Scientific tools for collecting and analyzing medical data in rhinology

Narzędzia naukowe do gromadzenia i analizy danych medycznych w rynologii

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
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E – Literature Search
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ABSTRACT: **Introduction:** In the era of „Evidence Based Medicine" knowledge of methodology and scientific trends is an indispensable tool for both practitioner and physician-scientist. The ability to interpret data obtained from the literature allows for better diagnosis, treatment and control of patients. The generally accepted structuring of published data and unification of research tools also allows for conducting original and review papers based on our own results.

The Aim: The purpose of our work was to search for and present scientific tools (questionnaires, scales and checklists) used to collect data in rhinology. The results of these studies were published in reputable magazines in the period 2000–2019 in English.

Material and method: To search for articles, we used MEDLINE, PubMed and Scopus date bases.

Conclusions: The use of generally accepted check-lists and questionnaires in the collection of clinical data and their assessment allows to significantly increase the quality of the collected data and their scientific attractiveness, which in turn is applied to the easier possibility of publishing the obtained results and further citing them in reputable specialist journals.

KEYWORDS: checklist, questionnaire, rhinology, statistical analysis, symptom score

STRESZCZENIE: **Wprowadzenie:** W czasach „Evidence Based Medicine" znajomość metodologii oraz trendów naukowych jest niezbędnym narzędziem zarówno dla lekarza-praktyka, jak i lekarza-naukowca. Umiejętność interpretacji danych uzyskanych z piśmiennictwa pozwala lepiej diagnozować, leczyć, ale również kontrolować pacjentów. Ogólnie przyjęta strukturyzacja opublikowanych danych oraz ujednolicenie narzędzi badawczych umożliwia także prowadzenie prac oryginalnych i poglądowych na podstawie własnych wyników.

Cel: Celem naszego tekstu było poszukiwanie i przedstawienie narzędzi naukowych (ankiet, skal i listy kontrolnej) używanych do gromadzenia danych w rynologii. Wyniki tych badań zostały opublikowane w renomowanych czasopismach w latach 2000–2019 w języku angielskim.

Materiał i metoda: Do poszukiwania artykułów wykorzystaliśmy bazy: MEDLINE, PubMed oraz Scopus.

Wnioski: Używanie ogólnie przyjętych *check-list* oraz ankiet w gromadzeniu i ocenianiu danych klinicznych pozwala istotnie zwiększyć jakość zgromadzonych danych oraz ich atrakcyjność naukową, co z kolei przykłada się na łatwiejszą możliwość publikacji uzyskanych wyników oraz dalsze ich cytowanie w renomowanych czasopismach specjalistycznych.

SŁOWA KLUCZOWE: analiza statystyczna, ankieta, *check-lista*, kwestionariusz, lista kontrolna, lista sprawdzająca

INTRODUCTION

In the era of "evidence-based medicine", the knowledge of scientific methodology and trends has become a necessary tool both for physician practitioners as well as physician scientists. The ability to interpret data obtained from literature allows to better diagnose, treat as well as monitor patients. Proper collection and elaboration of data as well as their analysis allow to share the acquired knowledge, but also to compare the obtained results with literature data. The generally accepted structurization of published data as consolidation of scientific tools also allows to conduct original works and reviews based on own merits. This is even more important in rare diseases, in which case only analysis of data from a series of various sources (often times such from many centers) allows to

highlight the macro-image of the pathology, reach proper conclusions, and verify the research hypothesis.

Criteria for research tools [1–4]:

1. Quality of life, both health-related and oriented towards functional and/or social status;

2. Ease of use (including estimated time to completion and availability);

3. Credibility and timeliness (based on reviewed literature);

4. Specificity for a given pathology.

The set of scientific tools must be selected well for the examined problem in order to provide the largest possible amount of data. Scientific tools ill-adapted to the study can be the reason for obtaining misleading or even erroneous results of little value.

Standardization in the analysis of a patient's ailments, the severity of the disease as well as the history and results of treatment may also form the foundation for the development of telemedicine [5, 6].

