

**MALAY VERSION ADAPTATION AND VALIDATION OF THE
RHINOSINUSITIS QUALITY OF LIFE QUESTIONNAIRE**

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LIST OF ABBREVIATIONS

CRS	Chronic rhinosinusitis
CRSsNP	Chronic rhinosinusitis with no nasal polyp
CRSwNP	Chronic rhinosinusitis with nasal polyp
CT scan	Computer tomography scan
Dr	Doctor
ENT	Ear, nose and throat
EPOS	European Position paper on rhinosinusitis
FESS	Functional endoscopic sinus surgery
HREC	Human Research Ethics Committee USM
HUSM	Hospital Universiti Sains Malaysia
HRPZII	Hospital Raja perempuan Zainab II
MREC	Medical Research & Ethics Committee MREC
ORL-HNS	Otorhinolaryngology and Head and neck surgery
RhinoQOL	Rhino Quality of Life
RSOM	Rhinosonunitis outcome measurement
RSDI	Rhinosinusitis Disability Index
SNOT	Sinonasal outcome test

ABSTRAK

Pengenalan:

Penyakit resdung merupakan penyakit keradangan hidung dan sinus yang mengganggu kehidupan peribadi, pekerjaan dan kehidupan sosial pesakit. Soal selidik kualiti hidup pesakit resdung merupakan soal selidik ringkas yang di jawab sendiri oleh pesakit yang mengalami penyakit resdung untuk menilai gejala dan kualiti hidup mereka.

Kaedah:

Kajian keratan rentas ini dijalankan di klinik telinga, hidung dan tekak (ORL) Hospital Raja perempuan Zainab II dan Hospital Universiti Sains Malaysia. Terjemahan ke hadapan dan ke belakang RhinoQOL dilakukan dan diuji untuk kesahihan “content and face validity”. Perbandingan di antara kumpulan pesakit dan kumpulan kawalan dilakukan menggunakan ujian “independent t-test and Pearson chi-square”. Sifat psikometrik (kesahihan, kebolehpercayaan, kebolehlungan dan responsive) akan dinilai.

Keputusan:

Kami memerhatikan 114 pesakit, dengan puratanya berumur 46 tahun dan 65% adalah pesakit lelaki. Pesakit yang mempunyai penyakit resdung dan mempunyai polip hidung adalah seramai 76.6%. Ujian kesahihan “Pearson’s correlation” menunjukkan setiap gejala dalam RhinoQOL versi Bahasa Malaysia mempunyai hubungkait yang rapat antara satu sama lain. Nilai kebolehpercayaan untuk setiap skala gejala adalah diterima, dalam lingkungan 0.6-0.9. Untuk ujian kebolehlungan, nilai “intraclass correlation” adalah baik dengan nilai melebihi 0.7. Ujian responsif menunjukkan terdapat perbezaan nilai yang besar sebelum dan selepas pembedahan menunjukkan bahawa soal selidik ini dapat menunjukkan perubahan selepas pembedahan.

Kesimpulan: Soal selidik RhinoQOL versi Bahasa Malaysia adalah standing dengan soal selidik RhinoQOL versi Bahasa Inggeris yang asal. Soal selidik ini adalah alat yang efektif untuk menilai gejala dan kualiti hidup pesakit resdung berdasarkan nilai kesahihan, kebolehpercayaan, kebolehulangan dan responsif yang diperoleh. Oleh itu, penggunaan soal selidik ini di dalam praktis harian adalah di syorkan.

Kata Kunci: Resdung; Soal selidik RhinoQOL; Bahasa Malaysia; Kesahihan; Responsif

ABSTRACT

Background:

Rhinosinusitis is an inflammatory disease of the nose and paranasal sinus that disrupts personal, professional, and social life. The Rhino Quality of Life (RhinoQOL) questionnaire is a short and self-administered questionnaire for assessing the symptoms and quality of life of patients with chronic rhinosinusitis (CRS).

