ORIGINAL STUDY

Medical and psychosocial evaluation of patients with complications after sinonasal surgery: Creating a questionnaire

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ABSTRACT

BACKGROUND. In our ENT practice, we have encountered situations where we had to evaluate and treat patients complaining of symptoms after a previous surgery. All these patients were capable and entitled to seek for legal advice as much as medical care. We felt the need to record their physical and emotional status and to monitor their evolution in these fields. For this reason, we created a questionnaire to help us not to disregard some important or delicate aspects of their condition.

MATERIAL AND METHODS. After evaluating all the existing ENT questionnaires, we decided to create a custom one in order to assess more of the sensitive topics as anger, sadness, regret or frustration. Questions needed to be asked in a certain manner and must be presented in a well-thought order, respecting some basic rules. The evaluation scale needed to be very clear, simple to complete and compare, and identical for all the questions.

RESULTS. Creating a questionnaire was a challenging task that led us to an 18-question survey, equally covering symptoms, feelings and quality of life. We used the test only for the patients who presented after a sinonasal surgery and who suggested that their symptoms were caused by the previous intervention.

CONCLUSION. A questionnaire is a simple and cheap way to evaluate patients. If the topics needed to be documented are not stated in a classic validated survey, a new evaluation instrument can be created. For patients with complications and sequelae after sinonasal interventions, we designed a new questionnaire that can be used to compare their treatment progression.

KEYWORDS: self-evaluation, questionnaire, symptoms, psycho-emotional, medico-legal.

INTRODUCTION

Historically speaking, a consensus regarding the first use of a questionnaire in medical practice is not obvious. The first acknowledgement about the existence of a medical questionnaire goes back in 1560s, in Spain¹, but according to most Internet sources it was officially invented in the mid-19th century and was used as a method of research in psychology².

Nowadays, this handy method of research has different forms. The easiest questionnaire to access is the Visual Analogue (or Analog) Scale, also known as its acronym VAS. VAS is free to use and it

has an adequate level repeatability; it is easy to use, quick to fill, reliable in tracking a patient progress (before and after surgery) and it does not require technical knowledge to evaluate it³.

VAS was essentially developed for pain measurement, but it can be easily directed to assess physical and psychic discomfort because it is a versatile instrument, adaptable to evaluate a lot of symptoms, feelings and other things that do not own a standardized, objective evaluation scale. For example, in Otorhinolaryngology (ENT) VAS is used to rate patients' perception of chronic rhinosinusitis severity, assessing how this condition influences their quality of life⁴. Along VAS, in ENT practice, there

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Table 1. Disease-Specific Outcome Instruments in Otolaryngology and Head and Neck Surgery (after Maureen Hannley⁶).**ALLERGY****Allergic Rhinitis**

- Rhinoconjunctivitis quality of life questionnaire (RQLQ)
- Rhinitis symptom utility index (RSUI)
- Paediatric allergic disease quality of life questionnaire (PADQLQ)
- Nocturnal rhinoconjunctivitis quality of life questionnaire (NRQLQ)

RHINOLOGY**Nasal Obstruction**

- Nasal Obstruction symptom evaluation scale (NOSE)

Rhinosinusitis

- Sino-nasal outcomes test (SNOT-20; SNOT-16)
- Chronic sinusitis survey (CSS)
- Sino-nasal assessment questionnaire (SNAQ-II)
- Rhinosinusitis disability index (RDI)
- Rhinosinusitis QOL survey
- Rhinitis symptom utility index (RSI)

LARINGOLOGY**Voice Disorders**

- Voice handicap index (VHI)
- Voice outcome survey (VOS)
- Voice function outcome measure (VFOM)

OTOLOGY**Otitis media**

- Otitis media-6 (OM-6)
- Chronic ear survey (CES)
- Otitis media clinical severity index (OM-CSI)
- Otitis media survey (OM7-27)
- Otitis media functional status questionnaire (OM-FSQ)
- Otitis media outcomes (OMO-22)
- Otitis media diary (OMD)
- Parents' questionnaire on consequences of OM on family life (PARENT-QOL)

Hearing Impairment

- Hearing satisfaction scale (HSS)
- Effectiveness of auditory rehabilitation scale (EAR)
- Hearing evaluation and auditory evaluation (HEAR-14)
- Hearing handicap inventory for the elderly (HHI-E)
- Hearing disability handicap scale (HDHS)