We hope that the results of our research will pave the way for planning future scientific research in rhinology in Poland. They will allow their implementation at the level consistent with Evidence-Based Medicine, which significantly enhances the quality of research and increases interest in publications at international level.

MATERIALS AND METHODS

The aim of our work was to search for and present scientific tools (surveys, scales and checklists) used to collect data in rhinology. The results of these studies were published in reputable journals in the period 2000–2019 in English. To search for articles, we used MEDLINE, PubMed and Scopus databases.

The search was performed using the keywords: "quality of life", "rhinology", "septoplasty", "sinus surgery", "questionnaire", "checklist" and their synonyms.

RESULTS

As a result of our work we managed to find a series of searched scientific tools which we divided into the following groups: Checklist, questionnaire.

It is a relatively simply scientific and clinical tool which provides control of correctness and quick assessment of the degree of completion of the data collection process. Usually, the checklist consists of a series of questions or issues regarding the patient, his health status and his environment. The beginning of the use of large-scale checklists in scientific research was observed in the 1960s. At present, checklists are used practically in every area of scientific projects. The effectiveness of a checklist depends on its

complexity. Accurate and detailed questions increase effectiveness but this extends the preparation time [1–3].

Advantages of the checklist:

- simplicity of use,
- easy data collection,
- minimal risk of losing important data,
- systematization of obtained data.

Examples of checklists in otolaryngology, head and neck surgery include [7–9]:

- *Adult Pre-Operative Surgery Checklist;*
- *Pediatric Surgery Pre-Operative Checklist;*

Checklists contain detailed information about the patient: his personal data (name, surname, age, gender, occupation), social conditions, accompanying diseases, medications used, allergies, previous treatments and operations, family diseases. Detailed questions regarding the course of a specific disease, used treatment methods and their outcomes as well as assessment of the additional tests performed to date and their further plan.

The acquired data allow to analyze the obtained results and draw proper conclusions about the course of disease, value of additional tests as well as the efficacy of treatment methods. All results refer to the studied population.

The abovementioned checklists do not strictly apply to all hospitals and are presented only as an example, which can be the basis for creating own checklists depending on the specificity of the department and the set objectives.

- *Sample endoscopic sinus surgery checklist* [10].

This checklist can serve as a template for doctors who perform endoscopic surgery of the nose and sinuses; the use thereof can help prevent adverse events during their implementation. It comprises 3 parts: 1 – preparation for surgery (completed before intubation) 2 – preparation for intervention (completed before starting the surgical stage of the operation) and 3 – finalization of surgery (completed before waking and extubating the patient).

We observed a tendency to create checklists used in the process of teaching otolaryngology residents to verify their level of knowledge and skills as well as progress in the teaching process.

- *Task specific checklist TSC for septoplasty surgery* (*septoplasty TSC*) – checklist developed by the authors to provide a reliable estimate of surgical skills of residents in otolaryngology performing septoplasty. A 5-degree scale is used to assess individual stages of septoplasty: examination of the nasal cavity including the nasal septum, local anesthesia, enabling surgical access, production of osseous-muco-periosteal flap, resection/reposition of the nasal septum, septal stabilization and application of a dressing;
- *Checklist for endoscopic sinus surgery* – assessment of

surgical skills of otolaryngology residents. Assessment of the performance of individual parts of endoscopic sinus surgery (preparation of the endoscopic set, removal of uncinate process, opening of anterior and posterior ethmoid cells, identification and opening of frontal and sphenoid sinuses) on a scale of 1 to 5. It allows to assess the skills of residents/surgeons and the progression of their skills during the learning process [12, 13];

- *CLOSE Preoperative ESS Radiographic Checklist* – checklist for otolaryngology residents for nasal or sinonasal endoscopic techniques, the purpose of which is to check the skills of CT of the sinuses prior to planned surgery. The abbreviation CLOSE comprises the first letters of anatomical points subject to analysis: C – *cribriform*, L – *lamina papricea*, O – *Onodi/Haller*, S – *Sphenoid*, E – *ethmoid* [14]. Many centers expand the checklist by additional information including: position of the anterior ethmoid artery, depth of olfactory fossa, width of posterior ethmoid bone, presence of agger nasi air cells or presence of bony dehiscence.

