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 EPOS criteria. In the next step, the questionnaire was validated to the findings from nasal
endoscopy to diagnose CRS (1). 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 (11). EPOS recommend to the haive minimum 2 out 4 criteria and addi-
tion 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. GA2LEN 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 GA2LEN questionnaire and
validate it to the paranasal sinuses CT findings of CRS in our
population.

Materials and methods
Questionnaire
The section of the GA2LEN questionnaire used to diagnose CRS
is based on the four cardinal symptoms in the EPOS guideline
and two additional questions. These symptoms are nasal bloc-

dage 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 (6). 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 (6).
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 Win-
dows version 7.2) for confidence interval 80% was a total of 120
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 otorhinolaryn-
gology clinic after reviewing the documented history and available CT
scans of the head and neck area that were showing the parana-
sal 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>
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<td>Age</td>
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<td>Less than 30 years</td>
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<tr>
<td>From 40 till 49</td>
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<td>From 50 to 59</td>
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<tr>
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<td>Master</td>
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<tr>
<td>PhD</td>
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</table>

Table 1. Demographic data of the participants.
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 GA\textsuperscript{LEN} 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 GA\textsuperscript{LEN} 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 GA\textsuperscript{LEN} questionnaire

<table>
<thead>
<tr>
<th>Questionnaire (4 questions)</th>
<th>Questionnaire (5 questions)</th>
<th>Tomassen et al. 2010</th>
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<tr>
<td>Sensitivity</td>
<td>62.1%</td>
<td>93.9%</td>
</tr>
<tr>
<td>Specificity</td>
<td>69.3%</td>
<td>59.6%</td>
</tr>
<tr>
<td>PPV</td>
<td>68.3%</td>
<td>71.25%</td>
</tr>
<tr>
<td>NPV</td>
<td>50%</td>
<td>90.2%</td>
</tr>
</tbody>
</table>

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

Table 2. Comparison of statistical parameters between the Arabic (GA\textsuperscript{LEN}) questionnaire 4 questions, 5 questions and the original English version.
Validation of Arabic (GA2LEN) questionnaire

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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Authorship contribution
HA and SA: Conceptualization, literature review, writing the proposal, Methodology, data extraction, data analysis, writing

References

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APPENDIX

Figure 1. The Ga\'LE\'N questionnaire in Arabic.

استبيان تشخيص التهاب الأنف والجيوب المزمن

بحسب شبكة التمييز الأوروبية الدولية للحساسية والربو

التاريخ:

الاسم:

الرجاء الإجابة على الأسئلة التالية بنعم أو لا:

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<td>هل شعرت بالصدأ في الأنف لأكثر من 12 أسبوعا خلال آخر 12 شهر؟</td>
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</tr>
<tr>
<td>نعم</td>
<td>هل عانتي من تغيير في لون الافرازات الأنف أو تغيير في لون المخاط النازل في الحلق لأكثر من 12 أسبوعا خلال آخر 12 شهر؟</td>
</tr>
<tr>
<td>لا</td>
<td>هل شعرت بنقص أو فقد حاد في الشم لأكثر من 12 أسبوعا خلال آخر 12 شهر؟</td>
</tr>
</tbody>
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استطلاع إضافية

هل أخبرتك أحد الأطباء من قبل بأن لديك التهاب مزمن في الجيوب الأنفية؟

هل لديك أي نوع من الحساسية الأنفية، ويشمل ذلك حمى القش؟

تم ترجمة الاستبيان بقسم الأنف والاذن والحنجرة، جامعة الملك سعود. الرياض. المملكة العربية السعودية

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