

**THE VALIDATION OF THE MALAY VERSION
SINO-NASAL OUTCOME TEST 22 (SNOT-22)
IN CHRONIC RHINOSINUSITIS PATIENTS**

BY

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LIST OF ABBREVIATIONS

AFRS	Allergic Fungal RhinoSinusitis
AR	Allergic Rhinitis
ASA	Aspirin
BP	Bodily Pain
CF	Cystic Fibrosis
CI	Confidence Interval
CRS	Chronic Rhinosinusitis
CRSsNP	Chronic Rhinosinusitis without Nasal Polyps
CRSwNP	Chronic Rhinosinusitis with Nasal Polyps
CSS	Chronic Sinusitis Survey
CT	Computed Tomography
DNS	Deviated Nasal Septum
Dr	Doctor
EAACI	European Academy of Allergology and Clinical Immunology
ENT	Ear, Nose and Throat
EPOS	European Position Paper on Rhinosinusitis and Nasal Polyps
EQ-5D	EuroQOL
FESS	Functional Endoscopic Sinus Surgery
GER	GastroEsophageal Reflux
GERD	GastroEsophageal Reflux Disease
GH	General Health
HUKM	Hospital Universiti Kebangsaan Malaysia
HUSM	Hospital Universiti Sains Malaysia
HRQOL	Health Related Quality Of Life
ICC	Intraclass Correlation Coefficient

i.e	that is
IgE	Immunoglobulin E
IgG	Immunoglobulin G
IgG2	Immunoglobulin G2
IgG3	Immunoglobulin G3
IQOLA	International Quality Of Life Assessment
KMO	Kaiser-Meyer-Olkin
LPR	LaryngoPharyngeal Reflux
MCS	Mental Component Summary
MH	Mental Health
MOS	Medical Outcome Study
NARES	Non Allergic Rhinitis with Eosinophilia Syndrome
NHANES III	Third National Health And Nutrition Examination Survey
NHP	Nottingham Health Profile
NP	Nasal Polyposis
ORL-HNS	Otorhinolaryngology-Head and Neck
PCS	Physical Component Summary
PF	Physical Functioning
PPSP	Pusat Perubatan Sains Perubatan
QOL	Quality of Life
RE	Role Emotional
RP	Role Physical
RSDI	Rhinosinusitis Disability Index
RSOM	Rhinosinusitis Outcome Measure
RSOM-31	Rhinosinusitis Outcome Measure 31 item
RTF	Rhinosinusitis Task Force

SD	Standard Deviation
SHS	Second Hand Smoker
SF	Social Functioning
SF-36	Medical Outcome Survey (MOS) Short Form 36
SIP	Sickness Impact Profile
SNOT-11	Sino-Nasal Outcome Test 11 items
SNOT-16	Sino-Nasal Outcome Test 16 items
SNOT-20+1	Sino-Nasal Outcome Test 20+1 items
SNOT-20	Sino-Nasal Outcome Test 20
SNOT-22	Sino-Nasal Outcome Test 22
TH2	T-Helper 2 Cell
US	United States
USA	United State Of America
USD	United State Dollar
USM	Universiti Sains Malaysia
VT	Vitality
WBQ	Well Being Questionnaire
WHO	World Health Organization

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ABSTRAK

Pendahuluan : Kronik Rinosinusitis adalah diagnosa otorinolaringologi yang utama dan melibatkan 14% daripada populasi am. Kronik Rinosinusitis adalah penyakit populasi am dan telah dikenalpasti menyebabkan kualiti hidup pesakit menurun tetapi sehingga kini masih tiada data kuantitatif yang dapat menunjukkan kesannya kepada kesihatan kita. Oleh itu, kesahihan, kebolehpercayaan dan alat yang responsif seharusnya dibina untuk mengkaji impak fizikal, mental, emosi, sosial dan profesional terhadap pesakit kronik rinosinusitis terutamanya di Malaysia.

Objektif: Menterjemah SNOT-22 ke Bahasa Melayu dan seterusnya menilai kebolehsanaan, kesahihan dan kebolehpercayaan SNOT-22 versi Bahasa Melayu.

