The GA²LEN survey for chronic rhinosinusitis prevalence studies: Arabic translation, cultural adaptation, and validation*

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Abstract

Background: Chronic rhinosinusitis (CRS) is a common disease that significantly impacts quality of life. Its prevalence varies between different geographical areas. This study aimed to validate the Arabic version of the EPOS criteria in the GA2LEN questionnaire to use it as a tool to estimate the prevalence of CRS in Arab countries.

Methods: This is multicentric cross-sectional validation study. The original English EPOS criteria used in the GA2LEN survey (four main questions and two additional questions) were translated into Arabic. The study was conducted at King Abdulaziz University Hospital – Riyadh and Qatif Central Hospital – Qatif in the period between October 2020 and August 2021. Groups of CRS and non-CRS patients were selected randomly from databases of the hospital and asked to participate in the study through phone calls. Sensitivity, specificity, positive, and negative predictive values were calculated for the Arabic questionnaire.

Results: Of 200 subjects contacted to complete the questionnaire, 128 agreed to participate and completed the survey. The Arabic version of the GA2LEN questionnaire was found to be reliable with high sensitivity and specificity. The reliability of the questionnaire increased when we added the question, "Has a doctor ever told you that you have chronic sinusitis?" to the main four questions. The sensitivity, specificity, and positive and negative predictive values were 93.9%, 59.6%, 71.25%, and 90.2%, respectively.

Conclusions: The Arabic version of the EPOS criteria in the GA2LEN questionnaire is a valid and reliable tool for epidemiological studies to estimate the prevalence of CRS.

Key words: Arabic questionnaire, chronic rhinosinusitis, diagnosis, epidemiology, prevalence, survey

Introduction

Chronic rhinosinusitis (CRS) is the inflammation of the sinonasal mucosa lasting for more than 12 weeks [1]. According to the latest classification adopted by EPOS, CRS can be primary or secondary. For each group, the disease may be due to different endotype dominances leading to various phenotype expressions [1].
Epidemiologically, prevalence studies are essential to developing a health economic module for any disease. Moreover, studying the prevalence will inform policymakers about the disease

burden, supporting the identification of priorities in healthcare, prevention, and policy [2]. Many epidemiological studies have been conducted worldwide on the prevalence of CRS. Different techniques have been used to diagnose CRS among the study populations [3-7]. The Global Allergy and Asthma European Network of Excellence (GA²LEN) conducted one of the largest epidemiological studies to estimate the prevalence of CRS in 12 European countries [5]. They structured a questionnaire to diagnose CRS according to the 2007 EP³OS criteria. In the next step, the questionnaire was validated to the findings from nasal

endoscopy to diagnose CRS [8]. The group concluded that this questionnaire had moderate reliability and was suitable for use in epidemiological studies to assess the prevalence of CRS. The same criteria were used in EPOS 2020 to diagnose CRS [1]. EPOS recommend to the have minimum 2 out 4 criteria and addition to clinical endoscopic or radiological finding to diagnose CRS. This is difficult to be applied in the mass epidemiological studies. Accordingly, EPOS epidemiological definition of CRS is based on the presence of symptoms without endoscopic or radiological findings. GA^{2}LEN study utilized this definition to diagnose CRS in the study group. For that having such a questionnaire will be very helpful in estimating the prevalence of this common condition specially in countries lacking registry systems.

This study aimed to establish an Arabic version of the EPOS criteria to diagnose CRS using the GA^{2}LEN questionnaire and validate it to the paranasal sinuses CT findings of CRS in our population.

Materials and methods

Questionnaire

The section of the GA^{2}LEN questionnaire used to diagnose CRS is based on the four cardinal symptoms in the EPOS guideline and two additional questions. These symptoms are nasal blockage or congestion, nasal discharge, facial pain or pressure, and reduction or loss of smell. The first additional question asked about self-reported doctor-diagnosed CRS and the second about self-reported nasal allergies [8]. The diagnosis of CRS was made based on EPOS epidemiological definition of CRS which is: presence of two or more symptoms, one of which should be either nasal blockage / obstruction / congestion or nasal discharge (anterior / posterior nasal drip): ± facial pain/pressure; ± reduction or loss of smell; for ≥12 weeks [1].