Methods:

This cross-sectional study is conducted at the otorhinolaryngology (ORL) clinic in the Hospital Raja Perempuan Zainab II and Hospital Universiti Sains Malaysia. The forward and backward translation of the RhinoQOL questionnaire into the Malay language was performed and tested for content and face validity. The comparison between patient and control groups were evaluated using the independent t-test and Pearson chi-square. The psychometric properties (validity, reliability, reproducibility, and responsiveness) were assessed.

Results:

We observed 114 patients (64 patients and 50 controls). The mean age was 46 years old, and 65% were male patients. CRS patients with nasal polyp account for 76.7%. The Pearson's correlation demonstrated that all the symptom scales correlate and measure the same things. The Cronbach's α coefficient value for each symptom scale was acceptable, within 0.6-0.9. Test-retest evaluation was good, with the value of intraclass correlation (ICC) more than 0.70. After the surgery, there was a significant improvement from baseline for all sub-scale scores, indicating clinical improvement.

Conclusions: The Malay version of the RhinoQOL is equivalent to the original English version. It is an effective tool to assess the CRS patients' symptoms and quality of life based on the validity, reliability, reproducibility, and responsiveness values obtained. Therefore, its use is recommended in daily practice.

Keywords: Chronic rhinosinusitis; RhinoQOL questionnaire; Malay language; Validity; Responsiveness

Chapter 1:

INTRODUCTION

1.1 INTRODUCTION

Chronic rhinosinusitis (CRS) is a serious health issue that causes significant disruption in personal, professional, and social life (1). It is a common disease worldwide characterised by mucosal inflammation of the nose & paranasal sinus. The prevalence rate varies between 6% and 15% over the world (1). Meanwhile, the prevalence of CRS varies between 5 and 15% in Europe, the United States, and Brazil (1). In the Asian region, Korea's prevalence rate is 7%, China 8%, and Singapore's is 2.7% (2). According to the 2007 Medical Expenditure Panel Survey, the national average spending on CRS is around \$8.6 billion per year (3). The CRS has a significant impact on socio-economics, healthcare costs, loss of productivity, and absenteeism (4). The important risk factors for rhinosinusitis are active and passive smoking, family history, asthma, and gastroesophageal reflux disease.

Based on the European Position Paper on Rhinosinusitis (EPOS 2020), the clinical diagnosis of rhinosinusitis is characterised by two or more symptoms, one of which should be either nasal blockage or congestion, nasal discharge (anterior or posterior nasal drip), facial pain or pressure, and reduction or loss of smell; and at least one of the following: endoscopic findings of polyps or mucopurulent discharge from the middle meatus or mucosal obstruction mainly in the middle meatus; and radiological findings by computer tomography (CT) scan which showed mucosal changes within the osteomeatal complex (1).

The term CRS refers to the symptoms that last longer than 12 weeks (1). The CRS is classified as either having a polyp (CRSwNP) or not having a polyp (CRSSNP) based on endoscopic findings (5).

For the endoscopic evaluation of CRS, the widely used classification is the Lund Kennedy endoscopic scoring system. The Lund-Kennedy endoscopy scoring system evaluates the endoscopic pathological findings within the nose and paranasal sinus, including polyps, discharge, and mucosal oedema. This scoring system is beneficial for assessing the CRS with polyposis before and after functional endoscopic sinus surgery. Computer tomography (CT) is another investigation used to evaluate the CRS objectively. A CT scan of the nose and paranasal sinus is commonly used to confirm the presence of CRS, determine its severity, and develop additional treatments. The objective findings can be accessed via the nasoendoscopy and computer tomography scan. However, all these investigations cannot measure the severity of the patient's subjective symptoms.

