BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2015-011018
Article Type:	Research
Date Submitted by the Author:	05-Jan-2016
Complete List of Authors:	Nkurunziza, Arcade; University of Rwanda College of Medicine and Health Sciences Huye Dusabejambo, Vincent; University of Rwanda College of Medicine and Health Sciences Huye; Kigali University Teaching Hospital, Gastroenterology Everhart, Kelly; Dartmouth College Geisel School of Medicine Bensen, Steve; Dartmouth College Geisel School of Medicine; Dartmouth-Hitchcock Medical Center Walker, Timothy; University of Rwanda College of Medicine and Health Sciences Huye; Butare University Teaching Hospital, Gastroenterology
Primary Subject Heading:	Gastroenterology and hepatology
Secondary Subject Heading:	Global health, Public health
Keywords:	Adult gastroenterology < GASTROENTEROLOGY, Gastroduodenal disease < GASTROENTEROLOGY, PRIMARY CARE, Epidemiology < TROPICAL MEDICINE

Validation of the Kinyarwanda-version Short Form Leeds Dyspepsia Questionnaire and Short Form Nepean Dyspepsia Index to assess dyspepsia prevalence and quality of life impact in Rwanda.

Arcade Nkurunziza, Vincent Dusabejambo, Kelly Everhart, Steve Bensen and Tim Walker

Corresponding Author:

Tim Walker,

Department of Internal Medicine,

University of Rwanda

BP 663, Huye, Sud, Rwanda

Email: timwalkerd@gmail.com

Phone: +250-784206851

Abstract

Objectives

We aimed to develop and validate Kinyarwanda versions of SF LDQ and SF NDI, to measure the frequency and severity of dyspepsia and associated quality of life impact in Rwanda.

Setting

A single, tertiary care centre in Rwanda.

Participants

200 consecutive Kinyarwanda-speaking patients referred to endoscopy (100 patients) or medical outpatients (100 patients).

Interventions

Kinyarwanda versions of the SF LDQ and SF NDI were developed from English versions by translation, with back translation, crosschecking and pilot testing. Study participants completed these questionnaires at enrolment (time 1), and then completed the surveys again with blinded phone interviewers three days later (time 2). 20 randomly selected participants, diagnosed with a peptic ulcer on index EGD, completed a third survey by phone at day 30 (time 3), after therapy.

Primary outcome measures

Internal consistency at time 1 (by Cronbach alpha) and test-retest reliability between time 1 and time 2 (Spearman's correlation coefficient) for both translated SF-LDQ and SF-NDI; validity vs clinical diagnosis (by ROC curve) and responsiveness to treatment for SF-NDI (by change in mean score). All outcomes were measured as per protocol.

Results

Cronbach's alpha of the translated SF-LDQ was 0.93, showing high internal consistency. Spearman's correlation coefficient comparing time 1 and time 2 was 0.978 (p-value < 0.001), demonstrating high reliability. Cronbach's alpha for the translated SF-NDI was 0.92. A cutoff score of 16 on the SF LDQ showed a sensitivity of 97% and a specificity of 71% for the diagnosis of dyspepsia, correctly classifying 89% of patients. In the responsiveness analysis, the mean SF- LDQ score was reduced from 20.1 prior to treatment to 13.9 after 30 days of treatment (p = 0.003).

Conclusion

The Kinyarwanda versions of the SF LDQ and SF NDI were valid, reliable and responsive to treatment.

Trial registration

Nil

Article Summary "Strengths and limitations of this study"

Strengths

- First study to validate the use of dyspepsia tools (SF LDQ and SF LDQ) in an African language population.
- Both dyspepsia symptom severity and quality of life impact measured concurrently in the same patient population.
- Study staff were blinded to time 1 survey results when administering time 2 surveys.
- 100% participant followup achieved from time 1 to time 2
- Both tools proved to be reliable, valid and responsive to treatment.

Weaknesses

- No gold standard comparison available to validate SF NDI, the dyspepsia quality of life tool, meaning that surrogate markers had to be used.
- Survey administration methods differed between time 1 and time 2: interpersonal interviews and phone-based interviews.
- Despite high sensitivity (97%), the SF LDQ appeared to be only moderately specific (71%) for the diagnosis of dyspepsia, suggesting the need for clinical confirmation prior to treatment.
- Use of the validated tools is likely to be restricted geographically within central Africa.

Introduction

Dyspepsia is a constellation of upper gastrointestinal symptoms that present a significant personal, social, and financial burden to patients and healthcare resources worldwide. (1,2) Although no standard, universal definition of dyspepsia adequately characterizes the symptom complex across diverse cultural and sociodemographic environments, clinicians tend to rely upon the presence of chronic, recurrent epigastric pain or discomfort as a platform for the diagnosis and management of patients presenting to primary and subspecialty healthcare with upper gastrointestinal complaints. (3)

The differential diagnosis of nonspecific upper gastrointestinal symptoms is broad. In the absence of alarm features, patients with chronic, recurrent upper abdominal pain or discomfort who have yet to undergo additional clinical evaluation are identified with a preliminary diagnosis of uninvestigated dyspepsia. In a meta-analysis of cross-sectional surveys reporting the prevalence of uninvestigated dyspepsia, Ford *et al* (2015) report a global prevalence of 20.8% (N 312 415; Range 1.8-57%; 95% CI 17.8-23.9), identifying significantly increased prevalence with a broad definition of dyspepsia, female gender, use of tobacco or nonsteroidal anti-inflammatory drugs (NSAIDs), and confirmed infection with *Helicobacter pylori.* (4)

Esophagogastroduodenoscopy (EGD) remains the gold-standard approach to the investigation of dyspepsia. Patients with evidence of structural disease on EGD are considered to have organic dyspepsia; gastroesophageal reflux disease (GERD) and peptic ulcer disease (PUD) are among the most common endoscopic diagnoses associated with dyspeptic complaints worldwide. (5-10) Dyspeptic patients without evidence of structural disease despite thorough clinical evaluation are diagnosed with functional dyspepsia (FD); the chronic symptom complex of FD is likely multifactorial, and is often attributed to a combination of visceral hypersensitivity and upper gastrointestinal dysmotility that varies with each individual and with time. (11) Unlike dyspepsia of organic origin, FD is not associated with an increased risk of mortality; however, it is significantly associated with decrements in health-related quality of life (HR-QoL). (12)

Rwanda

Despite growing evidence of significant disease burden, notably including gastric malignancy, *H pylori* infection, and peptic ulcer disease, associated with dyspeptic symptoms in Rwanda (13) and elsewhere in Sub-Saharan Africa (8) there remains a paucity of population-based data characterizing the epidemiology and clinical course of both organic and functional dyspepsia in these locations. Ford *et al* (2014) (14) calculated a prevalence

of dyspepsia in excess of 35% (N 1421; 95% CI 19.2-54) from two surveys (15,16) administered in Nigeria; if these data are representative of the African continent, the prevalence of uninvestigated dyspepsia in Africa approaches double that of the global population.