The English version of the questionnaire was translated into Arabic by two independent professional translators. Four rhinologists then checked these Arabic versions and compared them with the original English version. After discussion, the two Arabic versions were merged into one. This version was sent to another independent translator with no experience of the original English version for back-translation into English. No major differences were found between the original English and the back-translated version. The final Arabic version was used in a pilot study on 10 patients to assess its clarity (Appendix / Figure 1).

Study sample

The sample was recruited from the databases of King Abdulaziz University Hospital – Riyadh and Qatif Central Hospital – Qatif in the period between October 2020 and August 2021. The sample size calculated using the CDC tool (Epi Info™ For Windows version 7.2) for confidence interval 80% was a total of 120

Table 1. Demographic data of the participants.

Parameter		Number of participants
Age	Less than 30 years	19
	From 30 till 39	40
	From 40 till 49	31
	From 50 to 59	21
	60 years and above	17
Sex	Male	67
	Female	61
Marital status	Single	28
	Married	89
	Widow	3
	Divorced	8
Region	Al-Baha	1
	Al-Jouf	2
	Northern Borders	1
	Riyadh	90
	Qaseem	4
	Eastern Region	19
	Tabuk	1
	Jezan	1
	Aseer	4
	Makkah	3
	Najran	2
Education level	Uneducated	8
	Undergraduates	37
	Academic	36
	Bachelor	40
	Master	6
	PhD	3

candidates (including both groups). After reviewing the medical records of the patients who visited the rhinology and general ENT clinic in both institutes, a candidate list was generated for each study group. Computerized simple randomization was then performed to select 100 candidates from each group (200 in total) to accommodate for possible recruitment issues that could be faced and reach the targeted sample size (≥ 120 candidates). The included subjects were classified based on the clinical data into CRS and non-CRS groups. All participants in the CRS group were diagnosed in the clinic based on EPOS guidelines. The non-CRS participants were selected from the general otolaryngology clinic after reviewing the documented history and available CT scans of the head and neck area that were showing the paranasal sinuses. The patients' charts were reviewed for the absence of EPOS criteria for CRS. Lund Mackay score of 3 or less was used to exclude CRS as the EPOS2020 steering group regarded a total Lund-Mackay score of 3 or more whether uni- or bilateral to be clinically relevant to consider CRS [1]. The CT scans were reviewed by two authors separately to confirm the assessment.

Data collection

The questionnaire was administered by phone calls between October 2020 and August 2021, and data were recorded in web-based form. Each candidate was contacted on up to three

Table 2. Comparison of statistical parameters between the Arabic (GA²LEN) questionnaire 4 questions, 5 questions and the original English version.

	Questionnaire (4 questions)	Questionnaire (5 questions)	Tomassen et al. 2010
Sensitivity	62.1%	93.9 %	61.7%
Specificity	69.3%	59.6%	----
PPV	68.3%	71.25%	33.6%
NPV	50%	90.2%	83.9%

PPV: positive predictive value; NPV: negative predictive value.

occasions before considering them non-respondent. The interviewer explained the purpose of the survey and acquired verbal informed consent of all subjects involved in the study before commencing the interview. The interviewer was blinded to the diagnosis of each subject during the survey.

Statistical analysis

The Statistical Package for the Social Sciences software for Windows version 23 (IBM Corp., Armonk, NY, USA) was used to perform the analysis. The mean and standard deviation were calculated for numerical variables and the count and percentages for categorical variables. The chi-square test and Fisher's exact test were used to compare different means.

Ethical clearance and confidentiality

The protocol and instrument of surveillance were approved by the Institutional Review Board committee at King Saud University with number E-20-5074. Because this is a cross sectional validation study conducted through a phone call survey, only verbal informed consent was obtained from all subjects. The interviewer explained the purpose of the investigation and the procedures and acquired the informed consent of all subjects involved in the study before commencing the interview. Data confidentiality was assured, and the data will be used only for the stated purpose of the survey.

Results

The response rate was 64% (128 subjects), divided into 66 subjects from the CRS group and 62 from the non-CRS group. Across both groups, 52.3% were male. The subjects belonged to 11 out of 14 administrative regions of the Kingdom of Saudi Arabia. Other demographic data are provided in Table 1. Among the 66 known CRS subjects, 41 candidates were diagnosed based on the four main questions in the survey asking about the cardinal symptoms of CRS. Conversely, from the 62 non-CRS subjects, 43 candidates were not diagnosed with CRS based on the same four main questions in the survey. However, if we considered the question, "Has a doctor ever told you that you have chronic sinusitis?" in the diagnosis, the number of true

CRS cases increased to 62, and the number of true non-CRS cases decreased to 37. The sensitivity, specificity, and positive and negative predictive values, considering four and five questions, are all shown in Table 2.
Nasal allergies, including hay fever, were found in approximately 63% of the CRS subjects.