Functional endoscopic sinus surgery (FESS) has become the worldwide standard surgical intervention for CRS that is refractory to the medicinal treatment, with a success rate of between 67 % and 97.5 % (6). Compared to medical therapy, FESS dramatically lowers nasal blockage, loss of smell, and polyp growth in CRSwNP (7). Apart from these symptoms, FESS also dramatically reduces postnasal drip and headache in CRSwNP (8). Studies also reported that patients with CRSwNP have a higher post-operative quality of life than those without polyps (9). Therefore, all the CRS patients need to be assessed in terms of clinical symptoms and objective findings to determine the appropriate treatments.

1.2 LITERATURE REVIEW

A previous study by Fokkens W.J et al. in the EPOS (2020) recommends the subjective assessment of symptoms using validated questionnaires to get complete information on a patient's condition so that optimum treatment can be formulated. Over the last two decades, there have been many diseases-specific questionnaires established for rhinosinusitis patients because of their effectiveness in assessing the impact of the disease on the patients and monitoring the treatment response. These include the Sinonasal Outcome Test (SNOT-16), Sinonasal Outcome Test (SNOT-20), Sinonasal Outcome Test (SNOT-22), Rhinosinusitis Outcome measurement (RSOM-31), Rhinosinusitis Disability Index (RSDI), and Rhino Quality of Life Questionnaire (RhinoQOL).

Atlas et al. (2005) demonstrated the better validity, reliability and responsiveness of the RhinoQOL questionnaire compared to previously validated tools in assessing severity and outcomes of treatment for CRS if the questionnaire is validated in other populations. It is also one of the most commonly used tools to determine the quality of life outcomes in the patients treated for CRS, either medically or surgically (10). Furthermore, it is a simple and easy-to-use rhinosinusitis-specific questionnaire with solid psychometric properties (11). The questionnaire contents are easy to understand and require a short time to be completed.

The RhinoQOL questionnaire has been translated and validated in many languages, including French (12), Portuguese (13), and Morocco (14). Cerejeira R et al. revealed in their study that the Portuguese version of the RhinoQOL questionnaire could be used for Portuguese speaking patients with CRS equivalent to the original English version because they have the equal face and content validity and are helpful for their specific populations. In French, Marro M et al., showed that the French version of the RhinoQOL questionnaire is as reliable, valid, and sensitive to change as the English version. Meanwhile, in Morocco, Taoufik A et al. concluded that the Moroccan version of the RhinoQOL is a valid tool for assessing CRS patients. Therefore, the questionnaire was widely used for CRS patients compare with other similar diseases specific related questionnaires.

However, all these frequently used validated tools are available only in English. Besides that, one of the most significant challenges in adopting these instruments in daily clinical practice is a lack of available time and difficulty in understanding the complexity of the questionnaire. Thus, standardised quality of life measure tailored to the Malaysian population is necessary. Therefore, this study is designed to produce an equivalent Malay language version of the RhinoQOL with the involvement of Malaysian-speaking patients with CRS.

With the introduction of the Malaysian version of RhinoQOL, the surgeons can provide a simple, brief and understandable questionnaire to the CRS patients in Malay speaking populations to assess the CRS impact on them and subsequently give precise treatment to them.

Chapter 2:

OBJECTIVES

OBJECTIVES

2.1 GENERAL OBJECTIVE

To validate the Malay version of the Rhinosinusitis Quality of Life Questionnaire (RhinoQOL) as a screening tool to assess the CRS impact on individual patients.

2.2 SPECIFIC OBJECTIVES

1. To perform translation of the original English version RhinoQOL questionnaire into the Malay version of RhinoQOL.
2. To determine the validity of the Malay version of the RhinoQOL.
3. To measure the reliability of the Malay version of the RhinoQOL.

Chapter 3:

MANUSCRIPT

3.1 Title page

Malay version adaptation and validation of the Rhinosinusitis Quality of Life questionnaire

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3.2 Abstract

Background:

Rhinosinusitis is an inflammatory disease of the nose and paranasal sinus that disrupts personal, professional, and social life. The Rhino Quality of Life (RhinoQOL) questionnaire is a short and self-administered questionnaire for assessing the symptoms and quality of life of patients with chronic rhinosinusitis (CRS).

