Improvement of symptoms from nasal septal perforations after treatment with an obturator

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Abstract

Objective and background: Nasal septal perforations affect 0,9 % of the Swedish population and cause symptoms such as nasal obstruction, crusting, epistaxis, pain and whistling. A possible treatment is to close the perforation with an obturator, either prefabricated or custom-made. The aim of this study was to investigate whether nasal symptoms and quality of life in patients with nasal septal perforations improve with treatment with a custom-made obturator. Design: Prospective longitudinal study, Participants: Adult patients referred for fitting for a custom-made obturator, excluding those with malignancy, Mb Osler, autoimmune systemic illness, and cystic fibrosis. Methods: Participants completed a questionnaire with demographic questions, SNOT-22 and Visual analogue scales for symptoms such as nasal irritation, epistaxis, whistling, crusting, nasal pain. A follow-up questionnaire was completed between 7 and 15 months after insertion of obturator. Results: 34 patients were included. 21 responded to the follow-up questionnarie. 12 (57%) still used the obturator at follow-up. There was an improvement of all symptoms and improved SNOT-22 scores. The improvement was greater in the participants still using the obturator. Conclusion: The custom-made obturator improves symptoms and quality of life, but the success rate of treatment is only 57%. Further study is needed to find which patients with nasal septal perforations benefit from treatment with obturators.

Table of contents

Introduction

The prevalence of nasal septal perforations is 0,9 % in the adult population, according to previous Swedish studies (1). Possible causes include trauma, surgery of the septum, drug use, vasculitis, abuse of nasal sprays, infections and cancer (2). Symptoms vary in severity, from no symptoms to severe symptoms affecting quality of life. Common symptoms are nasal obstruction, pain, epistaxis, whistling sound from the nose and crust formation (2). The basal treatments are emollients and moisturising the nasal mucosa, and avoidance of trauma and nasal sprays that could worsen the perforation. To treat the perforation surgical techniques have been developed, but success rates vary from 30% to 100% and there is always a risk of reperforation (3). A treatment increasing in popularity is to close the perforation with an obturator, either prefabricated or custom-made. The obturator is often made out of silicone. Patients in the southern regions in Sweden can have a custom-made obturator fitted at Ansiktsprotetiska kliniken in Malmö.

Previous studies have shown that septum obturators can improve nasal symptoms and quality of life. (4) (5–9) A common problem seems to be that patients do not use their obturators (9).

Purpose

The purpose of this study is to investigate the symptoms in patients with nasal septal perforations before and after treatment with a custom-made obturator. Do nasal symptoms and quality of life improve with obturator treatment?

Methods

Adult patients seen at Ansiktsprotetiska kliniken in Malmö with nasal septal perforations between May 2019 and April 2020 were asked to participate in this study. Exclusion criteria were current malignancy, Mb Osler, autoimmune systemic illness, and cystic fibrosis. Included patients were asked to complete a questionnaire. The questionnaire consisted of a demographic questionnaire, Sino Nasal Outcome Test – 22 and five Visual Analogue Scales (VAS).

SNOT-22 is a questionnaire with 22 questions, designed to measure health related quality of life and sinonasal symptoms (10,11). Possible total scores range from 0 to 110, with higher scores implying worse symptoms and worse quality of life. Changes of 9 points or more are considered to be clinically significant(11). The SNOT-22 is validated in Swedish (12). Originally developed for patients with chronic rhinosinusitis, it has also been studied in patients with nasal septum deviation(13), enlarged turbinates (14) and septal perforations (15). Four domains within the SNOT-22 have been described, which help clinical interpretation of the questionnaire. These domains are rhinologic symptoms, ear-facial symptoms, sleep and psychological issues. (16) (12) In the Swedish version of SNOT-22, rhinologic symptoms are addressed in items number 1, 2, 3, 4, 5, 7, 8; ear/facial symptoms are addressed in item 6, 9, 10, 11, 12; sleep symptoms are addressed in items 13, 14, 15, 16; and psychological issues are addressed in items 17, 18, 19, 20, 21 and 22 (12). (10,11).

The VAS scales recorded five symptoms; irritation and dryness in the nose, epistaxis, nasal crusting, whistling noise when breathing, and nasal pain. Participants marked a 10 cm tall line with an ”X” to indicate the severity of their symptoms. The left end of the line was labelled ”No symptoms” and the right end was labelled ”Worst symptoms possible”. The distance from the left endpoint to the ”X” was measured in millimetres, giving a possible score between 0 and 100 millimetres. A higher score corresponds to worse symptoms.

Study participants completed the questionnaire during their first appointment at Ansiktsprotetiska kliniken. A cast of the septal perforation was made, and used to fabricate a silicone obturator. At the second appointment the obturator was inserted into the perforation. This type of obturator remains in place indefinitely, with no need for removal for cleaning.
A follow-up questionnaire was sent by mail 6 – 12 months after the first appointment. The follow-up questionnaire consisted of the same VAS scales, SNOT-22, and the question ”Do you still use your septum obturator?”.