Although EGD is the tool of choice to investigate dyspepsia in Rwanda, there are few facilities and trained providers equipped to provide EGD to Rwandan patients in this resource-limited healthcare setting. No other clinical tools are currently available to Rwandan health care workers to adequately assess dyspeptic patients' symptom severity, symptom frequency, or HR-QoL, limiting the diagnosis, management, and investigation of dyspepsia in a culturally-competent manner. However, as Rwanda is a small, centralized country that uses a single traditional language (Kinyarwanda) in addition to English, it is ideally suited for the use of a patient-completed questionnaire as a surrogate or adjunct to EGD in both primary and subspecialty healthcare settings.

Tool Selection

The Leeds Dyspepsia Questionnaire and the Nepean Dyspepsia Index, and their short-form equivalents (SF-LDQ and SF-NDI), are self-reported item-based questionnaires that were developed in English to quantify dyspeptic symptom severity and frequency and HR-QoL related to functional dyspepsia, respectively. (17,18) Specifically, the SF LDQ captures the frequency and severity of upper abdominal discomfort, heartburn, regurgitation, and nausea over the preceding 2 months. Each item is assigned a numerical score that is summed into a total score; scores greater than 14 have been indicative of dyspepsia in other populations. The SF NDI evaluates tension/anxiety, interference with daily activities, disruption of usual eating/drinking, knowledge of/control over disease symptoms, and interference with work/study with 2-item 5-point Likert scales, with a total score calculated as the mean of the 5 subscale scores. (19)

Due to their simplicity and brevity, there is robust precedent for translation and validation of both the SF LDQ and SF NDI for use in non-English speaking populations. (20) Notably, Mahadeva and colleagues translated and validated both the SF LDQ (21) and the SF NDI (22) into Malay and Malaysian English for use in a multi-ethnic Asian population with dyspepsia, and reported adequate reliability (internal consistency determined by Cronbach's alpha: 0.8 and 0.74; test-retest reliability determined by Spearman's coefficient: 0.98), validity (area under receiver operator curve: 0.71 and 0.77), and responsiveness to treatment (mean LDQ score reduced followed treatment with PPI: 17.0 to 14.0, P 0.08 in Malay, 18.0 to 11.0, P 0.008 in Malaysian English) for both versions of the translated LDQ questionnaire [N 310]. For translated versions of the SF NDI, Mahadeva *et al* (2009)

reported adequate internal consistency and test-retest reliability (Cronbach's alpha: 0.83-0.90; Spearman's coefficient: 0.83 and 0.90), and approximate validity with correlation to the SF-36, a validated, widely used clinical tool that measures generic HR QoL [N 143]. (22)

Study Objectives

The objective of this study was to develop and validate a reliable translation of the SF LDQ and SF NDI in Kinyarwanda for use in epidemiological and clinical applications in both primary and subspecialty healthcare settings in Rwanda. This study also assessed the responsiveness of the Kinyarwanda version of the SF LDQ to treatment in patients diagnosed with dyspepsia.

Methods

We used Mahadeva *et al* (2009) (22) and (2011) (21) as a model for the translation, prospective cross-sectional survey administration, and psychometric evaluation of the SF LDQ and SF NDI into Kinyarwanda. The study protocol was reviewed and approved by the Kigali University Teaching Hospital Ethics Committee.

Instrument Translation

We selected 3 medically-experienced colleagues who are fluent in both languages to translate the tools from English into Kinyarwanda. The study author, supervisor, and English-Kinyarwanda translators met to analyze the language and content of the English tools to guide culturally-appropriate translation. Once consensus was achieved, the translated tools were back-translated from Kinyarwanda to English by a separate team of 3 qualified translators in order to verify that the Kinyarwanda version of the tools maintained the integrity of the English versions. The study author, supervisor, and translators again met to discuss the language and content of the back-translated tools. The corrected Kinyarwanda version of both tools were then evaluated by two independent Kinyarwanda linguistic experts, who made corrections to the translated tools. The final Kinyarwanda versions of the SF-NDI and SF-LDQ were then completed by 10 KUTH employees selected to represent diverse age and sociodemographic backgrounds in a pilot test of the translated tool.

Instrument Administration

We prospectively recruited adult patients (age >17 years; N 200) who presented to outpatient medical care at Kigali University Teaching Hospital (KUTH), a national referral hospital in Rwanda (N 100) or who awaited EGD at the same location (N 100). The study

author and a trained research assistant approached consecutive patients in the waiting area of outpatient clinics and the endoscopic suite, explaining the purpose of the research and asking if they would like to be considered for enrollment in the study. Patients were excluded from the study if they reported a prior history of abdominal surgery, major medical disease requiring tertiary medical care, or current major psychiatric disease. Patients were also excluded from the study if they did not adequately speak and understand Kinyarwanda. Enrolled participants underwent a process of informed consent, agreeing to fill out the study tools at that time (time 1) and to be contacted by phone by study administrators to complete the tool a second time (time 2). Participants who were literate in Kinyarwanda were given a printed copy of the questionnaires to complete themselves at time 1. Trained personnel orally administered the tools to participants who were not literate in Kinyarwanda at time 1, and to all participants over the phone at time 2. Study personnel were blinded to time 1 survey results until all time 2 data were collected.

Data Collection

Time 1 data were collected at the time of participant enrollment at KUTH between November 2014 and January 2015. Each participant completed a Kinyarwanda version of the SF-LDQ and the SF-NDI, as well as basic demographic information. Time 2 data were collected 3 days later; participants were contacted by telephone by the study author or a trained research assistant and asked to orally complete a Kinyarwanda version of the SF-LDQ and SF-NDI.

In order to test the responsiveness of the SF-LDQ to treatment, we randomly selected 20 patients who underwent EGD and were diagnosed with peptic ulcer disease. These patients completed the SF-LDQ a third time (time 3), following 1 month of oral proton pump inhibitor (PPI) therapy with or without additional triple therapy for *Helicobacter pylori* infection.

Data Analysis

The translated Kinyarwanda dyspepsia questionnaires were evaluated by assessing their reliability. Additionally, the validity and responsiveness of the SF-LDQ were assessed. We used SPSS version 16.0 and Excel to compute the statistical parameters reported in this study. Participants who did not complete both the time 1 and time 2 surveys in full were excluded from analysis.

