

Patient Communication before General Anesthesia to Reduce Post-Operative Pain and Agitation after Endoscopic Sinus Surgery: A Randomized Clinical Trial

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Background: Patients often name post-operative pain as the most horrifying aspect of the surgery. The purpose of this study was to evaluate the effect of communication with patients on post-operative pain and agitation in the patients recovering from endoscopic sinus surgery.

Methods: This was a randomized clinical trial. Sixty patients scheduled for endoscopic sinus surgery were randomly allocated to control and intervention groups (30 patients in each group). A supportive and informative session was established for 20-30 minutes in two stages for the intervention group while the control group received routine information. After surgery, pain and agitation were assessed using the non-verbal pain scale, visual analog scale and Riker's sedation-agitation score.

Results: The average pain scores in the recovery room by non-verbal pain scale and visual analog scale were (3.4±1.6) and (6.2±3.0) for the control group and (1.2±1.5) and (3.0±3.3) for the intervention group, respectively (P≤0.001). The average agitation score in the recovery room for the control group and the intervention group were (4.6±0.6) and (4.1±0.3), respectively (P=0.008).

Conclusion: The results demonstrate that simple communication techniques before the surgery can be effective in reducing post-operative pain and agitation in patients recovering from endoscopic sinus surgery.

This clinical trial was registered from IRCT with registration number IRCT201404278589N3.

Keywords: communication; pain; agitation; general anesthesia; surgery

Millions of surgical operations are performed every day and patients often name “post-operative pain” as the most horrifying aspect of surgery. Studies have shown that prevalence rates for post-operative pain vary between 30 and 80% [1-3] and post-operative anxiety has been found to occur in 13% of patients [2,4].

Post-operative pain and agitation are major causes of delayed discharge from the hospital, imposing heavy costs on healthcare charges [1,5-6]. Nowadays medications are

used as the treatment for pain and agitation. However, using non-medication techniques of analgesia, have far less unwanted and negative effects while not risking dangerous drug interactions.

Lack of information about general anesthesia (GA) such as fear of anesthesia, fear of not waking up, fear of waking up before surgery ends (awareness), fear of the unknown and post operation pain are important causes of anxiety before the surgery [7]. Providing such information may decrease post-operative pain and anxiety [8].

Many studies have shown the need for more research on the influence of preoperative information on the experience of postoperative pain [7]. Pain and agitation are more prevalent in patients after otolaryngologic surgeries such as sinus endoscopy [9-10].

The aim of this study was to evaluate the effect of communication with patients on post-operative pain and agitation in patients recovering from functional endoscopic sinus surgeries.

Methods

This was a randomized clinical trial, which included all adult patients with normal verbal abilities who were scheduled for endoscopic sinus surgery at Ghaem Hospital, at Mashhad University of Medical Sciences and Amir Alam Hospital of Tehran University of Medical Sciences.