The introduction of a systematic approach to the review of pre-operative CT scans of the sinuses using a checklist improves the identification of critical variations of anatomical paranasal sinuses during preparation for surgery.

Surveys (questionnaires)

A questionnaire is a research tool comprising a series of questions (or other types of suggested answers) for the purpose of collecting information from respondent; it was proposed by the Statistics Society of London in 1838 [15, 16]. Questionnaires permit quantitative appraisal of the quality of our work; furthermore, they are used to standardize data, which allows for their comparison, analysis (clinical studies, reviews) and monitoring of the course of illness.

- *Visual analogue scale* (VAS) – the visual analogue scale is a psychometric instrument broadly used in the field of rhinology for subjective measurement of the severity of a patient's symptoms. In allergic rhinitis, VAS was found to correlate well with the severity of these nasal lesions, the severity of asthmatic lesions, and the quality of life questionnaire in patients with conjunctivitis allergic. In chronic rhinitis and sinusitis, the total VAS score is often used to classify symptoms according to the three-step scale: mild (1–3 points), moderate (4–7 points) and severe (8–10 points)) [17, 18];

- *WHOQOL-BREF questionnaire* – a general scale of quality of life developed by the World Health Organization. It allows to assess the global impact of treatment on all aspects of life using a questionnaire which is not specific for rhinology. The survey covers 26 items that measure the following broad domains: physical health, mental health, social relations and the environment. WHOQOL-BREF is a shorter version of the original instrument that may be more convenient to use in large scientific studies or clinical trials [19–21].

In 2018 in Poland, Rot et al. conducted an assessment of patients' quality of life before and after open septorhinoplasty using the WHOQOL-BREF questionnaire. Using the abovementioned survey, the level of quality of life before and 3 months after surgery was analyzed. Data standardization enabled to detect a statistically significant difference (improvement) in the quality of life in patients who have undergone surgery of the external nose. [19].

Short Form Health Survey

- *36-Item Short Form Health Survey (SF-36)* – is a 36-question questionnaire rating the health status reported by the patient. The SF-36 questionnaire was created during the planning of the Medical Outcome Study, which was conducted by RAND Corporation (the non-commercial US organization "Research and Development"). Since that time, a group of scientists from the original study has released the commercial version of SF-36, while the original SF-36 is available under public domain license for free from RAND (RAND-36). SF-36 and RAND-36 contain the same list of questions, of which each is rated on a scale of 0 to 8. The lower the score, the greater the patient's disability [22, 23];

- *12-Item Short Form Health Survey (SF-12)* – an abbreviated variant of the SF-36 is used in cases where only physical and mental health is of interest [24, 25];

- *6-Item Short Form Health Survey (SF-6D)* – an abbreviated variant of the SF-36 is broadly used in health economics as a variable in calculating the quality-adjusted life year to determine the cost-effectiveness of treatment [26];

Patient Health Questionnaire

- *Patient Health Questionnaire-2 (PHQ-2)* – the purpose of the questionnaire is a retrospective depression screen in patients over the past two weeks. PHQ-2 includes the first two questions of the PHQ-9 questionnaire. Patients who scored positive should be further evaluated using PHQ-9 to determine if they meet the criteria for depressive disorder [27, 28];

- *Patient Health Questionnaire-9 (PHQ-9)* – a universal tool for screening, diagnosing, monitoring and measuring the severity of depression. Answers are rated on a scale of 0 to 3 points. The combined scores 5, 10, 15 and 20 represent the cut-off points for mild, moderate, moderately severe and severe depression, respectively [27, 28];

- *EuroQol Five-Dimensional Questionnaire (EQ-5D)* – a standardized tool for measuring overall health. It is widely used in population health research, clinical trials, economic evaluation of therapy, and routine measurement of results in surgical treatment. The study has recently been approved for the assessment of patients with chronic sinusitis. The descriptive part of the questionnaire measures the status of health in categories of five dimensions (5D): mobility (ability to walk), self-care, usual activity, pain/discomfort and anxiety/depression. Each dimension has 3 possible states that provide 245 possible health states. As part of evaluation, respondents assess their overall health using the visual analogue scale (EQ-VAS) [29, 30].