Tinnitus

- Tinnitus handicap inventory (THI)
- Tinnitus severity questionnaire (TSQ)

Vertigo/ Dizziness

- Dizziness handicap inventory (DHI)
- Vertigo symptom scale (VSS)
- Vestibular activities of daily living (VADL)
- Vertigo, dizziness, imbalance questionnaire (VDI)
- UCLA dizziness questionnaire (UCLA-DQ)
- Dizziness patient-oriented severity index (D-POSI)
- Vertigo handicap questionnaire (VHI)

Ménière's Disease

- Ménière's disease outcomes questionnaire (MDOQ)
- Ménière disease patient-oriented symptom-severity scale (MD-POSI)

Facial Paralysis

- Facial clinimetric evaluation scale (FaCE)
- Facial disability index (FDI)

Cochlear Implants

- Nijmegen cochlear implant questionnaire

Hearing Aids

- Glasgow hearing aid benefit profile (GHABP)

HEAD AND NECK SURGERY**GERD/ EERD**

- Reflux symptom index (RSI)
- Reflux questionnaire (ReQuest)
- Supraesophageal reflux questionnaire
- GERD symptom frequency questionnaire (GSFQ)
- Gastroesophageal reflux disease-health related quality of life scale (GERD HR-QL)
- Quality of life questionnaire in gastroesophageal reflux (Reflux-qual)
- Quality of life in reflux and dyspepsia (QOL-RAD)

Adenotonsillitis

- Tonsil and adenoid health symptom index (TAHSI)

Sleep-Disordered Breathing

- Obstructive sleep disorders-6 (OSD-6)
- Obstructive sleep apnea-18 (OSA-18)
- Epworth sleepiness scale (ESS)
- Empirical sleepiness scale
- Functional outcomes of sleep questionnaire (FOSQ)
- Sleep disorders questionnaire (SDQ)
- Sleep apnea quality of life index (SAQLI)
- Symptoms of nocturnal obstruction & related events (SNORE)
- Pittsburgh sleep quality index (PSQI)

Head and Neck Cancer

- University of Washington quality of life instrument (rev.) (UW-QOL-R)
- Quality of life radiation therapy instrument (QOL-RTI)
- Neck dissection impairment index (NDII)
- EORTC quality of life (HN-35)
- Functional assessment of cancer therapy (FACT-HN)
- MD Anderson dysphagia inventory (MDADI)
- Head and neck quality of life scale (HNQOL)
- Head and neck oncology outcome assessment
- Comorbidity data collection form
- Xerostomia specific questionnaire (XQ)

are other internationally recognized and validated questionnaires^{5,6}. Those questionnaires refer to allergy, head and neck surgery, otology and dizziness, sleep disorders, voice-related quality of life (Table 1)⁶ and Rhinology (NOSE, RSI, RhinoQoL, SNOT-22/20/22, DyNaChron, etc.) (Table 2)⁵. All

these questionnaires address the assessment of symptoms severity and only some of them have questions regarding emotional, functional, work or social aspects.

A medical questionnaire, used for patients, is a tool to evaluate target subjects, in order to gather

Table 2. Chronic rhinosinusitis (CRS) - specific Patient Reported Outcome Measures (PROM) characteristics (after Rudmik et al.⁵). [CSS - Chronic Sinusitis Survey; RSOM-31 - 31-item Rhinosinusitis Outcome Measurement; RSDI - Rhinosinusitis Disability Index; SNOT - Sino-nasal Outcome Test; RSI - Rhinosinusitis Severity Inventory; Rhino QoL - Rhinosinusitis Quality of Life questionnaire; RSTF - Rhinosinusitis Task Force; SNQ - Sino-nasal 5-item questionnaire; DyNaChron - Dysfonctionnement Nasal Chronique Questionnaire; QOD - Questionnaire of Olfactory Disorders; DSS - Disease Severity Score; EQ-5D - EuroQol 5-Dimension; SCT - Script Concordance Test; HRQOL - Health-related quality of life]