Discussion

No previous work is available on the prevalence of CRS in Arab countries.
This study has validated the Arabic version of the EPOS criteria to diagnose CRS using the GA²LEN questionnaire as a preliminary step to use it in future studies to estimate the prevalence of CRS in Arab countries.
Several studies worldwide have used the same questionnaire. The prevalence of CRS was found to be approximately 8% in a study including 10,636 respondents from seven Chinese cities [6]. In the southwestern region of Iran (Bushehr), the questionnaire was completed by 5,201 participants. The overall CRS prevalence was 28.4% [9].
This study showed that adding the question, "Has a doctor ever told you that you have chronic sinusitis?" to the four main questions about CRS symptoms improved the sensitivity of the questionnaire from 62.1% to 93.9%. Moreover, it improved the positive and negative predictive values (Table 2). This showed that adding the question of (self-reported doctor-diagnosed CRS) is valuable in detecting CRS cases when CRS symptoms improve and possibly subside after treatment. Therefore, we recommend using the 5 questions for further future surveys. The reduction in specificity could be attributed to the fact that some other rhinological conditions, such as allergic rhinitis, sharing the same symptoms.
Generally, the statistical outcomes of this study were better than the original validity obtained by Tomassen et al. [8]. Since CT of paranasal sinuses is more sensitive in diagnosis CRS, selection of participants from both groups based on CT scan gives more power to this study. CT of paranasal sinuses showed sensitivity rate of 85-94% and it is superior to nasal endoscopy for diagnosis of CRS [10,11]. Based on this, the Arabic version of the EPOS criteria for diagnosing CRS using the GA²LEN questionnaire can be considered a valid tool for conducting epidemiological studies in the Arab countries. This provides motivation for conducting further studies to estimate the prevalence of CRS in our area.
This study is not without limitations. The selection of non-CRS cases was done retrospectively based on reviewing the charts and radiological criteria for CRS. The diagnosis was not confirmed clinically prospectively. Therefore, this may increase the chance of selection bias.

Conclusions

The Arabic version of EPOS criteria from GA²LEN questionnaire

to diagnose CRS is a valid tool to be used. This will be a corner stone for conduction larger epidemiological studied to estimate CRS prevalence in the Arab countries.

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Authorship contribution

HA and SA: Conceptualization, literature review, writing the proposal, Methodology, data extraction, data analysis, writing and reviewing the results, writing and reviewing the manuscript; AAQ and OM: Writing the manuscript, Review the results, reviewing tables, final review of manuscript.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and material

Not applicable.

Conflict of interest

No conflict of interest exists.

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APPENDIX

Figure 1. The Ga²LEN questionnaire in Arabic.

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استبيانُ تشخيص التهاب الأنف والجيوب المزمن
بحسب شبّكة التميُّز الأوروبية الدولية للحساسية والربو

التاريخ:

الاسم:

الرجاء الإجابة على الأسئلة التالية بنعم أو لا:

الإجابة		الأسئلة
لا ☐	نعم ☐	هل شعرت بانسداد في الأنف لأكثر من 12 أسبوعًا خلال آخر 12 شهرًا؟
لا ☐	نعم ☐	هل شعرت بألم أو ضغط حول الجَبْهَة أو الأنف أو العينين لأكثر من 12 أسبوعًا خلال آخر 12 شهرًا؟
لا ☐	نعم ☐	هل عانيت من تغير في لون افرازات الأنف أو تغير في لون المخاط النازل في الحلق لأكثر من 12 أسبوعًا خلال آخر 12 شهرًا؟
لا ☐	نعم ☐	هل شعرت بنقص أو فُقْد حاسَّة الشم لأكثر من 12 أسبوعًا خلال آخر 12 شهرًا؟
		أسئلة اضافية
لا ☐	نعم ☐	هل أخبرك أحدُ الأطبّاء من قبل بأن لديك التهاب مزمن في الجيوب الأنفية؟
لا ☐	نعم ☐	هل لديك أيّ نوعٍ من الحساسية الأنفية، ويشمل ذلك حمى القش ؟

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