Specifically, the internal consistency and test-retest reliability of the translated SF-LDQ and SF-NDI was determined by calculating Cronbach's alpha for time 1 and time 2 scores and Spearman's correlation coefficient between time 1 and time 2 scores, respectively. The validity of the SF-LDQ was determined against the gold standard of clinical diagnosis using

Receiver Operating Characteristic (ROC) curves. There is no gold standard for the measurement of health-related quality of life; therefore, the validity of the translated SF-NDI was estimated against SF-LDQ scores collected at time 1 during this study using ROC curves. We assessed the responsiveness of the SF-LDQ using Wilcoxon rank matched-pair testing by comparing the time 1 and post-treatment scores of 20 patients who were diagnosed with PUD on EGD, underwent 30 days of PPI therapy, and completed the tool a third time.

Results:

The final Kinyarwanda-translated versions of the SF LDQ and SF NDI tools are presented as Appendices 1 and 2.

A total of 200 study participants were enrolled between November 2014 and January 2015. The mean age of enrolled patients was 41 years. A majority of patients in the overall cohort were diagnosed with dyspepsia by a clinician (true dyspepsia prevalence among study participants 69%), including all of the patients awaiting EGD. Most patients were residents of Kigali (61%) and 62% were female [see Table 1].

SF LDQ

The response rates for the SF LDQ and SF NDI at both time 1 and time 2 were 100%. Cronbach's alpha was calculated at both Time 1 and Time 2 to assess the internal consistency of the translated SF LDQ, revealing a value of 0.93 at time 1 and 0.92 at time 2. The Spearman's correlation coefficient between time 1 and time 2 scores on the SF LDQ was 0.978. Response frequencies for each item on the SF LDQ are shown in Table 2.

The summed total score of the SF LDQ at time 1 was compared to the gold standard of clinical diagnosis by the treating physician, using a ROC curve (Figure 1). The point along the ROC curve that correctly classified the most participants was chosen as the SF LDQ cut off score for the diagnosis of dyspepsia. This SF LDQ cut off score of 16 showed a sensitivity of 97% and a specificity of 71% for the diagnosis of dyspepsia, correctly classifying 89% of study participants (kappa coefficient 0.75).

Among the 20 patients with peptic ulcer disease who received PPI therapy and were again interviewed at time 3, the mean SF LDQ score changed from 20.1 prior to treatment (time 1) to 13.9 after one month of therapy (time 3), with a p-value of 0.003 by Wilcoxon rank matched-pair testing.

SF NDI

Cronbach's alpha for the SF NDI was 0.96 at time 1 and 0.95 at time 2. The Spearman's correlation coefficient between time 1 and Time 2 scores on the SF NDI was 0.89.

The validity of the SF NDI was estimated by comparison of the per-patient total scores on the SF NDI and SF LDQ, using ROC curves plotted against clinical diagnosis (Figure 2). The area under each curve was similar (0.91 for SF LDQ vs 0.89 for SF NDI), and no statistical difference was apparent between the two curves (p=0.35).

Discussion:

This study demonstrates that tools developed for the study of dyspepsia prevalence and its impact on health-related quality of life in Western populations can be successfully adapted for use in an African language and cultural context. Obtained results indicate that Kinyarwadan versions of both the SF LDQ and SF NDI are reliable and internally consistent and that the SF LDQ displays a high correlation with African physicians' clinical diagnoses, with 89% of patients correctly classified by a SF LDQ >16 (area under ROC curve 0.91). While objective proof of the quality of life impact measured by the SF NDI was more difficult to obtain, secondary markers suggest a high correlation between SF NDI and SF LDQ scores, as well as high internal consistency and reliability for the SF NDI. Finally, the SF LDQ and SF NDI were responsive to changes with treatment in patients likely to respond to acid suppression, with a clinically and statistically significant fall in both scores in patients with clinically diagnosed PUD following initiation of a PPI.

The strengths of this study lie in clear and rigorous validation methodology applied to a Sub-Saharan linguistic and cultural context with significant dyspepsia-associated disease burden but without clinical precedent for evaluative tools available to treating physicians. This study's administration of both tools in written, oral, and phone-based forms realistically reflects the modes of communication that are routinely and necessarily employed for clinical and research purposes in Rwanda, ensuring that clinicians can confidently employ these tools without concern for compromised results.. Both tools were chosen for their simplicity and ease of use, further reducing survey length and complexity, barriers which can otherwise prove insurmountable in real-world African settings, where clinical demands often compete with research for the limited health care worker resources available. Additionally, the simultaneous evaluation of dyspeptic symptom prevalence and health-related quality of life enables this study to demonstrate for the first time that these domains are closely correlated in an African population, a link that bears important clinical and healthcare policy implications as Rwanda adapts to treat this patient population.

Although this is the first validation of the SF LDQ and SF NDI in Africa, similar studies have been performed in Malaysia and China; (21,23) together with the initial validation studies of these tools in Western populations, (17-19,24) these global results serve as a benchmark for the use of both long form and short form versions of the LDQ and NDI in multiple languages and varied populations.

Specifically, LDQ translations to Malay, Malaysian English and Mandarin (21,23) performed similar to the current study in terms of reliability (Spearman's coefficient 0.78-0.98), with a range of internal consistency (Cronbach alpha 0.74-0.80) lower than results reported for this

study population. Critically, LDQ results in historical populations were less valid than those obtained in this study when compared with clinical diagnoses in a mixed primary care and secondary care population (area under the ROC curves ranging from 0.71 - 0.84), save for a single Italian version of the SF NDI (Cronbach's alpha 0.90, Pearson's correlation coefficient 0.92, sensitivity 80% and specificity 82%) (25) .

Therefore, within the context of these geographically and demographically comparable validation studies, the results of this initiative to develop tools to measure the prevalence of dyspepsia and its impact on health-related quality of life in Sub-Saharan Africa impress with their robust validity. This relative success may be attributed to a number of observations, including differences in patient presentation, as African patients tend to present later in the course of other diseases, (26) differences in patient population, as this study enrolled patients at a tertiary care center, or differences in the cultural expression of dyspeptic symptoms. (27) It is also possible, but objectively indefensible, that the tools develop by this study are more culturally intelligible than those deployed in prior research settings, given the meticulous, multidisciplinary methods by which they were translated.