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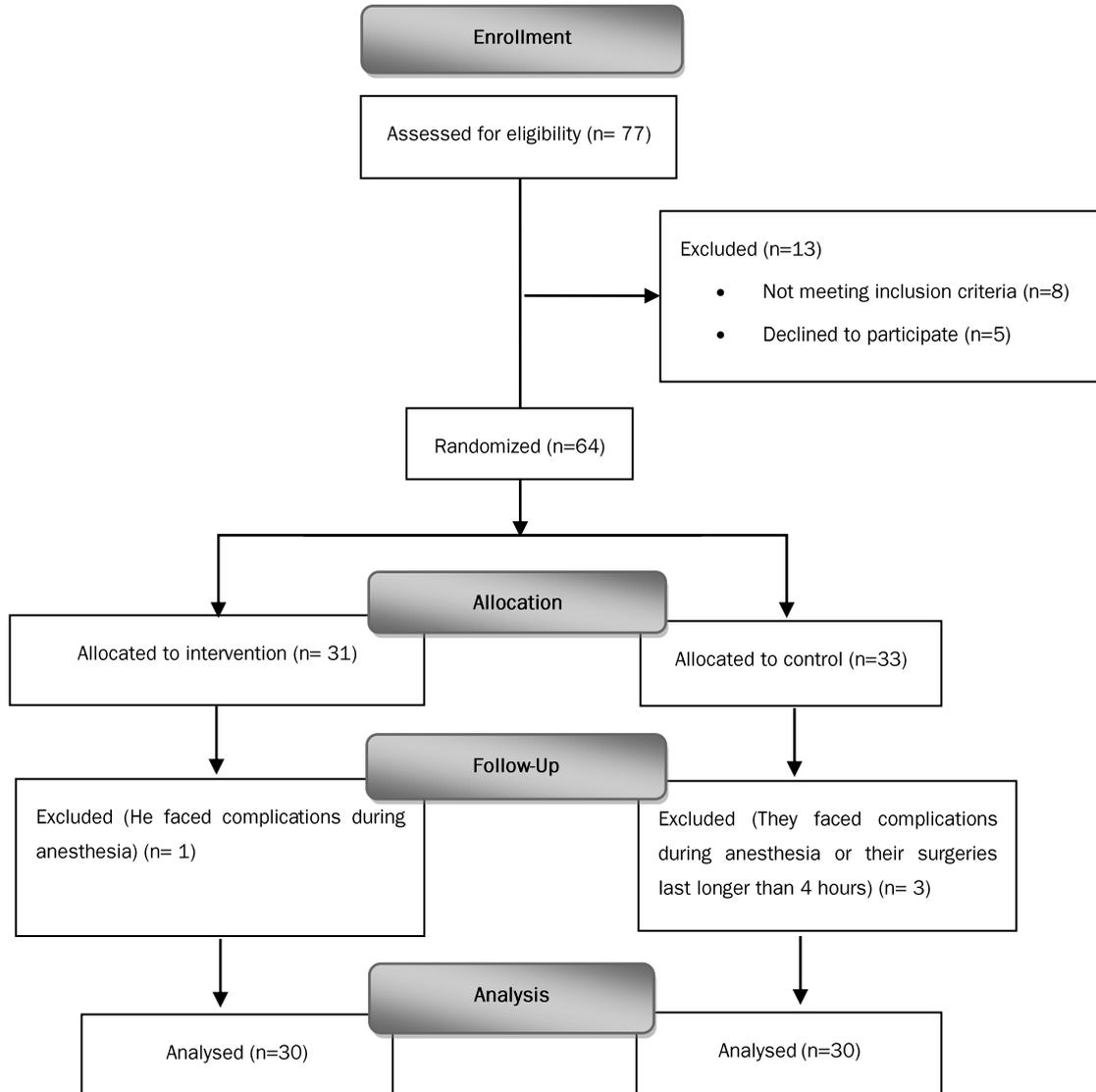
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After a pilot study according to power goal of 80% and confidence interval of 95%, calculated sample size was 25 per arm. Considering the dropout rate, 31 patients in the intervention and 33 patients in the control group were adequate to start the study. Finally, 64 patients, who were all non-smokers with no drug addiction or long-term (>6 months) use of analgesic and/or NSAIDs entered the study consecutively. Patients were diagnosed and scheduled for limited endoscopic sinus surgery (Maxillary Antrostomy, Ethmoidectomy and Sphenoidotomy with or without partial resection of the middle concha without Septoplasty including polyposis and sinusitis) by a faculty member of Otolaryngology department. After obtaining informed

consent, patients were assigned to two groups by computerized randomized block design forming intervention and control groups, named "A" and "B", respectively.

Patients who faced complications during anesthesia (cardiac arrest, bradycardia (HR<40) and bronchospasm), needed a more advanced sinus endoscopic surgery, in whom cautery was used for hemostasis or surgery, duration of longer than 4 hours were excluded from the study (4 individuals: 1 patient in group A and 3 patients in group B). Therefore 30 patients in each group were included in this study (Figure 1) illustrates the flowchart of the participants throughout the study.

