ROLE AND ADVERSE EFFECTS OF PREMEDICATION FOR REDUCING PAIN AND DISCOMFORT DURING FIBEROPTIC NASAL PHARYNGOSCOPY AND LARYNGOSCOPY

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ABSTRACT

INTRODUCTION

Fiberoptic nasal endoscopy is a common procedure. Pretreatment with many drugs has been tried to decrease discomfort and pain related to the procedure. It was our effort to study whether they are effective in reducing pain and discomfort of the procedure.

MATERIAL AND METHODS

It was a four-armed triple blind randomized controlled trial. Block randomization was done. Four arms were pretreated with placebo, decongestant spray, local anesthetic spray, and combination of decongestant and local anesthetic spray. Discomfort of pretreatment, discomfort of the procedure, pain due to procedure, ease of procedure and adverse effects were recorded by visual analogue score and analyzed by non-parametric tests. P value less than 0.05 was considered statistically significant.

RESULTS

There were 40 participants in each wing making a total of 160. There were 79 males and 89 females. Discomfort of pretreatment was significantly higher is groups treated with lidocaine spray alone or in combination ($p<0.001$). Discomfort due to procedure was lowest in group pretreated with placebo ($p=0.009$) and pain was comparable throughout the groups (0.15). The procedure of nasal endoscopy was easiest in group pretreated with decongestant spray ($p=0.02$). Adverse effect was highest in form of burning sensation and pain in groups treated with lidocaine ($p<0.001$).

CONCLUSION

Lidocaine spray caused a lot of discomfort in form of pain and burning sensation and was not able to decrease pain or discomfort, alone or in combination with decongestant, related to fiberoptic nasal endoscopy. Decongestant, however, made the procedure easier.

KEYWORDS Decongestant, Discomfort, Lidocaine, Nasal endoscopy, Pain

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INTRODUCTION

Fiberoptic nasal laryngoscopy and pharyngoscopy is one of the most common procedure done in an Ear, Nose, and Throat (ENT) clinic. Topical anesthesia and decongestant have been used to improve patient comfort level during the procedure. Recently, role of these agents has been questioned.

A Cochrane review published in 2011 did not find any role of topical treatment before the procedure.[1] Similarly, a systematic review and meta-analysis published in 2008 also did not find any evidence to support the use of topical treatment before fiberoptic nasal endoscopy.[2] However, most of the studies included in these studies had small sample size and were subjected to bias.

The objective of our study was to see whether topical anesthesia or decongestant or their combination provide any benefit or adverse effect in the patients undergoing fiberoptic nasal endoscopy. We believe it was the first of this type of study in our country.

MATERIAL AND METHODS

This was a four-arm, triple-blind study conducted in the out-patient clinic of Department of Otolaryngology of Lumbini Medical College and Teaching Hospital. The study was done from September 2018 till February 2020. It was approved by the Institutional Review Committee of the Hospital and was registered in a clinical trial registry (https://clinicaltrials.gov/ct2/show/NCT03620513).

All patients 18 years or above coming to the specific resident and undergoing fiberoptic laryngoscopy and pharyngoscopy during the study period were included in the study. Patient not consenting to the study or having sino-nasal mass or severe deviation of nasal septum were excluded. Those having active upper respiratory tract infection or known allergy to any medication used in the study were also excluded.

In a study by Paul et al, mean discomfort scale for placebo was 2.8 (SD = 1.1).[3] Presuming that the treatment would be able to reduce discomfort by at least 25%, mean would be 2.1. With alpha error = 0.05, power =80%, two tailed test, and same standard deviation, minimum sample size would be 40 in each wing that would make a total of 160 in four arms.

The participants were explained about the nature of the study and a written informed consent was taken. They were then randomized into four groups by blocks of four according to computer generated random numbers. Randomization and preparation of the participants was done by a trained resident who would not take part in the evaluation of these participants. The four groups were:

I. Placebo
II. Decongestant
III. Local anesthesia
IV. Combined decongestant and local anesthesia

Placebo consisted of two puff of normal saline spray in each nose with a spray gun attached to ENT work station. Two puff (about 0.18 ml) of oxymetazoline 0.05% (Nasivion™) was given in each nose with another spray gun attached to the same work station as premedication for the participants in the Decongestant group. For local anesthesia group, two puff of 15% lidocaine (15 mg total) was given in each nostrils. For combined decongestant and local anesthesia group, decongestant followed by local anesthesia was given as in previous groups. A gap of at least ten minutes was maintained from the time premedication was finished till the beginning of the nasal endoscopy.