Cara kajian dilaksanakan: Kajian ini merupakan kajian keratan rentas yang dijalankan di klinik umum ORL-HNS HUSM. 70 orang responden terlibat. SNOT-22 versi Bahasa Melayu dan SF-36 versi Bahasa Melayu yang telah diuji kesahihannya dilengkapkan oleh subjek. Proses penterjemahan melibatkan terjemahan ke hadapan, ke belakang dan ujian responden. Semakan kesahihan muka dan kesahihan kandungan dijalankan. SNOT-22 versi Bahasa Melayu diberi sekali lagi dalam tempoh dua ke empat minggu. Analisis meliputi penilaian anggapan skala, kebolehsanaan, kesahihan dan kebolehpercayaannya.

Keputusan: Mengenai penilaian ujian ini, kadar responsif subjek adalah 97.2% dalam penilaian awal dan 100% subjek dalam penilaian semula yang telah melengkapkan borang soal-selidik ini. Kesemua item dalam SNOT-22 versi Bahasa Melayu mempunyai nilai purata di antara 1.10 – 2.64 dan sisihan piawai dari 0.933 - 1.4861. Alpha Cronbach amat tinggi iaitu 0.89 di dalam ujian awal. Pekali korelasi intrakelas juga cemerlang iaitu 0.90. Analisis faktor menunjukkan kebanyakan item dalam SNOT-22 versi Bahasa Melayu boleh dibahagikan kepada 4 subdomain iaitu simptom hidung, telinga atau simptom muka, fungsi psikologi dan tidur. Kesahihan kumpulan menunjukkan SNOT-22 versi Bahasa Melayu boleh membezakan kumpulan kawalan dan pesakit ($t=15.33$; $p<0.001$). Pemeriksaan kesahihan serentak menunjukkan domain Fungsi Fizikal dalam versi Bahasa Melayu SF-36 mempunyai hubungkait secara signifikan dengan domain simptom telinga atau muka ($r=-0.259$, $p<0.05$) dan dengan isu psikologi ($r=-0.304$, $p<0.01$) di dalam versi Bahasa Melayu SNOT-22. Domain Kesakitan Badan dalam versi Bahasa Melayu SF-36 ($r=0.498$, $p<0.01$) juga mempunyai kaitan signifikan dengan isu psikologi dalam versi Bahasa Melayu SNOT-22. Kebanyakan domain di dalam versi Bahasa Melayu SF-36 dengan SNOT-22 mempunyai hubungkait yang lemah di antara satu sama lain. Tetapi walaupun begitu, kesahihan dan kebolehpercayaan versi Bahasa Melayu SNOT-22 sebagai alat yang responsif dalam menentukan kualiti hidup pesakit rhinosinusitis dapat ditentukan oleh kesahihan dalam aspek kandungan, konstruk dan diskriminan.

Kesimpulan: Penterjemahan Sino-Nasal Outcome Test 22 (SNOT-22) versi Bahasa Melayu boleh diterima. Kebolehsanaan dan anggapan skala dipenuhi. Kesahan adalah cemerlang dan kebolehpercayaannya dibuktikan. SNOT-22

adalah dicadangkan untuk digunakan oleh doktor dan penyelidik di Malaysia sebagai hasil ukuran laporan pesakit untuk penyakit sinus dan hidung seperti rhinosinusitis dan polyp hidung.

ABSTRACT

Introduction : Chronic rhinosinusitis (CRS) is a major otorhinolaryngology diagnosis and affects 14% of the general population. CRS is a disease of general population and it has been recognised to affect patient's quality of life but there has been no quantitative data that demonstrate the health burden that CRS may incur. Thus, valid, reliable and responsive instruments should be developed to assess this physical, mental, emotional, social and professional impact on CRS patients especially in Malaysia population.

Objectives : To translate Sino-Nasal Outcome Test-22 into the Malay language and to determine the feasibility, validity and reliability of the Malay version of SNOT-22.

Study Design and Methodology : This was a cross sectional study conducted at the ORL-HNS general clinic and rhinology clinic in HUSM. 70 CRS respondents were involved and 39 healthy participants recruited for the control group. The Malay translated SNOT-22 and a previously Malay validated SF-36 were administered by the respondents. The translation used forward, backward and respondent testing and has been reviewed for face and content validity. The Malay version of SNOT-22 was administered again at two to four weeks interval retesting 55 patients with CRS. The statistical analysis used was feasibility, cronbach's alpha, intraclass correlation coefficient, Pearson's correlation coefficient and factor analysis.