All research initiatives are subject to limitations. In this study, no gold standard for dyspepsia-related quality of life has been developed in Kinyarwanda; therefore, the validity of the SF NDI was evaluated with surrogate SF LDQ scores and contemporaneous clinical diagnoses. As this study focused exclusively on patients seeking medical care at a tertiary healthcare center, it is possible that the Kinyarwanda version of the SF LDQ might prove less discriminatory in other populations; however, the wide range of SF LDQ and SF NDI scores and the significant prevalence of incidental dyspepsia in the medical outpatient population (which likely resembles "primary" dyspepsia) suggest a diversity of patient illness experience that is reassuring. Finally, the initial administration of these tools (verbal or written) depended upon the literacy of each enrolled patient; all patients completed the surveys by telephone on re-administration. Although this heterogeneity could potentially have reduced the test-retest reliability of these tools, in fact reliability remained encouragingly high in our final study analysis. Further investigation of dyspepsia in African populations, with attendant translations of these tools into other African languages, will prove instructive areas for future research

Conclusion

The Kinyarwanda versions of the SF LDQ and SF NDI developed by this study proved reliable and valid, particularly when compared to the gold standard of clinical diagnosis. These tools are recommended for use in clinical and research initiatives involving the

prevalence of dyspepsia and its impact of health-related quality of life in Kinyarwanda-speaking patients of Sub-Saharan Africa.

Funding

This study was partially funded by the Rwandan Ministry of Health, via a Masters of Medicine (Internal Medicine) Research Grant. The views expressed are those of the authors and not of the Rwandan Ministry of Health.

Competing Interests

Nil

Contributorship Statement

TDW conceived the study; AN, VD and TDW designed the study; AN and VD carried out and supervised the interviews; AN, VD, KE, SB and TDW interpreted the data; AN, KE, SB and TDW drafted the manuscript; AN, VD, KE, SB and TDW critically revised the manuscript for intellectual content. All authors read and approved the final manuscript. TDW and AN are guarantors of the paper.

Study Ethical Approval

The study was approved by the Kigali University Teaching Hospital Ethics Committee.

Acknowledgements:

Thanks to Professor Nick Talley and Professor Brendan Delaney for kind permission to translate the SF-NDI and SF-LDQ tools.

Data Sharing Statement

A database containing de-identified patient level data for all study participants is available from the corresponding author upon request.

List of Tables, Figures and Appendices

Table 1: Demographic characteristics of study population

Characteristic	Number (%)		
Dyspepsia	137 (68)	**Occupation**	
No dyspepsia	63 (32)	Jobless	37 (19)
Gender		Farmer	48 (24)
Female	123 (62)	Student	26 (13)
Male	77 (38)	Private	46 (26)
Residency		Public	34 (17)
Kigali	121 (60)	Retired	9 (4)
East	28 (14)	**Marital status**	
West	8 (4)	Single	69 (34)
South	18 (9)	Married	105 (53)
North	25 (13)	Window	15 (7)
Education		Divorced	6 (3)
None	18 (9)	Separated	5 (3)
Primary	70 (35)	**Having children**	
Secondary	63 (32)	Children	138 (69)
University	49 (25)	No children	62 (31)

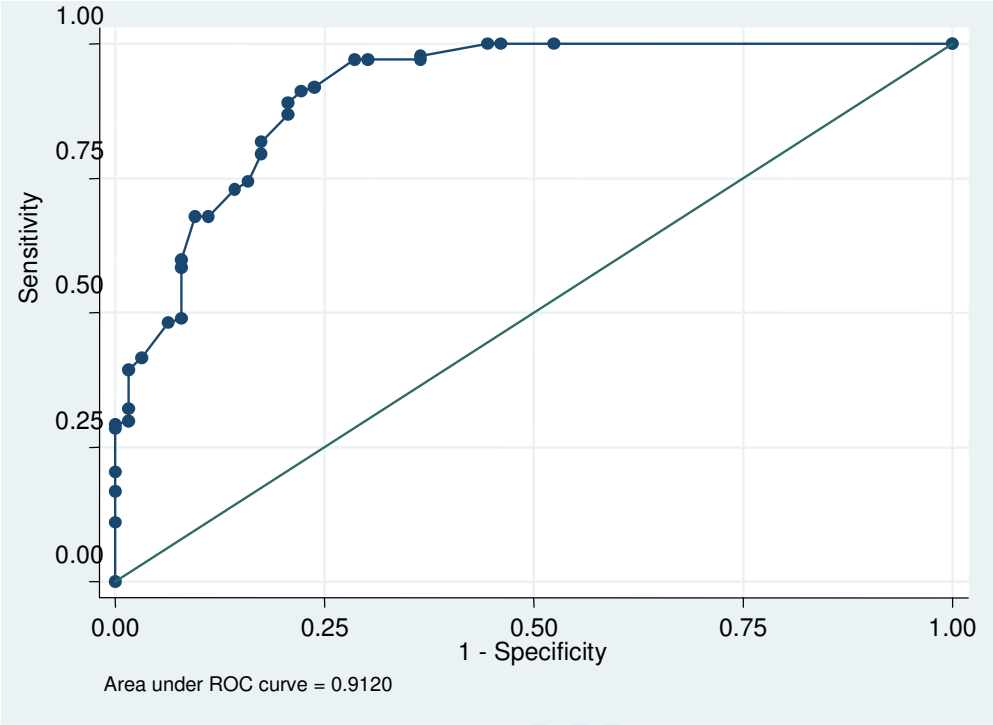
Notes: Residency refers to province of residence.

Table 2: Time 1 response frequencies for the SF LDQ

		Frequency (%)	Severity (%)
Indigestion	Not at all	38 (19)	44 (22)
	Less than once a month	14 (7)	14 (7)
	Between once a month and once a week	23 (11.5)	21 (10.5)
	Between once a week and once a day	42 (21)	44 (22)
	Once a day and more	83 (41.5)	77 (38.5)
Hearrtburn	Not at all	65 (32.5)	74 (37)
	Less than once a month	18 (9)	19 (9.5)
	Between once a month and once a week	28 (14)	25 (12.5)
	Between once a week and once a day	37 (18.5)	34 (17)
	Once a day or more	52 (26)	48 (24)
Regurgitation	Not at all	80 (40)	80 (40)
	Less than once a month	22 (11)	25 (12.5)
	Between once a month and once a week	25 (12.5)	27 (13.5)
	Between once a week and once a day	38 (19)	36 (18)
	Once a day and more	35 (17.5)	32 (16)
Nausea	Not at all	69 (34.5)	73 (36.5)
	Less than once a month	15 (7.5)	20 (20)
	Between once a month and once a week	24 (12)	24 (12)
	Between once a week and once a day	40 (20)	35 (17.5)
	Once a day or more	52 (26)	48 (24)

