transnasal and transoral in 58 and 2 and 56 and 4 subjects respectively. The procedure done was bronchial brushing, endobronchial biopsy, and bronchial washing/BAL in 10, 2, and 60 subjects from Group I and 60, 2, and 16 subjects from Group II respectively (Table 1).

It was seen that for scores of various components in various domains, the mean composite score for facial tension before crossing the vocal cord in Group I and II was 1.85±0.75 and 2.98±1.006 and after crossing the vocal cord was 2.21±0.896 and 2.95±1.064. Physical movement, before crossing the vocal cord, was higher in Group II compared to I and after crossing the vocal cord was higher in Group II. The respiratory response was higher in Group II before and after crossing the vocal cord. Calmness was higher in Group II before and after crossing the vocal cord. Sedation scores were similar in Group I and II both before and after crossing the vocal cord. Total scores were unacceptable in 4 and 8 subjects from Groups I and II before crossing vocal cords and in 4 and 12 subjects after crossing vocal cords in Groups I and II. Acceptable scores were seen in higher subjects from Group II before and after crossing the vocal cord. Ideal scores were higher in Group I compared to II both before and after crossing the cord. Mean scores were significantly higher in Group II before crossing the cord with p=0.002 and in Group II after crossing the cord with p=0.003 (Table 2).

The study results showed that for the Numeric rating scale for distress and cough in study subjects, NRS was mild in 56 and 38 subjects from Group I and II during flexible bronchoscopy and 60 and 60 subjects from Group I and II after flexible bronchoscopy. Moderate NRS for pain was reported in 4 and 22 subjects from Groups I and II during flexible bronchoscopy and in no subjects from any group 10 minutes after flexible bronchoscopy. Severe NRS was not reported in any subject from any group 10 minutes after flexible bronchoscopy. NRS for distress was mild in 32 and 14 subjects from Group I and II during flexible bronchoscopy and in 60 and 56 subjects from Group I and II 10 minutes after flexible bronchoscopy, moderate in 26 and 38 subjects from Group I and II during flexible bronchoscopy and 0 and 4 subjects 10 minutes after flexible bronchoscopy, and severe in 2 and 8 subjects during flexible bronchoscopy. The difference in Groups I and II was significant during flexible bronchoscopy with p=0.03 and non-significant in Groups I and II with p=0.488 (Table 3).

It was also seen that concerning the patient's perspective on cough and pain perception, sedation quality was excellent, good, fair, and poor in 4, 18, 34, and 4 subjects from Group I and 0, 10, 30, and 20 subjects from Group II. The difference was statistically significant with p=0.03. Discomfort during procedure was none, mild, moderate, and severe in 4, 34, 22, and 0 subjects from Group I and 0, 18, 38, and 4 subjects from Group II. The difference was statistically significant with p=0.03. Willingness to repeat the procedure was not willing, not sure, and willing in 4, 22, and 34 subjects from Group I and 8, 18, and 26 subjects from Group II. The difference was statistically non-significant with p=0.113. Mean VAS for cough perception was3.481±1.6213 and 5.281±5955 n Group I and II during flexible bronchoscopy and 4.048±1.6417 and 5.931±1.8037 2 hours after procedure. Mean VAS was significantly higher in Group II compared to I with p<0.001 (Table 4).

DISCUSSION

The present study assessed 120 subjects who had to undergo conscious sedation in daycare flexible bronchoscopy. The mean age of the study subjects was 48.91±11.63 and 52.41±12.67 years in Group I and II subjects. There were 26 males and 34 females in Group I and 32 males and 28 females in Group II. The mean BMI in Groups I and II was 21.81±3.05 and 21.88±2.99 kg/m2 respectively. Indications of bronchoscopy were infection, malignancy, and others in 46, 8, and 6 subjects from Group I and 34, 22, and 4 subjects from Group II. The mean bronchoscopy duration was 10.61±3.3.5 and 10.08±2.81 minutes in Groups I and II. Bronchoscopy route was transnasal and transoral in 58 and 2 and 56 and 4 subjects respectively. The procedure done was bronchial brushing, endobronchial biopsy, and bronchial washing/BAL in 10, 2, and 60 subjects from Group I and 60, 2, and 16 subjects from Group II respectively. These data were comparable to the studies of Kumar NR et al[5] in 2020 and Misra S et al[6] in 2021 where authors assessed subjects with demographic data comparable to the present study undergoing flexible bronchoscopy in their respective studies.

The study results showed that for scores of various components in various domains, the mean composite score for facial tension before crossing the vocal cord in Group I and II was 1.85±0.75 and 2.98±1.006 and after crossing the vocal cord was 2.21±0.896 and 2.95±1.064. Physical movement, before crossing the vocal cord, was higher in Group II compared to I

and after crossing the vocal cord was higher in Group II. The respiratory response was higher in Group II before and after crossing the vocal cord. Calmness was higher in Group II before and after crossing the vocal cord. Sedation scores were similar in Group I and II both before and after crossing the vocal cord. Total scores were unacceptable in 4 and 8 subjects from Groups I and II before crossing vocal cords and in 4 and 12 subjects after crossing vocal cords in Groups I and II. Acceptable scores were seen in higher subjects from Group II before and after crossing the vocal cord. Ideal scores were higher in Group I compared to II both before and after crossing the cord. Mean scores were significantly higher in Group II before crossing the cord with p=0.002 and in Group II after crossing the cord with p=0.003. These results were consistent with the findings of Shafa A et al[7] in 2019 and Anupriya J et al[8] in 2020 where scores of various components in various domains reported by the authors in their studies were comparable to the results of the present study.