Results : Regarding feasibility of this test, the response rate of each question items was 97.2% in the initial test and 100% in the retest. All items in SNOT-22 have means ranging from 1.10-2.64 with standard deviations ranged from 0.933-1.486. The Cronbach's alpha was high that is 0.89 in the initial test. The average intraclass correlation coefficient (ICC) was high that is 0.90 indicating good test-retest reliability. Factor analysis showed that Malay version SNOT-22 have four unique constructs that is the rhinological symptoms, ear or facial symptoms, sleep and psychological function. Discriminant validity demonstrate that Malay version SNOT-22 was able to discriminate between control group and patients ($t=15.33$; $p<0.001$). Concurrent validity findings showed that the subscale of Role Physical (RP) in Malay version SF-36 statistically correlates significantly with ear or facial symptoms ($r=-0.259$, $p<0.05$) and psychological issues ($r=-0.304$, $p<0.01$) in Malay version SNOT-22. Bodily Pain (BP) domains in Malay version SF-36 also statistically significant with psychological issues ($r=0.498$, $p<0.01$) within Malay version SNOT-22. Most of the domains within Malay version SNOT-22 were weakly correlated with the scales of Malay version SF-36. However, validity of the Malay version SNOT-22 as a reliable and valid tool for quality of life assessment is established by fulfillment of content, construct, and discriminant validity.

Conclusions : The translation of the Malay version SNOT-22 was acceptable. Feasibility was present and scaling assumptions were met. The reliability was excellent and validity is established. SNOT-22 is recommended for Malaysia's clinicians and researchers as a patient reported measure of outcome in sino-nasal disorders such as rhinosinusitis and nasal polyposis.

CHAPTER 1:

INTRODUCTION AND LITERATURE REVIEW

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

1.1 BACKGROUND OF STUDY

Chronic Rhinosinusitis (CRS) affects 5–15 % of the urban population in Europe and North America (Piccirillo et al., 2002; Mortuaire et al., 2010) with 18 to 22 million consultations in the USA (Hessler et al., 2007). The health care cost that was estimated was at 2.4 billion USD (Videler et al., 2007). The impact of the illness on the socioeconomic burden is significant, whereby it causes the loss of work productivity and time off work. Given the consequences and its socioeconomic impact, there has been considerable interest in assessing Health Related Quality Of Life (HRQOL) in chronic rhinosinusitis patients. Most clinical trials nowadays require outcome measures in patients quality of life.

“Quality of life” expression is rather vague and often means different things to different people. Many factors such as finances, spirituality, and health contribute to quality of life and may affect each other. Subjective well being, fulfillment of social roles and functional status are an important domains in medical care and clinical interventions. The aim of treatment strategies in each person depends on the relief of symptoms, disease progression and improvement of functional capacities. The goal of treatment can be achieved if the patient's estimation of his or her well being is taken into account. Therefore, before any therapeutic assessment done, one should take into account patient's quality of life in addition to traditional biomedical parameters (Siegrist and Junge, 1989).

Quality of life assessment has increasingly become an important tool in measuring the impact of chronic illnesses that is useful for improving patient's health care and in clinical trial research (Fayers and Machin, 2000). Recently, there has been increasing recognition that the impact of chronic illnesses and the outcome of treatments must be measured in terms of their influences on the quality of life together with inclusion of traditional indices such as morbidity and mortality (Saxena and Orley, 1997). There has been a gradual shift, away from relying on only clinical and laboratory illness indicators. The current trend is moving towards incorporation of patient's point of view (Wood-Dauphinee, 1999). As a result for increased need to better correlate between health care costs and quality of care, outcome measures related to functional capacity and well being has gained importance either equal to or greater than analyses based on symptoms or biologic and physiologic variables. This includes physical, psychological and social aspects, the areas that patients are most interested and familiar with (Meltzer et al., 1997). Physiologic measures provide information to clinicians, but it is of limited interest to patients because it usually correlates poorly with functional capacity and patients well being. Health related quality of life (HRQOL) outcomes have become key factors in the development and refinement of practise guidelines, the evaluation of patterns of medical care, and the assessment of therapeutic interventions (Juniper, 1997; Meltzer et al., 1997).