The above questionnaires are used to assess the quality of life in patients without taking into account the specifics of their illness.

Further scientific tools are created to study rhinological patients mainly with chronic sinusitis. The description of questionnaires often includes the term "Likert scale". It is a psychometric scale commonly used in scientific research, which uses questionnaires, which is based on scaling the answers in surveys (for example from 0 to 6 or from 1 to 6 points) [31].

- *31-Item Rhinosinusitis Outcome Measurement (RSOM-31)* – an abbreviated version of RSOM-44. The questionnaire was used to assess the health status in patients with chronic sinusitis and the quality of life. RSOM-31 includes 31 questions that permit the assessment of 7 areas: nose, eye, ear, sleep and general, emotional and functional problems. Ailments occurring in the life of a patient with chronic sinusitis are assessed according to a 5-point scale [32];
- *44-Item Rhinosinusitis Outcome Measurement (RSOM-44)* – a questionnaire containing 44 questions divided into 7 groups: rhinological, ocular, auricular, general, sleep quality, functional ailments (unpleasant breath odor, need for frequent use of tissues, need for frequent cleaning out of nose, frequent visits to the doctor), emotional ailments (easy irritability, anger, feeling of sadness, depression). Ailments are usually rated on a scale of 1 to 6 points at the beginning of treatment and 6 and 12 weeks after completion [32].

Sino-Nasal Outcome Test

- *16-Item Sino-Nasal Outcome Test (SNOT16)* – developed to provide a quick and easy assessment of ailments reported by patients with acute bacterial rhinitis. Items are ranked using a 4-point Likert scale to provide a total score of 0 to 48 [33, 34];
- *20-Item Sino-Nasal Outcome Test (SNOT20)* – the questionnaire was developed as a modification of the RSOM-31 questionnaire (*31-Item Rhinosinusitis Outcome Measure*). The patient was asked to rank the severity of 10 symptoms and 10 social and emotional consequences using a 6-point Likert scale and prioritize them according to the degree of their seriousness for the patient. The results cover a total symptom score of 0 to 100 and a list of the 5 most common symptoms. The guidelines advise against using SNOT-20 as a measure of results reported by patients with chronic sinusitis due to a lack of questions about nasal obstruction and smell [18, 35, 36];
- *22-Item Sino-Nasal Outcome Test (SNOT22)* – a measure of the result applicable to both the assessment of sinonasal symptoms and surgery (point range, 0–110). It is a modification of the SNOT-20 questionnaire from which questions (a total of 5) on the most troublesome symptoms were removed and 2 questions were added regarding nasal obstruction and taste/smell disorders [29, 37];
- *25-Item Sino-Nasal Outcome Test (SNOT25)* – another modification of the SNOT20 questionnaire, which consists in adding 5 additional questions: "nasal dryness," "impaired nasal breathing", "shortness of breath when breathing through the nose", "abnormally patent nose", and "scabbing within the nasal passages" [38]. The questionnaire is often used for patients with empty nose syndrome [29, 39];

