Validation of the Sino-Nasal Outcome Test-25 (SNOT-25) measure for patients with nasal septal perforation

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Dear Editor:

Nasal septal perforations (NSPs) are a common referral to specialist rhinology practice. A wide range of management options have been described but to be able to offer the most effective treatment modalities to our patients we must be able to capture quantitative data on patient symptom burden accurately and robustly.

The Sino-Nasal Outcome Test-22 (SNOT-22), whilst designed primarily for a different rhinological context (that of chronic rhinosinusitis) [1], has been employed in the setting of patients with nasal septal perforation and has been shown to have utility in quantifying symptom burden in patients with this condition [2]. However, large case series of patients with NSP report that the most common symptoms are those of crusting, bleeding and whistling [3]. Given that these symptoms are absent from the SNOT-22, it can be inferred that this tool is insufficient at truly capturing the symptomology of a patient with NSP. The continued utility of the SNOT-22 in this cohort of patients is therefore potentially unjustified.

In recognition of this deficiency and to improve clinical outcomes for patients with NSP, we augmented the standard SNOT-22 with the addition of three further items exploring the impact of nasal crusting, bleeding and the presence of a whistling sound on nasal breathing (full methods are outlined in online supplementary materials). The additional of these three items increased the SNOT-22 tool into a 25-question measure: the SNOT-25.

The validity of this instrument was examined through a variety of methods with data collected from a group of 88 patients with NSP previously seen in our institution. The external validity of SNOT-25 was established through correlation with an existing measure: the Nasal Obstruction Symptom Evaluation (NOSE) scale. The scores from the SNOT-25 were compared to sum scores taken from the NOSE questionnaire within the patient group. High levels of correlation were found (Spearman r2=0.804) when comparing the sum scores of the two surveys, suggesting they are measuring highly related parameters (Figure 1).

Known-group validity was demonstrated through comparison of SNOT-25 scores in the patient group (n=88, mean 58.6, standard deviation (SD) 26.0) with a control group of healthy volunteers (n=64, mean 19.1, SD 15.7) and the results analysed using an independent t-test. There was a statistically significant difference between pre-operative SNOT-25 scores in the patient group and those recorded from the control group ($p<0.001$).

The responsiveness of the measure was considered through analysing the impact of intervention, comprising placement of a custom-made 3D-printed nasal septal obturator, upon SNOT-25 scores. For those patients with complete follow up data (n=28), the impact of such intervention upon SNOT-25 scores was highly significant ($p<0.01$) at sum score level. Responsiveness was also explored at item level and revealed that each of the additional items in the SNOT-25 (Nasal crusting; Nasal bleeding; Nasal whistling) demonstrated significant change ($p<0.001$) following successful intervention. Other important items were those relating to Nasal obstruction and discharge (Runny nose; Thick nasal discharge) and items relating to symptoms within the accepted domains of psychological (items 14-20) and sleep dysfunction (items 14 and 15), all at $p<0.01$ [4]. Finally, the minimal clinically important difference of the SNOT-25 was calculated (as 0.5 SD of Δscore) [5] for this data set at 11.5. Full detailed results and figures are found in online supplementary materials.

In this study, we have demonstrated that the addition of three items considering specific symptomatology in this context increases utility of the survey measure for patients with NSP.

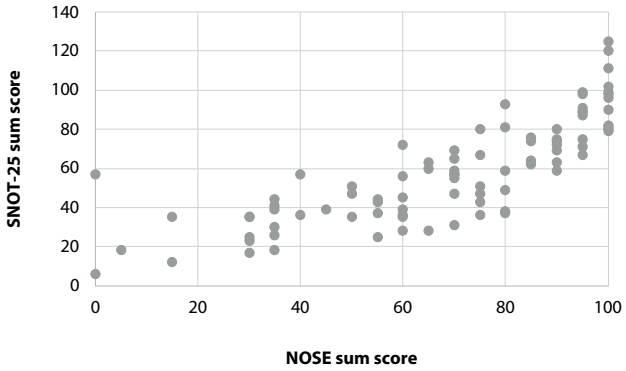

Figure 1. External validity assessment plotting correlation between SNOT-25 and NOSE survey scores (Spearman $r^2 = 0.804$).

The SNOT-25 has been shown to be a valid measure of symptom burden for these patients, and we would advocate other centres consider utilising this as a patient-reported outcome measure.

Authorship contribution

SPW and SCL designed the work, acquired and analysed the data, drafted, revised and approved the manuscript; SPW and SCL agree to be accountable for all aspects of the work.

Conflict of interest

The authors (SPW and SCL) have no conflicts of interest to declare which are relevant to this study.