PROM	Year developed	No. of questions	Domain assessed	Mode of administration
CSS	1995	6	CRS symptoms, Medication used	Self
RSOM-31	1995	31	Nasal, Eye, Ear, Sleep, General, Emotional, Functional	Self
RSDI	1997	30	Physical, Functional, Emotional	Self
SNOT-16	1999	16	Nose, cough, ear, headache, sleep, Productivity ⁷	Self
SNOT-20	2002	20	Cough, Ear, Headache, Sleep, Productivity, Emotional ⁸	Self
RSI	2003	20	CRS symptoms, Medication use, Work and Social	Self
RhinoQoL	2005	17	Symptoms and severity, Bothersomeness, Impact scale	Self
RSTF symptom score	2007	14	Nasal, Fever, Mouth, Cough, Ear, General symptoms ⁹	Self
SNOT-22	2009	22	Rhinologic, Sleep, Extranasal rhinologic, Ear/facial, Psychological	Self
SNQ	2009	5	Nasal, Facial pain ¹⁰	Self
DyNaChron Questionnaire	2012	78	Nasal obstruction, Anterior rhinorrhea, Posterior rhinorrhea, Sense of smell difficulty, Facial pain, Cough	Self
QOD	2012	25	Negative items, Positive items, Social items	Self
Adelaide DSS	2013	6	Symptoms HRQOL	Self
EQ-5D	2015	15	Mobility, Self-care, Usual activity, Pain/discomfort, Anxiety/depression	Self
SCT	2015	4	Symptoms, Productivity, Rescue medication use	Self

useful information in the evaluation of the clinic and not only. The use of a questionnaire facilitates the collection and analysis of data¹¹, without omitting to ask important questions. We collect general data related to the patient's anamnesis, personal and hereditary medical history, surgery, food and drug allergies, drug treatment.

This kind of patient self-evaluations are often

designed for statistical analysis of the responses and they are called 'surveys'¹². There are also 'questionnaires' which are used to collect data from a list of questions and they are not used to look for a bigger picture or a trend¹³.

In our quest to find a methodological assessment tool for patients with complications and sequelae after sinonasal surgery, we investigated the

Table 3. An example of a standard frequency scale.

Never	Rarely	Sometimes	Often	Regularly	Always
0	0	0	0	0	0

Table 4. Example of a classic VAS.

Never	Rarely	Sometimes	Often	Regularly	Always

Table 5. Modified VAS.

Never	Rarely	Sometimes	Often	Regularly	Always
0	2	4	6	8	10

ENT - Rhinology questionnaires available online, searching for a suitable one for this topic. We have encountered difficulties in identifying a questionnaire that included both rhinosinusal symptoms and psychosocial aspects of the patients. The closest to our needs was the Sino-Nasal Outcome Test - 22 questionnaire (SNOT-22). This test is used and works as "a predictor of postsurgical improvement in patients with chronic sinusitis"¹⁴. Unfortunately, the aspects we were looking to investigate in the targeted patients were briefly questioned (such as the psychosocial domain) and the questions were validated only for the patients before and after the first rhinosinusal surgery.

MATERIAL AND METHODS

We decided to design a questionnaire meant for use in paper-and-pencil administration, evaluating medical and psychosocial aspects in patients with sequelae and complications of/after surgery of the nose and paranasal sinuses.

We chose to create a questionnaire using the Visual Analogue Scale (VAS) style. We considered ap-

propriate to use a VAS model because it is an instrument designed to grade a characteristic or attitude that cannot easily be directly measured¹⁵.

In our opinion, these questions were considered important aspects when interviewing a patient who complains of symptoms following a sinonasal surgical intervention. From our point of view, this type of questionnaire is necessary for the evaluation of these particular patients at the time of presentation and for monitoring the treatment, especially considering that these clinical cases could become medico-legal cases in the future.

From a simple idea up to creating the analysis framework and implementing it, the path was challenging. Research work was needed to determine the best combination of variables to obtain a niche questionnaire. Creating a new investigation tool, as a questionnaire exemplifies, it may seem easy but there are many aspects to consider.

Firstly, some basic rules for questionnaire construction needed to be respected¹²:

- The questions should be formulated in a manner that everyone will interpret in the same way.
- Wording used will be clear and easy to understand, regarding the level of patient's education.

- Usage of appropriate vocabulary and/or explain term (in our case some medical words).
- The questions will have only one item to evaluate.
- The phrase construction will not use negatives: do not, no, not, etc.
- The questions will allow responders who have different opinions to give different answers.
- At the end of the list, the respondent is allowed to use an open question, so he/she can refer to a topic/aspect that maybe the creator of the test did not think of.
- Questions should not be leading, biased or assumptions.
- Checking for grammar mistakes, spelling and punctuation is highly important.