It was seen that for the Numeric rating scale for distress and cough in study subjects, NRS was mild in 56 and 38 subjects from Group I and II during flexible bronchoscopy and 60 and 60 subjects from Group I and II after flexible bronchoscopy. Moderate NRS for pain was reported in 4 and 22 subjects from Groups I and II during flexible bronchoscopy and in no subjects from any group 10 minutes after flexible bronchoscopy. Severe NRS was not reported in any subject from any group 10 minutes after flexible bronchoscopy. NRS for distress was mild in 32 and 14 subjects from Group I and II during flexible bronchoscopy and in 60 and 56 subjects from Group I and II 10 minutes after flexible bronchoscopy, moderate in 26 and 38 subjects from Group I and II during flexible bronchoscopy and 0 and 4 subjects 10 minutes after flexible bronchoscopy, and severe in 2 and 8 subjects during flexible bronchoscopy. The difference in Groups I and II was significant during flexible bronchoscopy with p=0.03 and non-significant in Groups I and II with p=0.488. These findings were in agreement with the studies of Zanaty OM et al[9] in 2015 and Hetta DF et al[10] in 2017 where numeric rating scores for pain and distress comparable to the present study were also reported by the authors in their respective studies.

The study results also showed that concerning patient's perspective on cough and pain perception, sedation quality was excellent, good, fair, and poor in 4, 18, 34, and 4 subjects from Group I and 0, 10, 30, and 20 subjects from Group II. The difference was statistically significant with p=0.03. Discomfort during procedure was none, mild, moderate, and severe in 4, 34, 22, and 0 subjects from Group I and 0, 18, 38, and 4 subjects from Group II. The difference was statistically significant with p=0.03. Willingness to repeat the procedure was not willing, not sure, and willing in 4, 22, and 34 subjects from Group I and 8, 18, and 26 subjects from Group II. The difference was statistically non-significant with p=0.113. Mean VAS for cough perception was3.481±1.6213 and 5.281±5955 n Group I and II during flexible bronchoscopy and 4.048±1.6417 and 5.931±1.8037 2 hours after procedure. Mean VAS was significantly higher in Group II compared to I with p<0.001. These results were in line with the findings of Sharma N et al[11] in 2018 and Riachy M et al[12] in 2018 where patients' perspectives on cough and pain perception reported by the authors in their studies were comparable to the results of the present study.

CONCLUSIONS

The present study, considering its limitations, concludes that dexmedetomidine in a nebulized form improves the comfort of subjects during the procedure. It decreases the pressure response during bronchoscopy and can be a cost-effective and safer agent in nebulized form for conscious sedation in bronchoscopy.

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Characteristics	**Group I (dexmedetomidine) n=60**	**Group II (placebo) n=60**
Mean age (years)	48.91±11.63	52.41±12.67
Gender		
Males	26	32
Females	34	28
Mean BMI (kg/m2)	21.81±3.05	21.88±2.99
Bronchoscopy indications		
Infection	46	34
Malignancy	8	22
Others	6	4
Mean bronchoscopy duration	10.61±3.3.5	10.08±2.81
Procedures done		
Bronchial washing/BAL	60	60
Endobronchial biopsy	2	2
Bronchial brushing	10	16
Bronchoscopy route		
Trans nasal	58	56
Transoral	2	4

Table 1: Baseline demographic data of study subjects

Parameters	**Before crossing the vocal cord**		**After crossing the vocal cord**	
	Group I	**Group II**	**Group I**	**Group II**
Mean composite scores				
Facial tension	1.85±0.75	2.98±1.006	2.21±0.896	2.95±1.064
Physical movement	1.81±0.832	2.41±1.004	2.21±0.896	2.98±1.015
Respiratory response	1.75±0.896	2.41±0.896	2.58±0.673	3.15±0.745
Calmness	1.58±0.673	2.31±0.842	2.08±0.546	2.81±0.745
Sedation	1±0.00	1±0.00	1±0.00	1±0.00
Total scores n (%)				
Unacceptable	4 (3)	8 (6)	4 (3)	12 (10)
Acceptable	4 (3)	18 (15)	20 (16.6)	26 (21.6)
Ideal	52 (43)	34 (28.3)	36 (30)	22 (18.3)
Mean scores	8.05±2.86	10.55±3.38	10.18±2.80	12.81±3.21
p-value	**0.002**		**0.003**	

Table 2: Mean scores of various components in various domains

Parameters	During flexible bronchoscopy		10-mins after flexible bronchoscopy	
	Group I	**Group II**	**Group I**	**Group II**
NRS for pain				
Mild	56	38	60	60
Moderate	4	22	-	-
Severe	-	-	-	-
p-value	**0.01**			
NRS for distress				
Mild	32	14	60	56
Moderate	26	38	-	4
Severe	2	8	-	-
p-value	**0.03**		0.488	

Table 3: Numeric rating scale for distress and cough in study subjects

Parameter	**Group I (n=60)**	**Group II (n=60)**
Sedation quality		
Excellent	4	0
Good	18	10
Fair	34	30
Poor	4	20
p-value	**0.03**	
Discomfort during procedure		
None	4	0
Mild	34	18
Moderate	22	38
Severe	0	4
p-value	**0.03**	
Willingness to repeat procedure		
Not willing	4	8
Not sure	22	18
Willing	34	26
p-value	0.113	
Mean VAS for cough perception.		
During flexible bronchoscopy	3.481±1.6213	5.281±5955
2 hours after procedure	4.048±1.6417	5.931±1.8037
p-value	**<0.001**	

Table 4: Patient's perspective on cough and pain perception