- *Empty Nose Syndrome 6-Item Questionnaire (ENS6Q)* – the questionnaire contains 6 typical symptoms of empty nose syndrome (nasal congestion, nasal burning, excessive "openness" of the nasal passages, scabs, dryness and feeling that too much air is entering the nose). The results of the questionnaire permit the differentiation of chronic rhinosinusitis from empty nose syndrome [40–42];
- *11-Item Sino-Nasal Assessment Questionnaire (SNAQ-11)* – the questionnaire consists of 11 questions about the nose, paranasal sinuses and the general condition of the patient with chronic rhinitis and sinusitis. The severity of symptoms is assessed from 0 to 5 points [35, 43];
- *St. George's Respiratory Questionnaire (SGRQ)* – the questionnaire consists of 50 questions grouped into three subgroups: symptoms, activity and impact on health. It is often used to assess the quality of life in patients with COPD [43];
- *Rhinosinusitis Disability Index (RSDI)* – a 30-item questionnaire consisting of 3 individual subgroups to measure the impact of sinusitis on the patient's physical, functional and emotional condition (point range, 0–120) [44, 45];
- *Chronic Sinusitis Survey (CSS)* – a 6-item questionnaire designed to measure sinusitis-specific symptoms and the use of medicines over the past 8 weeks (point range, 0–100) [46];
- *Questionnaire of Olfactory Disorders (QOD)* – the questionnaire was approved for assessing the impact of olfactory dysfunction on quality of life in patients with chronic rhinosinusitis. It consists of 52 questions divided into 3 groups: 39 negative elements (degree of suffering of the respondent), 5 positive elements (that give information on the way respondents cope with their olfactory disorders) and 8 social elements (that measure the reliability of patients' responses). Items rated on a scale of 0 (I disagree), 1 (I agree partly) to 2 (I agree), and the sum of scores from all 3 groups are calculated to a maximum score of 104 points;
- *Shirt-form McGill Pain Questionnaire (SF-MPQ)* – an abbreviated version of the original MPQ. It is used for quantitative and qualitative assessment of pain. The questionnaire includes 11 qualitative terms for pain (pulsating, constant, shooting, stabbing, sharp, blunt, squeezing, biting, burning, undulating, fear of pain), which the patients were asked to assess on a 4-level scale of intensity (no pain, light, moderate, severe) [35, 48];
- *Sinusitis Control Test (SCT)* – it has been recently developed to assess the degree of CRS control. The SCT questionnaire differs from other tools for assessing patients' quality of life in that it does not assess how patients perceive the impact of disease, but rather how well the disease is controlled with current therapy at a given time. The questionnaire includes 4 questions, 3 of which are answered using a 5-point Likert scale and 1 with a dichotomous question: "No" (score – 0) or "Yes" (score – 5). The results divide patients into 3 groups: well controlled (overall score 0–3), partially controlled (overall score 4–11) and poorly controlled (overall score 12–16) [29, 49];

- *Adelaide Disease Severity Score (DSS)* – it was developed as an abbreviated alternative to SNOT-22. The questionnaire asks patients to rank 5 common symptoms by severity (nasal congestion, rhinitis, runny nose, headache/facial pain and olfactory disorder) using a Likert scale from 0 (none) to 5 (severe). Beside 5 symptomatic elements, there is 1 question in which the patient is asked to define the degree of the ailment's impact on the quality of life according to the VAS scale from 0 (no effect) to 7 (maximum effect). A statistically significant correlation of the questionnaire results with the outcomes of SNOT-22, the Lund-Mackay and Lund-Kennedy scales was observed [50];

- *Dysfonctionnement Nasal Chronique Questionnaire (DyNaCron)* – developed to assess the impact of nasal symptoms on the patient's physical and psychosocial condition. The questionnaire consists of 78 questions divided into 6 groups. Each question is answered on a scale of 0 (no impact) to 10 (intolerable), and patients only need to answer questions about the conditions by which they are affected [29, 51];

- *Sinonasal 5-Item Questionnaire/ Sinus and Nasal Quality of Life Survey (SNQ/SN-5)* – developed to investigate chronic sinusitis. Five groups of ailments are assessed: sinus infection, nasal congestion, allergy symptoms, emotional stress and activity limitations. Each group comprises various clusters of symptoms and to assess them, we use a scale from 1 (never) to 7 (all the time) to obtain the average results in the studied ailment group. There is one question regarding the impact of ailments on the quality of life which is assessed according to the VAS scale from 0 (worst) to 10 (ideal) [52];