Methods:

This cross-sectional study is conducted at the otorhinolaryngology (ORL) clinic in the Hospital Raja Perempuan Zainab II and Hospital Universiti Sains Malaysia. The forward and backward translation of the RhinoQOL questionnaire into the Malay language was performed and tested for content and face validity. The comparison between patient and control groups were evaluated using the independent t-test and Pearson chi-square. The psychometric properties (validity, reliability, reproducibility, and responsiveness) were assessed.

Results:

We observed 114 patients (64 patients and 50 controls). The mean age was 46 years old, and 65% were male patients. CRS patients with nasal polyp account for 76.7%. The Pearson's correlation demonstrated that all the symptom scales correlate and measure the same things. The Cronbach's α coefficient value for each symptom scale was acceptable, within 0.6-0.9. Test-retest evaluation was good, with the value of intraclass correlation (ICC) more than 0.70. After the surgery, there was a significant improvement from baseline for all sub-scale scores, indicating clinical improvement.

Conclusions: The Malay version of the RhinoQOL is equivalent to the original English version. It is an effective tool to assess the CRS patients' symptoms and quality of life based on the validity, reliability, reproducibility, and responsiveness values obtained. Therefore, its use is recommended in daily practice.

Keywords: Chronic rhinosinusitis; RhinoQOL questionnaire; Malay language; Validity; Responsiveness

3.3 Introduction

Chronic rhinosinusitis (CRS) is a serious health issue that causes significant disruption in personal, professional, and social life ¹. It is a common disease worldwide characterised by mucosal inflammation of the nose & paranasal sinus. The prevalence rate varies between 6% and 15% over the world ¹. Meanwhile, the prevalence of CRS varies between 5 and 15% in Europe, the United States, and Brazil ¹. In the Asian region, Korea's prevalence rate is 7%, China 8%, and Singapore's is 2.7% ². According to the 2007 Medical Expenditure Panel Survey, the national average spending on CRS is around \$8.6 billion per year ³. The CRS has a significant impact on socio-economics, healthcare costs, loss of productivity, and absenteeism ⁴. The important risk factors for rhinosinusitis are active and passive smoking, family history, asthma, and gastroesophageal reflux disease.

Based on the European Position Paper on Rhinosinusitis (EPOS 2020), the clinical diagnosis of rhinosinusitis is characterised by two or more symptoms, one of which should be either nasal blockage or congestion, nasal discharge (anterior or posterior nasal drip), facial pain or pressure, and reduction or loss of smell; and at least one of the following: endoscopic findings of polyps or mucopurulent discharge from the middle meatus or mucosal obstruction mainly in the middle meatus; and radiological findings by computer tomography (CT) scan which showed mucosal changes within the osteomeatal complex ¹.

The term CRS refers to the symptoms that last longer than 12 weeks ¹. The CRS is classified as either having a polyp (CRSwNP) or not having a polyp (CRSSNP) based on endoscopic findings ⁵.

For the endoscopic evaluation of CRS, the widely used classification is the Lund Kennedy endoscopic scoring system. The Lund-Kennedy endoscopy scoring system evaluates the endoscopic pathological findings within the nose and paranasal sinus, including polyps, discharge, and mucosal oedema. This scoring system is beneficial for assessing the CRS with polyposis before and after functional endoscopic sinus surgery. Computer tomography (CT) is another investigation used to evaluate the CRS objectively. A CT scan of the nose and paranasal sinus is commonly used to confirm the presence of CRS, determine its severity, and develop additional treatments. The objective findings can be accessed via the nasoendoscopy and computer tomography scan. However, all these investigations cannot measure the severity of the patient's subjective symptoms.