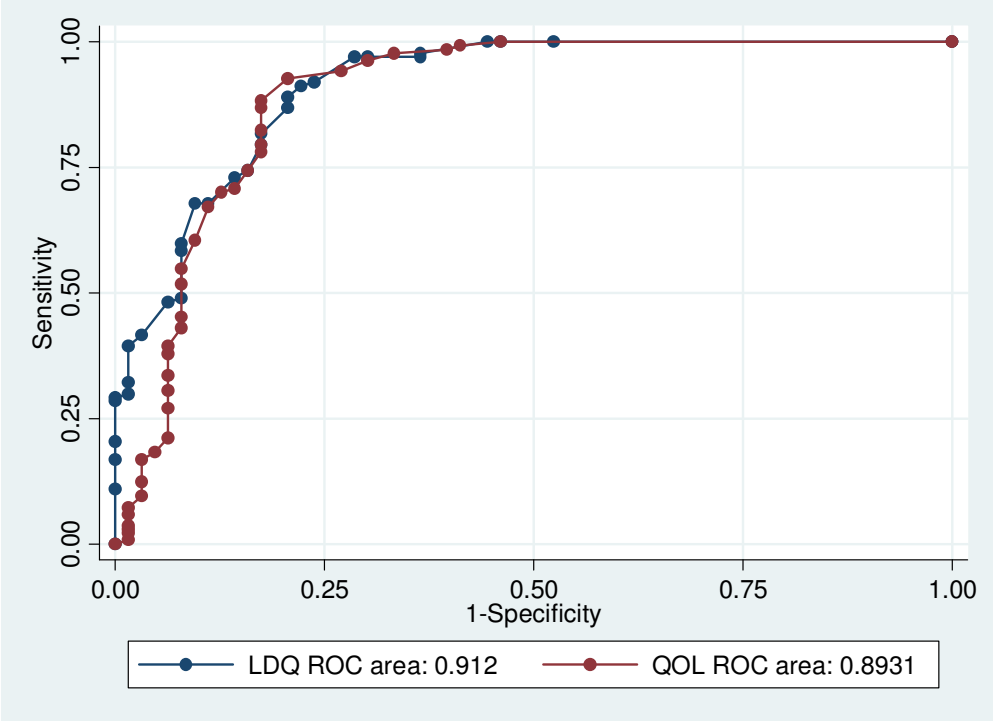
Notes: SF LDQ: Short Form Leeds Dyspepsia Questionnaire

Figure 1: ROC curve for SF LDQ total score at Time 1, plotted against clinical diagnosis



Notes: ROC: Receiver Operator Characteristic, SF LDQ: Short Form Leeds Dyspepsia Questionnaire

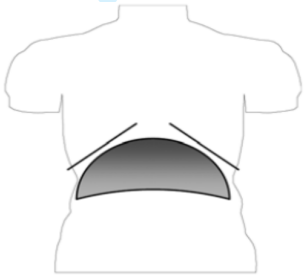
Figure 2: ROC curves for SF NDI and SF LDQ at Time 1, plotted against clinical diagnosis



Notes: ROC: Receiver Operator Characteristic, SF NDI (and "QOL" in key): Short Form Nepean Dyspepsia Index, SF LDQ (and "LDQ" in key): Short Form Leeds Dyspepsia Questionnaire

Appendix 1: Short Form Leeds Dyspepsia Questionnaire in Kinyarwanda

I. Incamake y'ibibazo by'urwaye igifu.

Ibimenyetso by 'uburwayi bw'igifu	**Ikibazo cya mbere gisubizwa kuri buri kimenyetso.**	**Ikibazo cya kabiri gisubizwa kuri buri kimenyetso.**
1. **Kugugara mu gifu**: kumva uribwa cyangwa ubangamiwe mu gifu. 	**Mu mezi abiri ashize wagaragaje ibi bimenyetso incuro zingahe?** **Hitamo igisubizo kimwe gusa kuri buri kibazo, ushyire V mu kazu bijyanye.** ☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(**Incuro imwe mu mezi abiri)** ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cyumweru. ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi. ☐ Incuro imwe cyangwa nyinshi ku munsi	**Mu mezi abiri ashize, ni kangahe ibi bimenyetso byabangamiye imibereho yawe (kurya, gusinzira, gukora, kwidagadura.)** **Hitamo igisubizo kimwe gusa kuri buri kibazo, ushyire V mu kazu bijyanye.** ☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(incuro imwe mu mezi abiri) ☐ Hagati y'incuro imwe mu kwezi n'inshuro imwe mu cyumweru ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi

2. **Ikirungurira**; ni ukumva wokerwa hagati mu gituza. 	☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(**incuro imwe mu mezi abiri)** ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cyumweru ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi	☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(**incuro imwe mu mezi abiri)** ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cyumweru ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi
3. **Kugarura mu kanwa ibiri mu gifu bisharira.**	☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(incuro imwe mu mezi abiri) ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cy'umweru ☐ Hagati y' incuro imwe mu cy'umweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi	☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(incuro imwe mu mezi abiri) ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cy'umweru ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi
4. **Iseseme**: kumva ushaka kuruka.	☐ Nta na rimwe ☐Munsi y'incuro imwe mu kwezi(incuro imwe mu mezi abiri) ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cyumweru	☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(incuro imwe mu mezi abiri) ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cyumweru

	☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi	☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi

Muri ibi bimenyetso bikurikira ni ikihe cyakuzahaje kurusha ibindi?

0. Ntibindeba ☐

1. Kugugara mu gifu ☐

2. Kugarura mu kanwa ibiri mu gifu bisharira ☐

3. Ikirungurira ☐

4. Iseseme ☐

Appendix 2: Short Form Nepean Dyspepsia Index in Kinyarwanda

1. Uburwayi bwawe bw'igifu bwaba bwarahungabanije amarangamutima yawe mu byumweru bibiri bishize?

0. Ntibindeba ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

2. Uburwayi bwawe bw'igifu bwaguteye kugira umunabi, umushiha, cyangwa ishavu mu byumweru bibiri bishize?

0. Ntibindeba ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

KUBANGAMIRWA MU MIRIMO YA BURI MUNSI

3. Uburwayi bwawe bw'igifu bwaba bwarabangamiye gahunda zawe zo kwidagadura (nko gutembera, gukina, siporo n' ibindi nk'ibyo) mu byumweru bibiri bishize?

0. Ntibindeba ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

4. Uburwayi bwawe bw'igifu bwaba bwarahungabanije uburyo ushimishwa no kwidagadura (gutembera, gukina, siporo n'ibindi nkibyo) mu byumweru bibiri bishize?

0. Ntibindeba ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

KURYA NO KUNYWA.

5. Uko wabashaga gufungura cyangwa kunywa (amasaha yo gufungura, ibyo ufungura n'ingano yabyo), byaba byarahungabanijwe n'uburwayi bwawe bw'igifu muri ibi byumweru bibiri bishize?

0. Ntibindeba ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

6. Kuryoherwa n'ibiribwa(apetit) cyangwa ibinyobwa n'uko wiyumva umaze kurya cyangwa kunywa, byaba byarahungabanijwe n'uburwayi bwawe bw'igifu muri ibi byumweru bibiri bishize?