HRQOL is defined as “the functional effects of an illness and its consequent therapy upon a patient, as perceived by the patient”. The final phrase is important because it emphasizes the impairments that the patients themselves consider as important (Juniper, 1997). HRQOL are components of overall quality of life which is determined primarily by the person's health and it can be influenced by clinical interventions.

Chronic rhinosinusitis (CRS) is extremely common in the general population regardless of ethnic background. It is a widespread global health disorder, increasing in both incidence and prevalence. It is not a life threatening disorder but it has been shown to have significant impact on quality of life (Wang et al., 2003; Hopkins et al., 2009). However, there has been no quantitative data that may demonstrate health burden that CRS may incur (Wang et al., 2003). Thus, valid, reliable and responsive instruments should be developed to assess these physical, mental, emotional, social and professional impact on CRS patients. Taking into account that each rhinosinusitis patients lead a wide range of life styles, having very different personalities, different cultural and personal expectations on health and their coping abilities, HRQOL outcome may differ markedly even among patients with the same severity of illness, thus offering varying potrait of patient's illness (Testa et al., 1996).

1.2 RHINOSINUSITIS, WHAT IT IS?

Rhinosinusitis is an inflammatory response involving the mucous membrane of nasal cavity and paranasal sinuses. Based on the International Classification of Diseases (ICD) - Tenth Revision, rhinosinusitis can be divided into two major groups that is acute and chronic. Acute rhinosinusitis is usually infectious in nature as compared to chronic disease which resulted from a wide range of processes.

Chronic Rhinosinusitis is defined as a group of disorder that is characterized by an inflammatory reaction of nasal and paranasal sinus mucosa of at least 12 weeks consecutively (Wang et al., 2003; Benninger et al., 2003). The Rhinosinusitis Task Force of the Sinus and Allergy Health Partnership has decided to use the term *rhinosinusitis* instead of *sinusitis*. It has been thought that sinusitis is almost always

accompanied by concurrent nasal airway inflammation, and usually sinusitis is preceded by rhinitis symptoms. Based on this reason, the term rhinosinusitis is used because it describes the spectrum of infectious and inflammatory conditions of the nasal and paranasal sinus more accurately (Meltzer et al., 2004).

There has been a lack of consensus regarding definitions and treatments because CRS is a spectrum of diseases with a range of appropriate treatments. There is also absence of widely accepted definitions for CRS. Recently, there have been multiple suggestions to redefine chronic sinus disease according to its pathophysiology and clinical properties.

1.3 Diagnostic Definition of CRS

In 1996, the American Academy of Otolaryngology-Head & Neck Surgery multidisciplinary Rhinosinusitis Task Force (RTF) defined adult rhinosinusitis diagnostic criteria as the presence of two or more ‘major’ symptoms or one major symptom with two or more ‘minor’ symptoms lasting for 12 or more weeks.

Following the disagreement regarding the 1996 criteria, in 2003 The Rhinosinusitis Task Force updated the definition of CRS by defining the disease as “a group of disorders characterized by inflammation of the mucosa of the nose and paranasal sinuses of at least 12 consecutive weeks’ duration” (Ressel, 2004). The task force recommends that all patients who meet with the clinical criteria for CRS to have a CT scan or quality photoendoscopy to confirm the diagnosis.

In this study, the diagnosis of CRS was made according to 2007 European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) criteria which is characterized by

presence of two or more cardinal symptoms and presence of either endoscopic signs or computed tomography (CT) changes (Table 1.1) (Lange et al., 2011). CT is not an option in our study therefore the diagnosis rests on symptoms and nasoendoscopy.

**Table 1.1: CRS Disease Characteristics
(adapted from Lange et al., 2011)**

Symptoms must be present longer than 12 weeks

Nasal obstruction

Hyposmia/anosmia

Facial pain/pressure

Nasal discharge (anterior/posterior nasal drip)

Endoscopic findings

Polyps

Mucopurulent discharge

Oedema/mucosal obstruction

Computed Tomography

Mucosal changes within the osteomeatal

complex and or sinus