Secondly, we had to be careful when formulating the actual written questionnaire.

Assessment scales

Using the frequency scale (never – rarely – sometimes – often – always) was imperative for grading the symptoms, and, in order to maintain consistency for the test, we used it for the psychosocial aspects as well. The frequency scale was revised concerning the correct order of the adverbs, as to not create confusions¹⁶. Construction of the classic frequency scale implies “o” type bullets, and the subject (in our case the patient) is required to fill in one of the bullets (Table 3).

We combined notions from the frequency scale and from the Visual Analog Scale, we drew a linear numeric scale and inserted some values. This allowed participants to select a certain value or any value in between them. Instead of using only a 10 cm long line, with margins and scaling words (and at the end measuring with a ruler to establish the grade awarded) (Table 4), we added some intermediate symmetrical lines and a light numerical scale (to help the responder complete more quickly and easily (Table 5). We did not use emoticons, as in a standard-classic VAS, because, from our personal point of view, they do not reflect answer choices.

Questions design

Asking a question or evaluating a statement? Using a personal approach of the question needed to be answered we found it to be a friendlier way to obtain honest answers. Instead of “How often do you feel nasal obstruction?” we stated, “I have a stuffy nose”. Therefore, questions became statements, written neutral in first-person.

The list of questions

We listed three types of statements, regarding sinonasal symptoms¹⁷, social life and psycho-emotional wellbeing. Each topic received equal interest.

Question order

Some people will not answer personal or intimate questions. For this reason, questions about

his/her feelings and about self-evaluation of the medical care received will be placed towards the end – it will make them more likely to answer¹⁸. In this extent, even if the patient refuses to answer these embarrassing topics, we still can get some information about the symptoms and his/her social life. The final questionnaire is summing 17 defined questions and one open question. This open question concedes freedom to report any other problem that we did not include in the defined questions. In case of an existing answer, this one will be remembered and will be included in follow-up questionnaires, for the same patient.

Naming the questionnaire

The new poll needs a title that does not mislead the reader/respondent or generate bias. We named it “ENT symptoms and general evaluation questionnaire”, avoiding words as “wellbeing”, “affected”, “important”, “most”, “satisfaction”, as we tried to keep it neutral.

Introduction for the respondent

Every test needs an opening word, a prologue. It is a short text with indications for responders, guiding them how they should read and respond. We used a polite greeting and thanked them for their attention: “We kindly ask you to answer these questions. Please check only one answer/option for each statement. Choose the answer that suits you the most for the time being. Attention! Q*16-17 are for follow-up, not for the first evaluation. Thank you!”.

Signing the questionnaire

The answers are not anonymous, but they are kept private and confidential and remain in the admission sheet or in the clinic personal archive (in case of follow-up meetings). The patient is asked to fill his/her name, the current date in the designated space and sign the paper sheet.

RESULTS

The final questionnaire, translated in English, is shown in Figure 1.

The list of statements to be evaluated by the patient are as follows:

1. I have a stuffy nose (nasal obstruction)
2. I have nasal purulent secretions (or crusts)
3. I smell a bad odor coming from my nose
4. I feel facial pressure
5. I have headache (or migraine)
6. I have nosebleeds
7. I am worried about my general health
8. I am worried about how my face/nose/eyes looks
9. Symptoms prevent me from being efficient at work

We kindly ask you to answer these questions. Please check only one answer/option for each statement.
Choose the answer that suits you the most in the time being. Attention! Q*16-17 are for follow-up, not for the first evaluation.
Thank you!

	Never	Rarely	Sometimes	Often	Regularly	Always
1. I have a stuffy nose (nasal obstruction)	0	2	4	6	8	10
2. I have nasal purulent secretions (or crusts)	0	2	4	6	8	10
3. I smell a bad odor coming from my nose	0	2	4	6	8	10
4. I feel facial pressure	0	2	4	6	8	10
5. I have headache (or migraine)	0	2	4	6	8	10
6. I have nosebleeds	0	2	4	6	8	10
7. I am worried for my general health	0	2	4	6	8	10
8. I am worried about my face/nose/eyes looks	0	2	4	6	8	10
9. Symptoms prevent me from being efficient at work	0	2	4	6	8	10
10. Symptoms prevent from doing my daily activities	0	2	4	6	8	10
11. Symptoms are interfering with my social life (meeting with friends)	0	2	4	6	8	10
12. I feel sad	0	2	4	6	8	10
13. I feel prejudiced	0	2	4	6	8	10
14. I feel angry	0	2	4	6	8	10
15. I regret doing the first surgery	0	2	4	6	8	10
16. *I feel content with my current treatment	0	2	4	6	8	10
17. *I feel that my symptoms are improving	0	2	4	6	8	10
18. Others (please mention what)	0	2	4	6	8	10

Figure 1. ENT symptoms and general evaluation questionnaire.