0. Ntibindeba ☐
1. Oya, ntanabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

UBUMENYI-IGENZURA.

7. Waba warigeze kwibaza ko uzahorana uburwayi bw'igifu mu byumweru bibiri bishize?

0. Ntibindeba ☐
1. Nta na rimwe ☐
2. Rimwe na rimwe ☐
3. Kenshi ☐
4. Kenshi cyane ☐
5. Buri gihe ☐

8. Waba waratekereje ko uburwayi bwawe bw'igifu bushobora kuba buturuka ku burwayi bukomeye (urugero: kanseri, uburwayi bw' umutima) mu byumweru bibiri bishize?

0. Ntibindeba ☐
1. Nta na rimwe ☐
2. Rimwe na rimwe ☐
3. Kenshi ☐
4. Kenshi cyane ☐
5. Buri gihe ☐

AKAZI- AMASOMO.

9. Uko wabashaga gukora cyangwa kwiga byaba byarahungabanijwe n'uburwayi bwawe bw'igifu muri ibi byumweru bibiri bishize?

0. Ntibindeba (sinkora, siniga) ☐
1. Oya, ntanabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

10. Uko ushimishwa n'akazi cyangwa amasomo, byaba byarahungabanijwe n'uburwayi bwawe bw'igifu mu byumweru bibiri bishize?

0. Ntibindeba (sinigeze nkora cyangwa ngo nige muri ibi byumweru bibiri bishize) ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

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STARD checklist for reporting of studies of diagnostic accuracy

(version January 2003)

Section and Topic	Item #		On page #
TITLE/ABSTRACT/ KEYWORDS	1	Identify the article as a study of diagnostic accuracy (recommend MeSH heading 'sensitivity and specificity').	1
INTRODUCTION	2	State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.	5
METHODS			
Participants	3	The study population: The inclusion and exclusion criteria, setting and locations where data were collected.	5-6
	4	Participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?	5-6
	5	Participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected.	5-6
	6	Data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?	5
Test methods	7	The reference standard and its rationale.	6-7
	8	Technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.	5-7
	9	Definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.	4-5, 8
	10	The number, training and expertise of the persons executing and reading the index tests and the reference standard.	5-6
	11	Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.	6
Statistical methods	12	Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).	6-7
	13	Methods for calculating test reproducibility, if done.	6-7
RESULTS			
Participants	14	When study was performed, including beginning and end dates of recruitment.	6
	15	Clinical and demographic characteristics of the study population (at least information on age, gender, spectrum of presenting symptoms).	8, 14
	16	The number of participants satisfying the criteria for inclusion who did or did not undergo the index tests and/or the reference standard; describe why participants failed to undergo either test (a flow diagram is strongly recommended).	8
Test results	17	Time-interval between the index tests and the reference standard, and any treatment administered in between.	6
	18	Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.	8
	19	A cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.	ROC curve: 16
	20	Any adverse events from performing the index tests or the reference standard.	NA
Estimates	21	Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).	8
	22	How indeterminate results, missing data and outliers of the index tests were handled.	8
	23	Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.	NA
	24	Estimates of test reproducibility, if done.	8
DISCUSSION	25	Discuss the clinical applicability of the study findings.	9-10

BMJ Open

Validation of the Kinyarwanda-version Short Form Leeds Dyspepsia Questionnaire and Short Form Nepean Dyspepsia Index to assess dyspepsia prevalence and quality of life impact in Rwanda.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2015-011018.R1
Article Type:	Research
Date Submitted by the Author:	26-Apr-2016
Complete List of Authors:	Nkurunziza, Arcade; University of Rwanda College of Medicine and Health Sciences Huye Dusabejambo, Vincent; University of Rwanda College of Medicine and Health Sciences Huye; Kigali University Teaching Hospital, Gastroenterology Everhart, Kelly; Dartmouth College Geisel School of Medicine Bensen, Steve; Dartmouth College Geisel School of Medicine; Dartmouth-Hitchcock Medical Center Walker, Timothy; University of Rwanda College of Medicine and Health Sciences Huye; Butare University Teaching Hospital, Gastroenterology
Primary Subject Heading:	Gastroenterology and hepatology
Secondary Subject Heading:	Global health, Public health
Keywords:	Adult gastroenterology < GASTROENTEROLOGY, Gastroduodenal disease < GASTROENTEROLOGY, PRIMARY CARE, Epidemiology < TROPICAL MEDICINE

Validation of the Kinyarwanda-version Short Form Leeds Dyspepsia Questionnaire and Short Form Nepean Dyspepsia Index to assess dyspepsia prevalence and quality of life impact in Rwanda.

Arcade Nkurunziza, Vincent Dusabejambo, Kelly Everhart, Steve Bensen and Tim Walker

Corresponding Author

Dr Tim Walker, FRACP, MBBS(Hons), MPHTM

Consultant Gastroenterologist, University Teaching Hospital, Butare

Department of Internal Medicine, School of Medicine, University of Rwanda

+250-(0)784206851

timwalkerd@gmail.com

Objectives

We aimed to develop and validate Kinyarwanda versions of SF LDQ and SF NDI, to measure the frequency and severity of dyspepsia and associated quality of life impact in Rwanda.

Setting

A single, tertiary care centre in Rwanda.

Participants

200 consecutive Kinyarwanda-speaking patients referred to endoscopy (100 patients) or medical outpatients (100 patients).

Interventions

Kinyarwanda versions of the SF LDQ and SF NDI were developed from English versions by translation, with back translation, crosschecking and pilot testing. Study participants completed these questionnaires at enrolment (time 1), and then completed the surveys again with blinded phone interviewers three days later (time 2). 20 randomly selected participants, diagnosed with a peptic ulcer on index endoscopy, completed a third survey by phone at day 30 (time 3), after therapy.

Primary outcome measures

Internal consistency at time 1 (by Cronbach alpha) and test-retest reliability between time 1 and time 2 (Spearman's correlation coefficient) for both translated SF-LDQ and SF-NDI; validity vs clinical diagnosis (by ROC curve) and responsiveness to treatment for SF-LDQ (by change in mean score). All outcomes were measured as per protocol.

Results

Cronbach's alpha of the translated SF-LDQ was 0.93, showing high internal consistency. Spearman's correlation coefficient comparing time 1 and time 2 was 0.978 (p-value < 0.001), demonstrating high reliability. Cronbach's alpha for the translated SF-NDI was 0.92. A cutoff score of 16 on the SF LDQ showed a sensitivity of 97% and a specificity of 71% for the diagnosis of dyspepsia, correctly classifying 89% of patients. In the responsiveness analysis, the mean SF- LDQ score was reduced from 20.1 prior to treatment to 13.9 after 30 days of treatment (p = 0.003).