Functional endoscopic sinus surgery (FESS) has become the worldwide standard surgical intervention for CRS that is refractory to the medicinal treatment, with a success rate of between 67 % and 97.5 % ⁶. Compared to medical therapy, FESS dramatically lowers nasal blockage, loss of smell, and polyp growth in CRSwNP ⁷. Apart from these symptoms, FESS also dramatically reduces postnasal drip and headache in CRSwNP ⁸. Studies also reported that patients with CRSwNP have a higher post-operative quality of life than those without polyps ⁹. Therefore, all the CRS patients need to be assessed in terms of clinical symptoms and objective findings to determine the appropriate treatments.

A previous study by Fokkens W.J et al. in the EPOS (2020) recommends the subjective assessment of symptoms using validated questionnaires to get complete information on a patient's condition so that optimum treatment can be formulated. Over the last two decades, there have been many diseases-specific questionnaires established for rhinosinusitis patients because of their effectiveness in assessing the impact of the disease on the patients and monitoring the treatment response. These include the Sinonasal Outcome Test (SNOT-16), Sinonasal Outcome Test (SNOT-20), Sinonasal Outcome Test (SNOT-22), Rhinosinusitis Outcome measurement (RSOM-31), Rhinosinusitis Disability Index (RSDI), and Rhino Quality of Life Questionnaire (RhinoQOL).

Atlas et al. (2005) demonstrated the better validity, reliability and responsiveness of the RhinoQOL questionnaire compared to previously validated tools in assessing severity and outcomes of treatment for CRS if the questionnaire is validated in other populations. It is also one of the most commonly used tools to determine the quality of life outcomes in the patients treated for CRS, either medically or surgically ¹⁰. Furthermore, it is a simple and easy-to-use rhinosinusitis-specific questionnaire with solid psychometric properties ¹¹. The questionnaire contents are easy to understand and require a short time to be completed.

The RhinoQOL questionnaire has been translated and validated in many languages, including French ¹², Portuguese ¹³, and Morocco ¹⁴. Cerejeira R et al. revealed in their study that the Portuguese version of the RhinoQOL questionnaire could be used for Portuguese speaking patients with CRS equivalent to the original English version because they have the equal face and content validity and are helpful for their specific populations. In French, Marro M et al., showed that the French version of the RhinoQOL questionnaire is as reliable, valid, and

sensitive to change as the English version. Meanwhile, in Morocco, Taoufik A et al. concluded that the Moroccan version of the RhinoQOL is a valid tool for assessing CRS patients. Therefore, the questionnaire was widely used for CRS patients compare with other similar diseases specific related questionnaires.

However, all these frequently used validated tools are available only in English. Besides that, one of the most significant challenges in adopting these instruments in daily clinical practice is a lack of available time and difficulty in understanding the complexity of the questionnaire. Thus, standardised quality of life measure tailored to the Malaysian population is necessary. Therefore, this study is designed to produce an equivalent Malay language version of the RhinoQOL with the involvement of Malaysian-speaking patients with CRS.

With the introduction of the Malaysian version of RhinoQOL, the surgeons can provide a simple, brief and understandable questionnaire to the CRS patients in Malay speaking populations to assess the CRS impact on them and subsequently give precise treatment to them.

3.4 Methodology

Study design

This was a cross sectional study conducted in Otorhinolaryngology-Head and Neck Surgery (ORL-HNS) clinic, Hospital Raja Perempuan Zainab II (HRPZ II) Kota Bharu and Hospital Universiti Sains Malaysia (HUSM) Kubang Kerian for 15 months from May 2020 until August 2021.

Study population

For this study, two separate groups were recruited. The first group included 64 patients diagnosed with chronic rhinosinusitis with nasal polyps (CRSwNP) or without nasal polyps (CRSsNP) and plan for functional endoscopic sinus surgery (FESS). The required sample size for this study is 64 patients based on the sample size calculated ¹⁷.