Figure 1- Flowchart of participants.



Primary Outcome

The primary outcome of this study was the comparison of pain score in the intervention versus control group.

Secondary Outcomes

The secondary outcomes of this study were the comparison of agitation score and pain threshold in the intervention versus control group.

Informative and supportive communication

Both groups received routine information verbally which consisted of time and type of the anesthesia and surgery, cares before and after the surgery and persons who meet them. Patients of group A also were involved in a 15-20 minute of face to face informative and supportive communication once in the night before the surgery and once again for 5-10 minutes just before the surgery. Informative and supportive communication for the

intervention group according to our experiences and a literature review, were comprehensive explanation about the duration of anesthesia, common complication of the anesthesia after the surgery, duration of the surgery, common complication of the surgery, nasal obstruction after the surgery, feeding after the surgery and also giving reassurance to them. Patients were also asked to explain their feeling about the anesthesia and surgery, then they were trained by a nurse to control their fear and anxiety if it existed (with a specific program designed by a psychologist-which consists of relaxation technique; diaphragmatic and deep breathing combined with visualization and passive concentration-). Pain management after the surgery was explained to the patients in group A and it was emphasized the patients' own role in pain management then they were encouraged to participate in their own treatment by asking for the analgesic at the early stage if it's needed to prevent the peak of pain [7, 11-14].

Pain threshold of the patients was assessed night before the surgery using a dish containing water at 4°C and they were asked to put their dominant hand into it and withdraw when their hand started to ache. This time was assessed using a chronometer. Pain threshold intensity also was assessed using Borg CR10 Numeric Pain Rating Scale (0= no pain, 10= worst pain).

All the patients were given the same medications for anesthesia; Pre-medication, induction agent and relaxants included that was used were fentanyl [3], thiopental (5 mg/kg), atracurium (0.5 mg/kg). Anesthetics used during surgery were propofol infusion (100-200 /min) remifentanyl infusion (0.1_0.2 /min), oxygen 50%, nitrous oxide 50%. Our medications for reversal were atropine (0.02 mg/kg) and prostigmine (0.04 mg/kg).

After surgery, every patient was under the care of the same nurse who was kept blind to each patient group in recovery. Pain severity was estimated using visual analog scale (VAS) and non-verbal pain scale (NVPS). The VAS

was a 10cm ruler where patients defined the degree of their pain on it from no pain to worst pain. The NVPS contained five assessment dimensions: Face, Activity (Movement), guarding, physiologic aspects I (vital signs), and physiologic aspects II (skin, pupillary response, perspiration) which each of the dimensions score from 0 to 2. Agitation was scaled using Riker's Sedation-Agitation Scale (SAS: 1= unarousable, 2=Very sedated, 3=Sedated, 4=Calm and cooperative, 5=Agitated, 6=Very agitated and 7=dangerous agitation). Non-verbal pain scale, visual analog scale and Riker sedation-agitation score were estimated for each patient after the surgery when entering the recovery room, during their stay at the 15th minute and as they left the recovery room. The latter method was used in patients who were unable to answer questions in recovery due to sleepiness. The non-verbal pain score was validated by Odhner et al in 2003 [15]. Riker was validated by Riker et al in 2001 [16].

Statistical Analysis

The data generated by these scales were then analyzed using IBM SPSS statistics version 22. P values<0.05 was considered statistically significant. The T-test and Mann-Whitney test was used to compare the groups. Paired sample T-test and Wilcoxon Rank Sum test was used to compare each group before and after the surgery.

Results

The patients had an average age of 34.6±11.0 years within the range of 18 to 61 years. Seventy percent of group B and 53.3% of group A were males. The average BMI of patients was 26.5±4.4 (39.5-19.5). The demographic data had no significant differences between the two groups (all P > 0.05) (Table 1). There was no statistically significant difference between the two groups in pain threshold and pain threshold intensity (P > 0.05) (Table 2).