Premedication scoring was done by a trained nurse before the nasal endoscopy procedure. Nasal endoscopy was done by a senior consultant (Associate Professor or above) in all cases. Machida fiber laryngoscope (FLT-SIII) with outer diameter of 4.7 mm was used for the naso-pharyngoscopy and laryngoscopy. Procedure was done in a sitting position. Water based jelly with no active medication was used to smear the scope for lubrication in all cases. Post procedure scoring was done by the same nurse. Score for the ease of procedure was determined by the consultant. Participants, the nurse, and the consultant were blinded to the study. Scoring was done with the help of visual analogue score (VAS) ranging from 1 to 10 (Table 1). VAS has been tested as a reliable and valid too to measure pain and discomfort in various circumstances.[4-6] Premedication soring was done for discomfort of pre-treatment. Post procedure scoring was done for pain during insertion of scope, discomfort due to insertion of scope, and ease of procedure.

Table 1. Interpretation of VAS scores

Title	VAS 1	VAS 10
Discomfort of pre-treatment	No discomfort at all	Most severe discomfort that can be imagined of
Pain due to insertion of scope	No pain at all	Most severe pain that can be imagined of
Discomfort due to insertion of scope	No discomfort at all	Most severe discomfort that can be imagined of
Ease of procedure	Most difficult	Most easy

Other data were collected as per pre-formed proforma which included demographic details, chief complains, side effects of medication etc. The data were entered in Microsoft Excel™ 2008 and imported to SPSS™ 16 (Statistical Package for Social Sciences) for analysis. All the paper proforma were preserved for any future reference. Descriptive statistics were

presented as mean, standard deviation (SD), frequency and percentages. Categorical data were analyzed with chi-square test. Ordinal data were compared with non-parametric tests. P value less than 0.05 was considered as statistically significant.

RESULTS

There were 40 participants in each of four groups making a total of 160 participants. There were 79 male and 89 female participants. They were homogeneously distributed across the groups (X^2=1.88, df=3, p=0.6). The mean age of participants was 44.04 years (SD = 14.5). Age wise, participants were distributed homogeneously across the groups (F=0.64, df=3, p=0.59). The most common complain of the participants was foreign body (FB) sensation in the throat (n=73, 45.6%). Of the total participants 20.6% (n=33) had a prior experience of nasal endoscopy. Nose was normal in 37.5% (n=60) participants. Others had deviated nasal septum (DNS) away from the side of insertion (n=58, 36.3%), DNS towards the side of insertion (n=24, 15%), and inferior turbinate hypertrophy (n=18, 11.3%). Of the total participants who had DNS, 10 (19.5%) had inferior turbinate hypertrophy.

Discomfort and pain due to insertion of scope, and ease of procedure across the groups was analyzed with Kruskal-Wall is Test. The results are presented in Table 2 which shows that the score for discomfort of pre-treatment, discomfort of scope insertion, and ease of procedure were significantly different in at least one of the four groups. Pain due to insertion of scope was comparable across the groups.

Table 2. Discomfort or pain during the procedure and ease of procedure across the groups

Scoring for	Sum of Ranks				Test score (H)#	DF	P	Remarks
	Group I	Group II	Group III	Group IV				
1. Discomfort of pre - treatment	50.02	64.3	105.61	102.06	46.29	3	<0.001	**
2. Discomfort of insertion of scope in nose	66.38	76.67	100.33	78.62	11.61	3	0.009	*
3. Pain due to insertion of scope in nose	76.16	70.15	92.15	83.54	5.28	3	0.15	
4. Ease of procedure	88.29	92.54	64.71	76.46	9.87	3	0.02	*

** highly significant; * significant; # Kruskal Wallis test

Further analysis was done for pair wise comparison for each score (except for pain score) with Bonferroni correction. The results are shown in Table 3 which shows discomfort of pretreatment was significantly higher in group III and group IV as compared to group I or group II. Similarly, discomfort of insertion of scope was significantly higher in group III as compared to group I. Ease of procedure was highest (easiest) in group III as compared to group II. It was comparable in all other pair wise comparison.

Table 3. Pair wise comparison for scores across the groups (after Bonferroni correction)

Groups		Difference of test score between two groups	P	Remarks
Discomfort of pre-treatment	1-2	-14.28	0.9	
	1-3	-55.59	<0.001	**
	1-4	-52.04	<0.001	**
	2-3	-41.31	<0.001	**
	2-4	-37.76	0.001	*
	3-4	-3.55	1	
Discomfort of insertion of scope	1-2	-10.3	1	
	1-3	-33.95	0.006	*
	1-4	-12.25	1	
	2-3	-23.65	0.13	
	2-4	-1.95	10.26	
	3-4	-21.7	0.21	
Ease of procedure	1-2	-4.25	1	
	1-3	-23.58	0.95	
	1-4	-11.83	1	
	2-3	-27.83	0.026	*
	2-4	-16.08	0.6	
	3-4	-11.75	1	

** highly significant; * significant

Most participants (n=135, 84.4%) highly recommended the procedure to their friend or family members. Fisher exact test showed that the recommendation data was not significantly different across groups (p=0.963).