Funding

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Ethics approval

Ethical approval for this study was obtained from the Health Research Authority prior to commencement (IRAS project ID 307246; REC reference 22/PR/0899).

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SUPPLEMENTARY MATERIAL

Materials and methods

In keeping with recommended practice, this report was produced in adherence to STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guidelines [1].

Study design

Ethical approval for this study was obtained from the Health Research Authority prior to commencement (IRAS project ID 307246; REC reference 22/PR/0899). The first component of this work comprised the retrospective audit of patients with nasal septal perforation (NSP) presenting to Liverpool University Hospitals (LUH) between January 2017 and August 2020 under the care of the senior author. This was followed by case note review, to ensure patients met necessary criteria (as listed below under Setting and participants) and collation of demographic, aetiological, and PROM data. The SNOT-25 was administered to all patients both pre- and postoperatively. Each of the twenty-five items are answered through an identical fixed response format, scored between 0 (no problem) and 5 (problem as bad as it can be) (Table S1). Accordingly, sum scores from the SNOT-25 measure can range 0-125. At these same time points, patients also routinely completed the Nasal Obstruction and Symptom Evaluation (NOSE) scale, previously been shown to be useful in the setting of surgical closure of NSP [2]. The second component consisted of the prospective recruitment of a control group of healthy volunteers comprising a convenience sample of NHS staff. These participants also completed both a SNOT-25 and NOSE survey for use in assessing known-group validity.

Setting and participants

All data was collected within Liverpool University Hospitals NHS Foundation Trust. Inclusion and exclusion criteria are as follows:
Inclusion Criteria - Male and females; 18 years and older; Any ethnicity; Patient group (Known NSP; Have undergone custom obturator insertion; Patients have completed both pre- and post-operative SNOT-25 and NOSE surveys); Control group (Members of staff within Liverpool University Hospitals NHS Foundation Trust; Not known to have NSP; Have provided consent to complete a SNOT-25 and NOSE questionnaire)
Exclusion Criteria - Do not meet all of inclusion criteria; Control group: any previously diagnosed sinonasal conditions by a GP or ENT surgeon.

Statistical methods

PROM data, comprising both SNOT-25 and NOSE surveys, from the patient and control groups were collated and cleaned in Microsoft Excel (Microsoft Excel for Mac, Version 16.60, Microsoft, Redmond, WA, USA) and The Statistical Package for Social Sciences version 27.0 software (IBM Corp.; Armonk, NY, USA). Statistical analysis aimed to examine the validity of the SNOT-25 instrument. Testing for normality, using the Shapiro-Wilk test, demonstrated that SNOT-25 scores were normally distributed ($W=0.98$, $p=0.24$). Accordingly, parametric analyses were performed when considering the patient group as a whole. However, non-parametric testing was employed for sub-group analysis due to the smaller size of these samples. Initially data from the patient group was analysed, and comparisons made between SNOT-25 and NOSE scores pre and postoperatively using Spearman correlation coefficient. Correlation of the new SNOT-25 with an existing and established PROM (in this case the NOSE survey) makes a case for its external validation. The validity of SNOT-25 was further examined with comparison of SNOT-25 scores between the patient and control groups (using an independent t-test), aiming to establish known-group validity, since if the SNOT-25 can accurately capture the symptom burden of patients with NSP, scores should significantly differ from patients known to have none of these symptoms. Finally, the impact of septal obturator placement was analysed. Paired Wilcoxon testing was used to analyse changes in SNOT-25 outcomes over the operative period. Changes in scores (between pre- and postoperative data collection) was examined with responsiveness analysed and discussed in detail at both sum score and item level. Minimal clinically important difference (MCID) was also calculated to determine, in this context, the smallest clinically meaningful change in SNOT-25 for appreciable patient benefit. Given the nature of this study, a distribution-based method (0.5 standard deviation of Δ–score considering pre- and post-intervention scores within the patient group) was chosen, in keeping with recommendations elsewhere [3].

Results

Sample

Data from eighty-eight participants (treated between January 2017 and August 2020) with NSP was collected. Demographic, aetiological, radiological and data on treatment can be found in Table S2. Decisions regarding conservative management were made based on a combination of symptom burden and patient choice. Similarly, for those undergoing intervention, choice between conventional silastic and 3D printed custom nasal septal obturators were based on a combination of assessment of perforation size and shape, the success of previous treatment for that individual and informed decision making. Data for patients undergoing each different arm of treatment is tabulated in Table S3. Sixty patients were reviewed in clinic, completing preoperative SNOT-25 and NOSE surveys, and listed to undergo placement of a 3D printed custom nasal septal obturator – this was

performed in the operating theatre under general anaesthesia owing to the tight personalised fit of the custom obturators. Fifty of these patients underwent their procedure, of which 11 (22%) did not complete postoperative PROMs. Review of this treatment group also showed that 11 patients (22% of those undergoing intervention) reported extrusion of the prosthesis postoperatively, four patients (8%) requested removal and that, intraoperatively, it was not possible to adequately place the obturator owing to poor fit within the perforation in two patients (4%). Of the fifteen patients who underwent placement of a standard silastic nasal septal button (Medasil Surgical Ltd., Leeds, UK), ten were followed up in clinic with completed PROMs.