Table 1- Demographic information of control and intervention groups.

Demographic information	Control group (B)		Intervention group (A)		
	Number	Percentage	Number	Percentage	
Gender	Male	21	70	16	53.3
	Female	9	30	14	46.7
Marital status	Married	21	70	21	70
Education	High School or Higher	10	33.3	11	36.7
Surgery experience	Yes	16	53.3	18	60

Table2- Comparison of the mean pain threshold and the mean pain threshold intensity in the control and intervention groups

Variable	Control		Intervention		Test results
	Mean±SD	Number	Mean±SD	Number	
Pain Threshold (seconds)	28.0±15.9	30	27.6±16.6	30	T-test P=0.931, t= 0.0
Pain Threshold Intensity	3.4±1.3	30	3.1±1.3	30	Mann-Whitney test P=0.401, z= 0.8

Statistical analysis revealed a significant difference between the two groups in terms of NVPS, VAS and SAS when entering the recovery room, during their stay and as they left ($p<0.005$). Using Freedman's test and analysis of repeated measures suggested that there were not any significant difference between the scales of pain at these

three points (Table 3-4). In this study, 22 patients (13 patients in the control group and 9 patients in the intervention group) were not able to participate in VAS while entering the recovery room because they were not fully awake.

Table 3- Comparison of the mean pain scores using NVPS in the control and intervention groups.

Variable	Control		Intervention		Mann-Whitney test between groups
	Mean±SD	Number	Mean±SD	Number	
Pain					
Entering the recovery	3.3±1.7	30	1.4±1.5	30	$P<0.001$, $z= 3.9$
During the recovery	3.5±1.6	30	1.3±1.5	30	$P<0.001$, $z= 4.2$
Leaving the recovery	3.4±1.5	30	1.1±1.5	30	$P<0.001$, $z= 4.5$
Test results for intra group comparison	Repeated measures $F=0.9$, $df=2$, $p=0.393$		Friedman $\text{Chi-square}=0.2$, $df=2$, $p=0.368$		

Table 4- Comparison of the mean pain score using VAS in the control and intervention groups.

Variable	Control		Intervention		Mann-Whitney test between groups
	Mean±SD	Number	Mean±SD	Number	
Pain					
Entering the recovery	5.8±3.8	17	2.3±3.2	21	$P<0.001$, $z= 2.8$
During the recovery	6.4±2.8	30	3.4±3.4	30	$p=0.001$, $z= 3.3$
Leaving the recovery	6.5±2.7	30	3.5±3.0	30	$P<0.001$, $z= 3.5$
Test results for intra group comparison	Repeated measures $F=2.1$, $df=2$, $p=0.134$		Friedman $\text{chi-square}=5.4$, $df=2$, $p=0.066$		

Mean duration of stay in the recovery room was 24 minutes in the control group and 30 6 minutes in the intervention group. Statistical analysis revealed no significant difference between these two groups. ($p=0.674$) Also, there was no statistically significant difference between the mean duration of surgery of two groups.

(114±48 in the control group and 126±48 in the intervention group; $p=0.387$)
Friedman's test also suggested significant differences between the agitation levels when entering the recovery, during the stay and leaving for each patient ($p=0.004$). (Table 5)

Table 5- Comparison of the mean agitation score in the control and intervention groups.