Statistical analysis was performed with SPSS. For the SNOT-22 simple mean imputation was used for missing data, when at least 50% of the 22 items had been completed. This means that the mean of the values of the completed item is used as the value of the missing data. Wilcoxon signed rank test was used to compare VAS and SNOT-22 scores before and after treatment. The difference in SNOT-22 score and VAS scores was calculated for each patient, and then the mean was calculated.
Studiepopulation/urval

Ethics

The Regional Ethics Review Board at Lund University approved the study protocol. The patients gave their written, informed consent to participate and were informed that participation in the survey was voluntarily, and would not mean any change in care.

Results

34 patients, 14 men and 20 women, were prospectively included. The age ranged between 18 to 81 years, mean age 49 years. See Table 1. 13 participants had allergies. 6 had asthma or Chronic Obstructive Pulmonary Disease. 8 had sinus disease. 2 had ASA intolerance. In total, 17 participants had one or more of these diseases. VAS scales showed results as follow: Irritation median 53 (range 0 – 100), epistaxis median 47 (range 0 – 100), crusts median 71 (range 2 – 100), whistling median 51 (range 0 – 100), pain median 10 (range 0 – 68). The mean value for the sum of SNOT-22 was 34,4 (standard deviation 22,2). Scores for the four SNOT-22 domains showed highest score for nasal symptoms; mean 15,0 (SD 6,8). Mean scores for the ear/facial domain, sleep domain and psychological domain were 4,8 (SD 5,3), 7,6 (SD 5,9) and 8,8 (SD 7,6) respectively. See Table 2.

Table 1. Demographics and comorbidities in study participants. COPD – Chronic Obstructive Pulmonary Disease. ASA – Acetylsalicylic Acid

	N (percentage)
Female gender	20 (59%)
Allergies	13 (38%)
Asthma or COPD	6 (18%)
Sinus disease, including nasal polyposis	8 (24%)
ASA intolerance	2 (6%)
Any of the mentioned diseases	17 (50%)

Table 2. Symptom scores before and after treatment. NS = not significant. VAS = Visual analogue scale

	Mean (SD) before treatment (n=34)	Mean (SD) after treatment (n=20)	Median (range) before treatment (n=34)	Median (range) after treatment (n=20)	Wilcoxon signed rank test, comparing medians before and after
SNOT-22 score	34,4 (22,2)	20,6 (13,5)	30 (4-83)	20 (0-51)	NS
Rhinological domain score	15,0 (6,8)	10,7 (5,0)	16 (3-27)	11 (1-19)	NS
Ear/facial domain score	4,8 (5,3)	3,0 (3,7)	2,5 (0-19)	2 (0-13)	NS
Sleep score	8.7 (5,9)	3,3 (3,5)	6,5 (0-20)	4 (0-11)	NS
Psychological domain score	8,8 (7,6)	4,6 (4,9)	7,0 (0–25)	3 (0-15)	NS
Irritation VAS	47,9 (31,6)	36,5 (26,7)	53 (0-100)	36,5 (3-93)	NS
Epistaxis VAS	30,6 (30,7)	22,7 (26,6)	47 (0-100)	9 (0-83)	P = 0,049
Crusting VAS	62,7 (29,0)	44,1 (29,2)	71 (2-100)	40 (0-96)	NS
Whistling VAS	46,1 (23,7)	17,0 (22,0)	51 (0-100)	5,5 (0-74)	P = 0,002
Pain VAS	18,1 (20,9)	9,8 (14,7)	10 (0-68)	2 (0-54)	P = 0,007

21 participants (62%) answered the follow-up questionnaire after between 7 and 15 months. One patient left the study due to other diseases. Out of the 21 who answered the follow-up questionnaire, 12 (57%) still used their septum obturator. 7 (33%) did not, and 2 left the question unanswered. 5 patients had lost their obturator when it fell out when sneezing, and 2 patients had removed the obturator because of either worsening nasal obstruction or increased crusting and odour. One patient reported that they had removed the obturator and declined to fill in any of the questionnaires. We attempted to reach the two patients who did not report if they used the obturator, but one participant was recently deceased and the other was not reachable.

Analysis was performed for the entire group of 21 respondents, see Table 2. In the follow-up questionnaires, VAS scales showed improvement for all five symptoms and SNOT-22 was improved. The mean improvement for SNOT-22 scores was 10,2 (SD 24,8).

VAS for the five symptoms and SNOT-22 scores before and after treatment were compared with Wilcoxon signed rank test. There was a significant difference for epistaxis, whistling and nasal pain. The differences for irritation, crusting and SNOT-22 scores were non-significant.

The Mann-Whitney U test was performed to investigate whether other diseases affected the symptoms and SNOT-22 scores. Only for whistling was there a significant difference, with participants with other diseases having higher scores for whistling after treatment.