Adverse effects of pre-treatment medication were present in 63 (39.4%) participants. The most common adverse effect was burning sensation in the nose reported by 41 (25.6%) participants followed by itching nose or sneezing in 13 (8.1%). Adverse effect was present in 12.5% (n=5), 35% (n=14), 57% (n=23), and 52.5% (n=21) in group I, II, III and IV respectively. Chi-square test showed that the difference was statistically significant (X^2=20.8, df = 3, p < 0.001).

Adverse effect of procedure was present in 75 (46.9%) of the participants. All these except one developed gag reflex. Chi-square test revealed that the difference was not significant (X^2=5.9, df=3, p = 0.18).

DISCUSSION

We carried out this study to analyze whether pre-medication with nasal decongestant and/or local anesthesia for fiberoptic nasal laryngoscopy and pharyngoscopy would reduce

discomfort. We included 160 participants equally divided into four arms. Similar number of participants were included by few other studies.[7,8] There were 49 and 50 participants respectively in two arms in a study by Gaviola.[9] Other studies had fewer participants as compared to ours.[10-13]

There were almost equal number of male and female participants overall and they were homogeneously distributed across the groups. Age-wise too, participants were homogeneously distributed across the groups. These homogeneous distributions assured that the randomization was effective for age and gender.

Foreign body or a lump sensation in the throat was the most common indication for the fiberoptic nasal endoscopy. Psychological distress is common in our community because of poverty, poor social support system, separated family etc.[14,15] Globus sensation in throat is significantly related to psychological distress.[16] In addition, increase in the cases of throat cancer in society has elevated the fear of having the same.

Discomfort of pre-treatment was significantly higher in group III and IV as compared to group I and II. Oxymetazoline alone did not cause significant discomfort as compared to placebo. But when lidocaine was given, discomfort score significantly increased. Lidocaine is known to cause pain and burning sensation during local infiltration or topical application believed in part due to its acidic nature.[17] Studies comparing adverse effects of nasal lidocaine spray are rare. In a study, 15 (60%) out of 25 of the participants receiving lidocaine nasal spray complained about local irritation.[18]

Discomfort due to insertion of scope was significantly higher in participants receiving lidocaine spray alone compared to placebo group. There was no significant difference between other groups. We had believed that lidocaine nasal spray would decrease sensation of nasal mucosa and thus would decrease discomfort related to insertion of scope into the nasal cavity but it increased the discomfort score. A possible explanation can be that the lidocaine would be able to relieve the pain sensation but patients can still feel some pressure or movement; and these participants had already experienced highest level of discomfort due to pre-treatment. A cross-over type of study might be able to address this problem.[19]A similar result was found in a study comparing discomfort and pain score for rigid nasal endoscopy.[12] Another study compared discomfort due to nasoendoscopy in children with normal saline as placebo, xylometazoline as decongestant, and combination of lidocaine with xylometazoline. They did not find statistically significant difference in discomfort score.[11] Two studies found that the discomfort score was significantly lower with lidocaine.[1,10]

Pain due to insertion of nasal endoscope was comparable across the groups. Lidocaine or decongestant was not able to decrease pain score as compared to placebo. We believe that the procedure is virtually painless if done carefully by a senior consultant avoiding undue pressure and trauma to nasal structures. There was no significant difference in pain score by topical lidocaine in a study by Bonaparte et al.[10] In another study, combination of oxymetazoline and lidocaine provided statistically significant low pain score.[12]

Most of the participants highly recommended the procedure to their friends or family if advised by the doctors. Only one participant, from placebo group, made a strong negative recommendation. This shows that the level of discomfort or pain was at a low and bearable level even in the placebo group.

Adverse effects of pre-treatment medication were common with burning sensation in nose being the most common followed by itching nose and sneezing. Adverse effects were significantly lowest in placebo group. Lidocaine might be the cause of burning sensation in most cases in part due to its acidic nature.[17]

Adverse effects of procedure were also common; all except one developed gag reflex. One participant developed vomiting. Occurrence of these events were comparable across groups.

A single centric study and participants coming to a resident being only included were some of the weaknesses of the study.

CONCLUSION

Discomfort of pre-procedure treatment was high among the treatment group, particularly with lidocaine. Pre-procedure treatment failed to reduce discomfort and pain associated with nasal endoscopy procedure. Decongestant nasal spray was useful to make the procedure easy. Based on our study, we believe that pretreatment with lidocaine and decongestants for nasal endoscopy may be avoided.

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