Variable	Control		Intervention		Mann-Whitney test between groups
	Mean±SD	Number	Mean±SD	Number	
Agitation					
Entering the recovery	4.8±0.7	30	4.3±0.6	30	$p=0.008$, $z= 2.6$
During the recovery	4.7±0.6	30	4.1±0.4	30	$P<0.001$, $z= 3.8$
Leaving the recovery	4.3±0.6	30	4.0±0.1	30	$p=0.006$, $z= 2.7$
Test results for intra group comparison	Friedman $\text{chi-square}=13.8$, $df=2$, $p=0.001$		Friedman $\text{chi-square}=11.2$, $df=2$, $p=0.004$		

The severity of pain was also categorized into "mild", "moderate", "severe" and "unbearable". The analysis of data obtained by this evaluation revealed a significant decrease of "severe" pain from 23.3% in group B to 3.3%

in group A. The "unbearable" pain also reduced from 20% in group B to 6.7% in group A. Fisher test suggested that this difference was significant ($p=0.001$). (Table 6)

Table 6- Comparison of the pain intensity in the intervention and control groups.

Pain intensity	Control group		Intervention group		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
Mild (0-2)	1	3.3	11	36.7	12	20.0
Moderate (2.5-5)	3	10.0	7	23.3	10	16.7
Severe (5-8)	7	23.3	1	3.3	8	13.3
Unbearable (8-10)	6	20.0	2	6.7	8	13.3
	Fisher exact:		p=0.001			

Six patients (20%) in the control group and 3 patients (10%) in the intervention group needed analgesic in the otolaryngology ward which was acetaminophen. Statistical analysis revealed no significant difference between two groups. (p=0.278)

Discussion

In this study, we demonstrated that informative communication before surgery may decrease post-operative pain and agitation in the recovery room. The average pain scale estimated using NVPS and VAS was lower in the intervention group while entering, during the stay and leaving the recovery room. None of the patients had horrifying agitation (Grade 7). The prevalence of severe agitation (grade 6) and moderate agitation (grade 5) was significantly lower in the intervention group.

Some studies that evaluated the effect of medications on post-operative pain [17] and agitation [18-19] have shown that using medications decrease pain. In these studies, 40-73.3% of patients, experienced severe pain after surgery, but in our study, only 3.3% of our patients suffered such pain. These studies demonstrated 32% decrease in the average pain score, which is far less than what we achieved with our intervention (56.8%). Gramke estimated the average pain of the rhinologic surgeries to be 40 scores higher than abdominal surgeries using VAS [20]. In that study, 26% of patients had horrifying agitation (Grade 7) and 32-48.7% were severely agitated (Grade 6) but in our study only 3.3% of group A patients had Grade 6 agitation and none of our patients experienced horrifying agitation (Grade 8) even though, agitation after rhinologic surgeries is more frequent [10]. Furthermore, none of our patients suffered medications adverse reactions such as nausea and vomiting.

The effect of having supportive and informative communication with patients on the reduction of their pain and agitation may be caused by the decrease in their anxiety and increase of their faith in the anesthesiology and surgery team [7]. In an era where medical sciences are rapidly developing and more efficient and less harmful diagnostic methods are invented every day, methods of communication with the patients should also improve with the same pace. Not spending adequate time for communicating effectively with patients may cause many unwanted complications, having both psychological and physical effects on the patients. Findings have indicated that having a 30 minutes communication with patients may decrease recovery from pain and agitation by an average of 56.8% and 10.8%, respectively.

Pain is a complex and multifactorial experience and pain management must be comprehensive and multidisciplinary. In this study, we evaluated the effect of communication with patients on the post-operative pain and we tried to eliminate other factors which affect their pain experience but, there were many environmental and psychological factors that could not be eradicated and might affect our results. Future studies with large sample size could provide us with more accurate evidence regarding the useful effects of informative and supportive communications.

This simple but effective intervention probably imposes a very little cost on healthcare systems and takes very little time out of nursing staff and physician working hours and has many more benefits such as reducing stress, improving the quality of life [19], and patients' trust in their physician [21]. Therefore, we suggest this technique be applied to pre-surgery protocols in hospital and healthcare centers.

Conclusion

Post-operative pain and agitation in patients were decreased by an average of 56.8% in pain and 10.8% in agitation with a proper communication for 20-30 minutes. Simple communication techniques before surgery can be effective in reducing post-operative pain and agitation in patients recovering from endoscopic sinus surgery.

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