Conclusion

The Kinyarwanda versions of the SF LDQ and SF NDI were valid, reliable and responsive to treatment.

Trial registration

Nil

Article Summary "Strengths and limitations of this study"

Strengths

- Both dyspepsia symptom severity and quality of life impact measured concurrently in the same patient population.
- Study staff were blinded to time 1 survey results when administering time 2 surveys.
- 100% participant follow-up achieved from time 1 to time 2

Weaknesses

- No gold standard comparison available to validate SF NDI, the dyspepsia quality of life tool, meaning that surrogate markers had to be used.
- Survey administration methods differed between time 1 and time 2: interpersonal interviews and phone-based interviews.

Introduction

Dyspepsia is a constellation of upper gastrointestinal symptoms that present a significant personal, social, and financial burden to patients and healthcare resources worldwide. (1,2) Although no standard, universal definition of dyspepsia adequately characterizes the symptom complex across diverse cultural and sociodemographic environments, clinicians tend to rely upon the presence of chronic, recurrent epigastric pain or discomfort as a platform for the diagnosis and management of patients presenting to primary and subspecialty healthcare with upper gastrointestinal complaints. (3)

The differential diagnosis of nonspecific upper gastrointestinal symptoms is broad. In the absence of alarm features, patients with chronic, recurrent upper abdominal pain or discomfort who have yet to undergo additional clinical evaluation are identified with a preliminary diagnosis of uninvestigated dyspepsia. In a meta-analysis of cross-sectional surveys reporting the prevalence of uninvestigated dyspepsia, Ford *et al* (2015) report a global prevalence of 20.8% (N 312 415; Range 1.8-57%; 95% CI 17.8-23.9), identifying significantly increased prevalence with a broad definition of dyspepsia, female gender, use of tobacco or nonsteroidal anti-inflammatory drugs (NSAIDs), and confirmed infection with *Helicobacter pylori.* (4)

Esophagogastroduodenoscopy (EGD) remains the gold-standard approach to the investigation of dyspepsia. Patients with evidence of structural disease on EGD are considered to have organic dyspepsia; gastroesophageal reflux disease (GERD) and peptic ulcer disease (PUD) are among the most common endoscopic diagnoses associated with dyspeptic complaints worldwide. (5-10) Dyspeptic patients without evidence of structural disease despite thorough clinical evaluation are diagnosed with functional dyspepsia (FD); the chronic symptom complex of FD is likely multifactorial, and is often attributed to a combination of visceral hypersensitivity and upper gastrointestinal dysmotility that varies with each individual and with time. (11) Unlike dyspepsia of organic origin, FD is not associated with an increased risk of mortality; however, it is significantly associated with decrements in health-related quality of life (HR-QoL). (12)

Rwanda

Despite growing evidence of significant disease burden, notably including gastric malignancy, *H pylori* infection, and peptic ulcer disease, associated with dyspeptic symptoms in Rwanda (13) and elsewhere in Sub-Saharan Africa (8) there remains a paucity of population-based data characterizing the epidemiology and clinical course of both organic and functional dyspepsia in these locations. Ford *et al* (2014) (14) calculated a prevalence

of dyspepsia in excess of 35% (N 1421; 95% CI 19.2-54) from two surveys (15,16) administered in Nigeria; if these data are representative of the African continent, the prevalence of uninvestigated dyspepsia in Africa approaches double that of the global population.

Although EGD is the tool of choice to investigate dyspepsia in Rwanda, there are few facilities and trained providers equipped to provide EGD to Rwandan patients in this resource-limited healthcare setting. No other clinical tools are currently available to Rwandan health care workers to adequately assess dyspeptic patients' symptom severity, symptom frequency, or HR-QoL, limiting the diagnosis, management, and investigation of dyspepsia in a culturally-competent manner. However, as Rwanda is a small, centralized country that uses a single traditional language (Kinyarwanda) in addition to English, it is ideally suited for the use of a patient-completed questionnaire as a surrogate or adjunct to EGD in both primary and subspecialty healthcare settings.

Tool Selection

The Leeds Dyspepsia Questionnaire and the Nepean Dyspepsia Index, and their short-form equivalents (SF-LDQ and SF-NDI), are self-reported item-based questionnaires that were developed in English to quantify dyspeptic symptom severity and frequency and HR-QoL related to functional dyspepsia, respectively. (17,18) Specifically, the SF LDQ captures the frequency and severity of upper abdominal discomfort, heartburn, regurgitation, and nausea over the preceding 2 months. Each item is assigned a numerical score that is summed into a total score; scores greater than 14 have been indicative of dyspepsia in other populations. The SF NDI evaluates tension/anxiety, interference with daily activities, disruption of usual eating/drinking, knowledge of/control over disease symptoms, and interference with work/study with 2-item 5-point Likert scales, with a total score calculated as the mean of the 5 subscale scores. (19)

Due to their simplicity and brevity, there is robust precedent for translation and validation of both the SF LDQ and SF NDI for use in non-English speaking populations. (20) Notably, Mahadeva and colleagues translated and validated both the SF LDQ (21) and the SF NDI (22) into Malay and Malaysian English for use in a multi-ethnic Asian population with dyspepsia, and reported adequate reliability (internal consistency determined by Cronbach's alpha: 0.8 and 0.74; test-retest reliability determined by Spearman's coefficient: 0.98), validity (area under receiver operator curve: 0.71 and 0.77), and responsiveness to treatment (mean LDQ score reduced followed treatment with PPI: 17.0 to 14.0, P 0.08 in Malay, 18.0 to 11.0, P 0.008 in Malaysian English) for both versions of the translated LDQ questionnaire [N 310]. For translated versions of the SF NDI, Mahadeva *et al* (2009)

reported adequate internal consistency and test-retest reliability (Cronbach's alpha: 0.83-0.90; Spearman's coefficient: 0.83 and 0.90), and approximate validity with correlation to the SF-36, a validated, widely used clinical tool that measures generic HR QoL [N 143]. (22)

Study Objectives

The objective of this study was to develop and validate a reliable translation of the SF LDQ and SF NDI in Kinyarwanda for use in epidemiological and clinical applications in both primary and subspecialty healthcare settings in Rwanda. This study also assessed the responsiveness of the Kinyarwanda version of the SF LDQ to treatment in patients diagnosed with dyspepsia.

Methods

We used Mahadeva *et al* (2009) (22) and (2011) (21) as a model for the translation, prospective cross-sectional survey administration, and psychometric evaluation of the SF LDQ and SF NDI into Kinyarwanda. The study protocol was reviewed and approved by the Kigali University Teaching Hospital Ethics Committee.