- *Rhinosinusitis Quality of Life survey (RhinoQol)* – a 17-question questionnaire that assesses three areas: the frequency of symptoms, the severity of symptoms and the scale of their impact on the quality of life. Assessments of individual subjects are ranked from 0 (worst possible health) to 100 (best possible health) [53];

- *Rhinosinusitis Symptom Inventory (RSI)* – it evaluates the "main" and "minor" symptoms of chronic sinusitis observed over the past 3 months on a Likert 6-point scale (0 means no symptoms; 5 means very severe). Furthermore, it documents the consumption of medicines, visits to the doctor and absence at work directly related with chronic sinusitis [54];

- *Rhinitis Symptom Utility Index (RSUI)* – developed as a preference-based measure of rhinitis symptoms. The questionnaire consists of 10 questions about the severity and frequency of impaired nasal breathing, runny nose, sneezing, itching, watery eyes and throat during the last 14 days. This is a short and user-friendly questionnaire. The results reflect the daily course of rhinitis. RSUI can bea useful measure in clinical research on the cost-effectiveness of the applied treatment of rhinitis [55, 56].

Symptom Severity Scale/Lesion Severity Scale

The use of the Symptom Severity Scale and the Lesion Severity Scale allows for universal determination of the severity of disease, observation of the course and results of treatment. Classifications created on the basis of results are likely to be useful in assessing the prognosis of the course of disease or in choosing the treatment method depending on the disease stage.

- *Meltzer score* – a scale used to describe lesions found during nasal endoscopy. Lesions rated on a scale of up to 4 points: 0 – no polyps, 1 – polyps confined to the middle meatus, 2 – multiple polyps occupying the middle meatus, 3 – polyps extending beyond middle meatus, 4 – polyps completely obstructing the nasal cavity [57];

- *Pre-/postoperative Lund-Kennedy endoscopy scores* – a system for assessing lesions (polyps, swelling, discharge, scars, scabs) in the nasal cavity on a scale of 0 to 2;

- *Modified Lund-Kennedy scoring system* (MLK) – a system for assessing lesions (polyps, swelling, discharge) in the nasal cavity on a scale of 0 to 2;

- *Lund-Mackay scores (LM)* – a scale used to describe lesions in the paranasal sinuses and nasal cavity visible on computed tomography. Evaluation of maxillary, anterior, posterior, sphenoid and frontal sinuses on a scale of 0 to 2 (discrete lesions or lack thereof, 1 – partial opacification, 2 – total opacification) and patency of the ostiomeatal complex (0 – patent, 2 – obstructed) [58];

- *Rhinosinusitis Task Force symptom score (RSTF)* – the system was developed as a measure to assess the symptoms of chronic sinusitis. Patients were asked to assess 5 major (facial pain/pressure, facial congestion, nasal congestion, nasal discharge and olfactory impairment) and 7 minor symptoms (headache, fever, halitosis, fatigue, toothache, cough and earache) using the visual analog scale (VAS) from 0 (no symptoms) to 10 (maximum severity). Two additional assessments from 0 to 10 according to the VAS scale are issued by the doctor based on the examination indicating fever (acute) and the presence of purulent nasal discharge [59].

CONCLUSION

The use of scientific measures such as checklists, questionnaires, and disease severity scales can be of great benefit not only in the completion of scientific studies, but also in the teaching process of young otolaryngologists and in the diagnosis and treatment of patients with nasal and sinus diseases. Owing to this, the obtained data is easier to standardize, which facilitates communication between doctors and permits the development of such a direction as telemedicine.

The use of generally accepted checklists and questionnaires in the collection and evaluation of clinical data allows to significantly enhance the quality of collected data and their scientific attractiveness, which in turn translates to an easier possibility of publishing the obtained outcomes and further citing them in reputable specialist journals.

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