Their aged above 18 years old and understand Malay language well. The patients with underlying or were diagnosed with other nasal pathologies such as benign or malignant tumors were excluded from the study. The patients with chronic immunosuppressive diseases such as diabetes mellitus (DM), Human Immunodeficiency virus (HIV) and tuberculosis also excluded. Other exclusion criteria were pregnancy women.

The second group consisted of asymptomatic control that aged above 18 years old, able to read and speak Malay language well, and never diagnosed with chronic rhinosinusitis (CRS).

Written consent in Malay language was obtained from each participant. All patients involved in this study answered the Malay version of RhinoQOL in the ORL clinic. It was a self- administered questionnaire and took about 5 to 10 minutes for participants to complete it.

Sampling method

Sampling method was done using purposive sampling method whereby those patients who fulfilled the inclusion and exclusion criteria were included in the study.

Administration of the questionnaire

Method of administration of the Malay version of RhinoQOL was by a self- administered technique.

Cross-cultural adaptation

The translation aimed to ensure all contents of the questionnaire are equally clear, precise and equivalent in all ways to its original version. Therefore, the processes of translation play an essential aspect of a good questionnaire. The translation method began with the original English version of the RhinoQOL questionnaire translated into the Malay language independently by two native Malay speakers, a medical officer from the otorhinolaryngology department and a professional translator without a medical background, who were both bilingual in Malay and English language. For this study, a professional translator from the language centre of Universiti Sains Malaysia(USM) was appointed. A panel consisting of these two translators and the principal investigator critically reviewed the translation in forming the first draft of the Malay version of RhinoQOL. Another two independent professional translators who had no idea of the original version of the questionnaire translated back this draft into English. The back-translation was assessed for equivalence with the original English version. Then, six otorhinolaryngologists reviewed this draft for content validity ^{15,18}. After the establishment of the content validity, the expert committee comprising of these six otorhinolaryngologists, the translator, and language professionals reviewed and discussed the discrepancies between the original, forward-translated, and back-translated versions. Thus, the final version of the Malay version of RhinoQOL was produced. The feedback forms of the translated RhinoQOL questionnaire from these six otorhinolaryngologists were reviewed to

establish content validity. The Malay version of the RhinoQOL questionnaire was distributed to ten patients independently for face validity before applying it to the study populations ¹⁶. The patients gave comments based on their understandings.

Validation of the Malay RhinoQOL

The participants in the patient (study) group were required to answer the questionnaire thrice. For the first time, the patients were required to complete the Malay RhinoQOL questionnaire on the same day during a clinic visit. Subsequently, they were given two weeks' appointments from the first-time meeting. The last session was three months after surgery. The control group completed the questionnaire twice, during the first visit and two weeks after the first-time meeting. During the enrollment, all the participants in the study group will be performed the nasal endoscopic examination and the CT of the paranasal sinus to assess the nasal condition and severity of the nasal polyp. The endoscopic findings will be scored based on the Lund-Kennedy endoscopic score, and the results of the CT paranasal sinus will be achieved based on Lund-Mackay CT staging. The relation between the symptoms in the RhinoQOL questionnaire, endoscopic and CT scan findings will be analyzed.

The comparison between patient (study) and control groups was evaluated using the independent t-test and Pearson chi-square. The construct validity using the Pearson's correlation test was determined by correlating the responses obtained for each item with the other items in the RhinoQOL questionnaire as well as the relation between the RhinoQOL with the objective assessments, Lund-Kennedy endoscopic and Lund-Mackay CT staging. The psychometric properties (reliability, reproducibility, responsiveness) were carried out by the internal consistency, test-retest reliability, and Paired t-test. Reliability or internal consistency of items in the questionnaire were tested with Cronbach's alpha. A second RhinoQOL questionnaire was administered to the patients two weeks following the initial test to test for

test-retest reliability. The patients who suffered from common cold, influenza, or respiratory tract infection between two tests were excluded from the study.