10. Symptoms prevent me from doing daily activities
11. Symptoms interfere with my social life (meeting with friends)
12. I feel sad
13. I feel prejudiced
14. I feel angry
15. I regret doing the first surgery
16. *I feel content with my current treatment
17. *I feel that my symptoms are improving
18. Others (please mention what)

This questionnaire was created to assess patients who presented with complications and/or sequelae after surgical interventions in the sinonasal area, complementary to anamnesis and clinical examination. Patients had their first intervention in other ENT Departments. These patients did not have a good outcome after the first surgery, and they were liable to pursue legal action. We had in mind that the patient's chart is a legal document and it must be written with accuracy¹⁹. Therefore, all cases details were thoroughly documented, and all the available documentation was filed, including this questionnaire.

The list of statements/questions patients were asked to answer referred equally to clinical ENT and general symptoms, as well as to psycho-emotional and social aspects, in a balanced proportion.

After its preliminary consideration (identify construct of interest) and its developing, the questionnaire needed to undergo a process, in order to be validated. We respected the basic steps of development process found in international guidelines²⁰:

- ✓ establish expert committee,
- ✓ identify dimensionality of construct,
- ✓ determine questionnaire format,
- ✓ determine items format,
- ✓ items development,
- ✓ determine questionnaire length,
- ✓ review and revise initial items pool.

This questionnaire could not be validated due to some restrictions:

- preliminary pilot testing: our intended population is a narrow range of patients;
- using principal components analysis (PCA): we did not create questions that measure the same thing; although we have identified three themes, questions could not be aggregated as loading onto same factors²¹;
- the standard test of internal consistency is Cronbach's Alpha (CA) – it could not be used because the statistic result was not the intended purpose of the questionnaire.

As stated above, this questionnaire was not designed for analytical or statistical purposes. Its main goal was to record and monitor the patient's symptoms, feelings and disturbance of general wellbeing and social life. We used it to compare symptom dynamics for each patient. We did not use it to compare data between patients because the postsurgical complications were caused sequent to different interventions.

We started to use this questionnaire since 2015 and the results of this work is yet to be published in the PhD thesis entitled "Medico-legal and psychosocial aspect in patients with sequels and complications after sinonasal surgery". This idea origins in this epoch of malpractice, of medical specialists being accused of delivering improper medical care, in an era of media inquests and public discredit of doctors. This thesis approaches delicate subjects like patients' postsurgical complaints, their evolution with proper medical treatment, patients' legal options at a certain point in time, the doctor's opinion about the case and ways that situations like that can be avoided. We considered it a way to learn from others' mistakes, an opportunity to publish a wide research-connecting medical and law topic.

CONCLUSIONS

It is recommended for doctors to use all available tools in their daily practice, for their patients' favourable outcome. Even if a questionnaire is not a routinely used instrument in patient care, sometimes one may come in handy. In case of medico-legal situations, it is better to foresee certain aspects of the case and to act accordingly, meaning to log-in detailed conditions, even those we usually only speak about with our patients (e.g., general interference of the symptoms in daily life).

Patient evaluation is preferable to be performed using a validated questionnaire. If none of the available ones fulfils your requirements, it is not forbidden to create a new one. The new questionnaire can be validated by group studies. Even if it is not a validated tool, in its repeatability characteristic, it can be a loyal assessment and monitoring mean to check patients individually.

Our new questionnaire helped us gather information about patients with complications or sequelae after sinonasal surgery, performed in other ENT clinics.

We used the idea of a Visual Analogue Scale, enriched with more adverbs, graphic marks. More than other known ENT questionnaires, we focused upon psychosocial aspects. We use it in our clinic as a monitoring device for patients' treatment. We felt that it was necessary to not overlook certain aspects and to register them in the observation sheet, as personal extra malpractice coverage. This new-created questionnaire is not intended and validated for statistical usage.

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