External validity

The scores from the SNOT-25 were compared to sum scores taken from the NOSE questionnaire within the patient group. High level of correlation was found (Spearman r^2=0.804) when comparing the sum scores of the two surveys, suggesting they are measuring highly related parameters (Figure S1).

Known group difference validity

The ability of SNOT-25 to reflect known group differences was examined to help determine the measure's validity. The 88 pre-operative SNOT-25 scores (mean 58.6, standard deviation (SD) 26.0) were compared to a control group of 64 healthy volunteers (mean 19.1, SD 15.7) and the results analysed using an independent t-test. There was a statistically significant difference between pre-operative SNOT-25 scores in the patient group and those recorded from the control group ($p<0.001$).

Responsiveness and clinically appreciable sensitivity

For those patients with full follow up data (n=28), mean pre-operative and post-operative scores are plotted in Figure S2 and tabulated in Table S4. The impact of intervention upon SNOT-25 scores was highly significant ($p<0.01$) at sum score level. Responsiveness was also explored at item level and presented in Table S5. Finally, MCID of the SNOT-25 was calculated (as 0.5 SD of Δ-score) for this data set at 11.5.

References

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Table S1. Sino-Nasal Outcome Test-25 (SNOT-25). Addition of three items corresponding to specific symptoms described by patients with nasal septal perforation absent from SNOT-22 survey. Items are scored from 0 (no problem) to 5 (problem as bad as it can be).

Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how 'bad' it is by circling the number that corresponds with how you feel using this scale	No problem	Very mild problem	Mild or slight problem	Moderate problem	Severe problem	Problem as bad as it can be
23. Nasal crusting	0	1	2	3	4	5
24. Nasal bleeding	0	1	2	3	4	5
25. Nasal whistling	0	1	2	3	4	5

Table S2. Demographic, aetiological and radiological data for patients with NSP within the patient group.

Total n	88
Age (mean, range) years	50.5 (27-85)
Sex (n, %)	
Female	48 (54.5%)
Male	40 (45.4%)
Aetiology	
Surgery	29 (33%)
- Septal surgery	- 20 (22.7%)
- Other surgery (papilloma, carcinoma, craniofacial, pituitary)	- 4 (4.5%)
- Nasal cautery	- 5 (5.7%)
Cocaine use	20 (22.7%)
Trauma	15 (17.0%)
Vasculitis	4 (4.5%)
Idiopathic	21 (23.9%)
Smoking status	
Never smoked	48 (54.5%)
Current smoker	21 (23.9%)
Ex-smoker	11 (12.5%)
Perforation size (CT in 73 patients)	
Maximum A-P length on axial section	1.8 (0.2 – 4.7)
Maximum height on coronal section	1.2 (0.5 – 2.5)
Treatment	
Only conservative	13 (14.8%)
Silastic septal button	15 (17.0%)
3D printed nasal septal obturator	60 (68.2%)

Table S3. Patient data grouped according to method of treatment.

Treatment	Conservative	Silastic septal button	3D printed nasal septal obturator
Total n	13 (14.8%)	15 (17.0%)	60 (68.2%)
Age (mean, range) years	50.2 (27-79)	48.7 (33-67)	50.9 (27-85)
Sex (n, %)			
Female	8 (61.5%)	9 (60.0%)	31 (51.7%)
Male	5 (38.5%)	6 (40.0%)	29 (48.3%)
Perforation size (mean, range, cms; CT in 73 patients)			
Maximum A-P length on axial section	1.4 (0.2-2.5)	1.1 (0.7-2.2)	1.95 (0.6-4.7)
Maximum height on coronal section	1.2 (0.6-1.9)	0.85 (0.5-1.8)	1.31 (0.5-2.5)
Symptom burden (mean, SD)			
SNOT-22 score	46.5 (SD 29.4)	40.0 (SD 21.8)	51.4 (SD 23.1)
SNOT-25 score	55.4 (SD 31.3)	49.5 (SD 23.2)	61.5 (SD 25.3)
NOSE score	59.2 (SD 25.9)	63.3 (SD 30.2)	71.3 (SD 26.3)

Table S4. Patient reported outcome measures collected both pre- and postoperatively in patients undergoing intervention. Data presented is mean sum score; SD (standard deviation).