As for the responsiveness, the patient (study) group will be given the RhinoQOL questionnaire before the functional endoscopic sinus surgery(FESS) and three months following surgery. All the surgical procedures were performed by a rhinologist using the same surgical technique.

STATISTICAL ANALYSIS

Data obtained were entered and analyzed via SPSS version 26 (IBM Corp, Armonk, NY). The descriptive analysis was used to summarize the socio-demographic features among the cases and controls. The data obtained were expressed as mean (SD=standard deviation) for numerical and n=frequency (%) for categorical variables.

Both groups were compared using an independent t-test and Pearson's Chi-Squared test to assess the significant association between age and gender. The construct validity by Pearson's correlation test calculated the inter-item correlation coefficient comparison between the three main domains (symptom scales) in the Malay RhinoQOL items as well as the correlation between the RhinoQOL questionnaire with the objective assessments, Lund-Kennedy endoscopic and Lund-Mackay CT staging ¹⁹.

The independent t-test was used to analyze the RhinoQOL score before and after the surgery between the two groups to determine whether the questionnaire could differentiate between the two groups. Reliability or internal consistency of the items in the questionnaire was tested with Cronbach's alpha. Scores of 0.6-0.7 are acceptable, while a score of 0.7 or greater generally indicates good internal consistency ²⁰.

In test-retest reliability, two-way random average measures intraclass correlation coefficients (ICC), with a positive rating for reliability given at >0.70 . ICC is a method to test the agreement between total scores on two different occasions by administering the Malay RhinoQOL questionnaire twice and measuring its stability ²¹.

The responsiveness of the questionnaire or pre and postoperative evaluation was assessed by comparing the score for all items at the baseline and three months post-surgery using Paired t-test. The score before surgery would be greater than after surgery. The responsiveness is also analyzed by comparing the difference in magnitude of the effect before and after surgery. The magnitude of the effect would be large after surgery ¹³.

3.5 Results

Demographic

A total of 64 participants were recruited for the patients (study group), and 50 participants were recruited for the control. The minimum age was 18 years old. The mean age for the patient (study) group was 46.73 years old with a standard deviation of 15.11. The mean age for the control group was 45.22 years old, with a standard deviation of 13.65. There was more than half male (65%) among all samples in the population.

Independent t-test resulted in an insignificant p-value ($p = 0.581$), showing no significant mean difference of age between patient and control group. The Pearson's Chi-squared test also resulted in an insignificant p-value with $p > 0.950$, indicating that there is no significant association in gender in both groups. (Table 1)

Among the patient (study) group, CRSwNP comprised about 76.6%, with male gender prominent about 46.9%. (Table 2). Both genders and types of CRS (CRSwNP and CRSsNP) demonstrated the highest mean score for the symptom bothersomeness scale. (Table 3 and Table 4)

Construct validity

Pearson's correlation test demonstrated a significant positive correlation between scores of the three domains under the RhinoQOL questionnaire ($p < 0.001$). The strength of the correlation ranged from moderate to high ($r = 0.68-0.88$). This shows that all the domains (symptom scales) in the questionnaire correlate to each other and measure the same thing while not distinct from each other. (Table 5)

Pearson's correlation test also demonstrated a significant positive high correlation between the RhinoQOL score, Lund Kennedy endoscopic score, and Lund Mackey CT score ($r = 0.94-0.95$, $p < 0.001$). This shows that the questionnaire can capture the same things as the other two objective assessments. (Table 6)

For the correlation between different items in the RhinoQOL questionnaire for pre and post-test, there was a significant positive correlation for all of the items ($p < 0.050$). The strength of the correlation ranged from fair to high ($r = 0.32-0.85$). This shows that the questionnaires can still capture the same result even after a gap in between. (Table 7)

There was a significant mean difference in the RhinoQOL score between comparison groups ($p < 0.001$). The samples in the study group have higher mean RhinoQOL scores than the control group for both pre and post-test results. This shows that the score of the Rhino Questionnaire succeeds in differentiating between the two groups. (Table 8)