The data set was then split in two subsets, based on whether the participants still used their obturator. Wilcoxon signed rank test was performed again to compare differences before and after treatment. See Table 3. The group without obturator had no significant difference for any symptom or SNOT-22 scores before and after treatment. The group with a remaining obturator had significant differences for all symptoms except crusting. In the group with obturator the mean improvement was 19,8 (std 27,0). The group without obturator had a lesser improvement, mean 1,7 (std 5,0). The symptom scores also show a greater improvement in the group with the remaining obturator.

Table 3. Symptom scores in the group with a remaining obturator and in the group with no obturator. SD = standard deviation. NS = non significant. VAS = Visual Analogue Scale

	Mean (SD) with obturator (n = 12)	Mean (SD) , no obturator (n = 6)	Median (range) after treatment, with obturator (n=12)	Median (range) after treatment, no obturator (n=6)	Mean improvement (SD), with obturator	Mean improvement (SD), no obturator	Wilcoxon signed rank test, Comparing before and after treatment, with obturator	Wilcoxon signed rank test, Comparing before and after treatment, no obturator
SNOT-22 before treatment	38,2 (33,5)	26,4 (16,8)						
SNOT-22 score after treatment	18,3 (8,8)	16,3 (10,7)	17,5 (3-36)	21 (0-25)	19,8 (27)	1,7 (5,0)	P = 0,031	NS
Irritation VAS	32,8 (27,4)	32,8 (21,5)	27(3-93)	42 (3-52)	23,7 (34,1)	9,8 (SD 32,8)	P = 0,041	NS
Epistaxis VAS	8,2 (13,8)	33,8 (21,5)	1,5 (0-40)	41(2-53)	44,8 (34,5)	13,2 (31,3)	P = 0,01	NS
Crusting VAS	33,1 (30,0)	54,5 (18,6)	24,5 (0-96)	49,5 (34-80)	36,2 (42,3)	9,5 (15,4)	NS	NS
Whistling VAS	13,3 (18,4)	29,7 (27,6)	5,5 (0-64)	33 (0-74)	37,0 (27,5)	14,2 (34,1)	P = 0,008	NS
Pain VAS	7,6 (10,0)	9,3 (21,9)	2,5 (0-30)	0,5(0-54)	21,5 (22,6)	3,5 (5,4)	P = 0,013	NS

The Mann-Whitney U test was performed to compare symptoms and SNOT-22 scores in the group with a remaining obturator and the group with no obturator. The significant differences found were higher scores for pain before treatment and lower scores for epistaxis in the group with a remaining obturator.

Discussion

In this prospectively conducted study, treatment with an obturator improves symptoms such as whistling, epistaxis, irritation and pain, and also improves health related quality of life.

Potential weaknesses are that this is a small study with a quite large loss to follow-up. The time to follow-up is relatively short, between 7 and 15 months. There is no data collected regarding the size and location of the septal perforations, nor the case of perforation.

In two other studies, patients with nasal septal perforations had a mean SNOT-22 score of 50,2 (SD 23,5) (15) and 50.8 (SD 23.8) (17). In this study, the mean SNOT-22 score was 34,4 (SD 22,2), that is, somewhat lower than previous studies but still higher than the average scores for healthy controls (7 in two studies (18)(19)). Our participants had higher scores for the nasal domain than the other domains before and after treatment. No other studies available have investigated SNOT-22 improvement after treatment for septal perforation. The mean improvement in the current study was 10,2 which is just above the minimal clinically important difference of 9 (11). In the group with a remaining obturator the improvement was larger; 19,8.

The success rate of treatment, that is the amount of participants who retained their obturator, in this study was 57%. Other studies have shown success rates for septum obturators between 33% and 75% (9). Reasons in this study for discontinuing treatment was either loss of the obturator due to sneezing, or worsening of symptoms such as nasal obstruction and crusting. In a previous study with a similar custom-made obturator, reasons for removal were difficulties in removing and replacing the oburator, discomfort and enlargening perforation (4). The difference is that the obturators in this study did not have to be removed for cleaning, which would seem to be an advantage.

VAS for pain minimal clinically important difference range from 10 – 18 mm in studies. In this study, the mean improvement for the different VAS range from 21 to 44, which suggest a clinically relevant improvement. Epistaxis shows the greatest improvement. Crusting might not be improved with treatment. A possible explanation might be that crusts can still collect at the edges of the obturator.

There is significant improvement for all symptoms except crusting in the group with a remaining obturator. SNOT-22 sums are also significantly improved. This suggests that septal obturators relieve symptoms and are a valid treatment for nasal septal perforations. However, only 57% retained the obturator.

Conclusion

Treatment with a septum obturator improves symptoms such as whistling, epistaxis, pain and irritation and health related quality of life as measured with SNOT-22. However, many patients do not keep their obturator. Further study is needed to increase the success rate of treatment and to identify which patients should be offered other treatments.

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