Technique	**Silastic septal button (n=10)**	
	Preoperative	**Postoperative**
Symptom burden		
SNOT-25 score	49.5 (SD 23.2)	18.7 (SD 17.0)
SNOT-22 score	40.0 (SD 21.8)	15.7 (SD 15.0)
NOSE score	63.3 (SD 30.2)	23.6 (SD 18.6)
Technique	**3D printed nasal septal obturator (n=18)**	
	Preoperative	**Postoperative**
Symptom burden		
SNOT-25 score	61.5 (SD 25.3)	28.2 (SD 17.1)
SNOT-22 score	51.4 (SD 23.1)	24.1 (SD 15.9)
NOSE score	71.3 (SD 26.3)	23.3 (SD 20.1)
Technique	**Overall intervention (n=28)**	
	Preoperative	**Postoperative**
Symptom burden		
SNOT-25 score	56.7 (SD 22.7)	25.2 (SD 16.5)
SNOT-22 score	49.0 (SD 23.7)	22.1 (SD 15.4)
NOSE score	68.4 (SD 27.2)	23.4 (SD 19.6)

Table S5. SNOT-25 item level responsiveness. Emboldened items are those significant at p<0.001.

Paired Wilcoxon testing	**Z statistic**	**p value**
1. Need to blow nose	-2.84	0.005
2. Sneezing	-1.29	0.197
3. Runny nose	**-3.56**	**0.000**
4. Nasal obstruction	**-4.67**	**0.000**
5. Loss of smell or taste	-2.69	0.007
6. Cough	-2.43	0.015
7. Post-nasal discharge	-1.87	0.061
8. Thick nasal discharge	**-3.50**	**0.000**
9. Ear fullness	-3.12	0.002
10. Dizziness	-2.67	0.008
11. Ear pain	-1.27	0.203
12. Facial pain/pressure	-2.49	0.013
13. Difficulty falling asleep	-3.14	0.002
14. Waking up at night	**-3.57**	**0.000**
15. Lack of a good night's sleep	**-3.88**	**0.000**
16. Waking up tired	**-4.34**	**0.000**
17. Fatigue	**-4.70**	**0.000**
18. Reduced productivity	**-4.26**	**0.000**
19. Reduced concentration	**-4.52**	**0.000**
20. Frustrated/restless/irritable	**-4.19**	**0.000**
21. Sad	-3.12	0.002
22. Embarrassed	-2.85	0.004
23. Nasal crusting	**-4.71**	**0.000**
24. Nasal bleeding	**-3.94**	**0.000**
25. Nasal whistling	**-4.56**	**0.000**

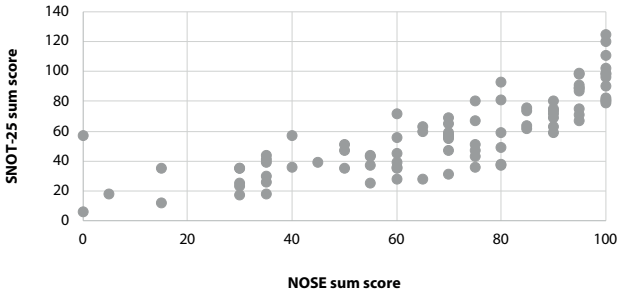

Figure S1. External validity assessment plotting correlation between sum scores with SNOT-25 and NOSE surveys (Spearman r2=0.804).

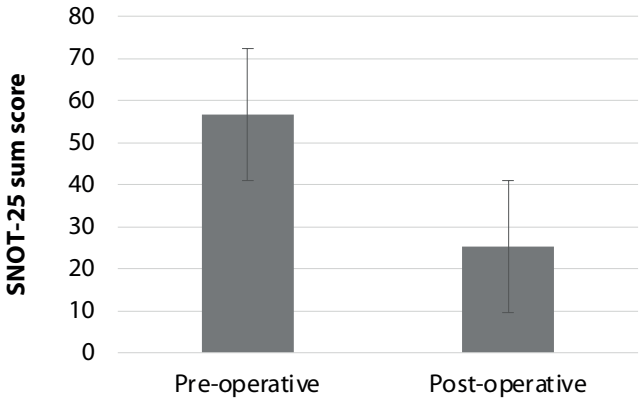

Figure S2. Mean pre- and postoperative SNOT-25 sum score in patients undergoing intervention (n=28; p<0.01).