Reliability

The overall internal consistency using Cronbach alpha for each domain was acceptable, with the value ranging from $\alpha = 0.61$ to $\alpha = 0.976$ for each main domain. Deleting any items from the scales will affect the internal consistency. (Table 9)

Test-retest

The test-retest result for each item between 1st and 2nd measurements using ICC were good with values of more than 0.70. (Table 10)

Responsiveness and response sensitivity

Paired t-test was applied in determining the difference of the item's score between pre-operative and post-operative. There was a significant mean difference between pre and post-test results for all items and the total score ($p < 0.001$). The score for all items was reduced from pre to post-test measurement. (Table 11). The magnitude of the effect on all domains is large (symptom frequency = 2.125, symptom bothersomeness = 1.74, and symptom impact = 2.04), which indicated significant responsiveness and improvement in quality of life. An effect magnitude between 0.2 to 0.5 is considered a mild improvement, between 0.5 and 0.8, moderate improvement and greater than 0.8, a large improvement in quality of life. (Table 12)

3.6 DISCUSSION

A reliable screening tool is required to quickly predict CRS symptoms and their impact on the patient's quality of life because of the high prevalence of delayed surgery for a group of patients that are refractory to medical treatment. A quick and reliable screening test can enable clinicians to make more reasonable diagnostic decisions for further diagnostic assessment or treatment. Questionnaires can be appropriate tools for that purpose since they can be applied and scored quickly as part of routine daily practice. A gold standard questionnaire for CRS does not currently exist. Many disease-specific tools evaluated the CRS, such as the Rhinosinusitis Outcome measure (RSOM-31), Sinonasal Outcome Test (SNOT 20, SNOT 22) and Rhino Quality of Life questionnaire (RhinoQOL).

Among these specific rhinology questionnaires, the RhinoQOL questionnaire has demonstrated good psychometric properties than the others, and it has previously been validated in English, Portuguese, Moroccan, and French. Besides that, the RhinoQOL questionnaire can differentiate the patients with or without CRS symptoms. It has three main symptom scales that measure the CRS symptoms' frequency, bothersomeness, and impact on patient life. This justification was the primary rationale for choosing the RhinoQOL questionnaire for the Malay language validation. The original English version of the RhinoQOL was translated into the Malay language, and a validation study was conducted.

The age of our study participants was 18 years old and above because they would be able to give written consent for involvement in this study. Based on our research, the participants could fully complete the questionnaire without difficulty in a short duration, and most of them did not need any assistance. They understood and were comfortable answering all the items in the questionnaire. Furthermore, the questionnaire can be used in the outpatient setting with good

acceptability and not as a burdensome tool. Analysis of the questionnaire's performance in the CRS patients provides clinicians with a set of predictive parameters for various levels of CRS impact on the patient quality of life.

Similar to the previously reported literature, our study demonstrated a higher prevalence of CRS among the male population than the female (Table 2). This study corresponded to the previous studies by the French and Portugal versions of the RhinoQOL questionnaire. Among these patients, the CRS patients with nasal polyps (CRSwNP) has a higher prevalence compared to CRS patients with no nasal polyps (CRSsNP), which responded well to the previously validated Portugal version of RhinoQOL. We also found no significant association in age and gender between the study and control groups (Table 1). Both genders were associated with a lower score in the impact scale than frequency and bothersomeness scales (Table 3). Meanwhile, the CRSwNP patients have a higher total score for the bothersomeness scale than the CRSsNP patients (Table 4).

Our study showed a significant positive correlation between scores of the three domains (symptom scales) under the RhinoQOL questionnaire. This analysis indicates that all the symptom scales in the questionnaire correlate to each other and measure the same thing while not distinct from each other (Table 5). These strong correlations showed that the RhinoQOL questionnaire could evaluate precisely the frequency and bothersomeness of the CRS symptoms and their impact on a patient's quality of life.