Instrument Translation

We selected 3 medically-experienced colleagues who are fluent in both languages to translate the tools from English into Kinyarwanda. The study author, supervisor, and English-Kinyarwanda translators met to analyze the language and content of the English tools to guide culturally-appropriate translation. Once consensus was achieved, the translated tools were back-translated from Kinyarwanda to English by a separate team of 3 qualified translators in order to verify that the Kinyarwanda version of the tools maintained the integrity of the English versions. The study author, supervisor, and translators again met to discuss the language and content of the back-translated tools. The corrected Kinyarwanda version of both tools were then evaluated by two independent Kinyarwanda linguistic experts, who made corrections to the translated tools. The final Kinyarwanda versions of the SF-NDI and SF-LDQ were then completed by 10 KUTH employees (5 nurses, 3 administrators, 2 service personnel) selected to represent diverse age (mean age 35 years; range 18-52 years) and sociodemographic backgrounds (7 female; 7 with university-level education) in a pilot test of the translated tool. None of the participants in the pilot administration of either tool encountered any difficulties with the Kinyrwanda translation, completing both tools without assistance. Therefore, no further changes were made to either tool prior to their use with study participants.

Instrument Administration

We recruited adult patients (age >17 years; N 200) who presented to outpatient medical care at Kigali University Teaching Hospital (KUTH), a national referral hospital in Rwanda (N 100) or who awaited EGD at the same location (N 100). The study author and a trained research assistant approached patients in the waiting area of outpatient clinics and the endoscopic suite, explaining the purpose of the research and asking if they would like to be considered for enrollment in the study. Patients were excluded from the study if they reported a prior history of abdominal surgery, major medical disease requiring tertiary medical care, or current major psychiatric disease. Patients were also excluded from the study if they did not adequately speak and understand Kinyarwanda. Enrolled participants underwent a process of informed consent, agreeing to fill out the study tools at that time (time 1) and to be contacted by phone by study administrators to complete the tool a second time (time 2). Participants who were literate in Kinyarwanda were given a printed copy of the questionnaires to complete themselves at time 1. Trained personnel orally administered the tools to participants who were not literate in Kinyarwanda at time 1, and to all participants over the phone at time 2. Study personnel were blinded to time 1 survey results until all time 2 data were collected.

Data Collection

Time 1 data were collected at the time of participant enrollment at KUTH between November 2014 and January 2015. Each participant completed a Kinyarwanda version of the SF-LDQ and the SF-NDI, as well as basic demographic information. Time 2 data were collected 3 days later; participants were contacted by telephone by the study author or a trained research assistant and asked to orally complete a Kinyarwanda version of the SF-LDQ and SF-NDI.

In order to test the responsiveness of the SF-LDQ to treatment, we randomly selected 20 patients who underwent EGD and were diagnosed with peptic ulcer disease. These patients completed the SF-LDQ a third time (time 3), following 1 month of oral proton pump inhibitor (PPI) therapy with or without additional triple therapy for *Helicobacter pylori* infection.

Data Analysis

The translated Kinyarwanda dyspepsia questionnaires were evaluated by assessing their reliability. Additionally, the validity and responsiveness of the SF-LDQ were assessed. We used SPSS version 16.0 and Excel to compute the statistical parameters reported in this study. Participants who did not complete both the time 1 and time 2 surveys in full were excluded from analysis.

Specifically, the internal consistency and test-retest reliability of the translated SF-LDQ and SF-NDI was determined by calculating Cronbach's alpha for time 1 and time 2 scores and Spearman's correlation coefficient between time 1 and time 2 scores, respectively. The validity of the SF-LDQ was determined against the gold standard of clinical diagnosis using Receiver Operating Characteristic (ROC) curves. There is no gold standard for the measurement of health-related quality of life; therefore, the validity of the translated SF-NDI was estimated first against SF-LDQ scores collected at time 1 during this study using ROC curves, and then using the Mann-Whitney U test to establish known groups construct validity of the total and five subscale scores of the SF-NDI relative to the severity (increased symptom severity defined as SF-LDQ ≥ 15) of dyspeptic symptoms. (22) We assessed the responsiveness of the SF-LDQ using Wilcoxon rank matched-pair testing by comparing the time 1 and post-treatment scores of 20 patients who were diagnosed with PUD on EGD, underwent 30 days of PPI therapy, and completed the tool a third time.

Results:

The final Kinyarwanda-translated versions of the SF LDQ and SF NDI tools are presented as Appendices 1 and 2.

A total of 200 study participants were enrolled between November 2014 and January 2015. The mean age of enrolled patients was 41 years. A majority of patients in the overall cohort were diagnosed with dyspepsia by a clinician (true dyspepsia prevalence among study participants 69%), including all of the patients awaiting EGD. Most patients were residents of Kigali (61%) and 62% were female [see Table 1].

SF LDQ

The response rates for the SF LDQ and SF NDI at both time 1 and time 2 were 100%. Cronbach's alpha was calculated at both Time 1 and Time 2 to assess the internal consistency of the translated SF LDQ, revealing a value of 0.93 at time 1 and 0.92 at time 2. The Spearman's correlation coefficient between time 1 and time 2 scores on the SF LDQ was 0.978. Response frequencies for each item on the SF LDQ are shown in Table 2.

The summed total score of the SF LDQ at time 1 was compared to the gold standard of clinical diagnosis by the treating physician, using a ROC curve (Figure 1). The point along the ROC curve that correctly classified the most participants was chosen as the SF LDQ cut off score for the diagnosis of dyspepsia. This SF LDQ cut off score of 16 showed a sensitivity of 97% and a specificity of 71% for the diagnosis of dyspepsia, correctly classifying 89% of study participants (kappa coefficient 0.75).

Among the 20 patients with peptic ulcer disease who received PPI therapy and were again interviewed at time 3, the mean SF LDQ score changed from 20.1 prior to treatment (time 1) to 13.9 after one month of therapy (time 3), with a p-value of 0.003 by Wilcoxon rank matched-pair testing.

SF NDI

Cronbach's alpha for the SF NDI was 0.96 at time 1 and 0.95 at time 2. The Spearman's correlation coefficient between time 1 and Time 2 scores on the SF NDI was 0.89.

The validity of the SF NDI was first estimated by comparison of the per-patient total scores on the SF NDI and SF LDQ, using ROC curves plotted against clinical diagnosis (Figure 2). The area under each curve was similar (0.91 for SF LDQ vs 0.89 for SF NDI), and no statistical difference was apparent between the two curves (p=0.35).

Known groups construct validity of the total and subscale scores of the Kinyrwanda version of the SF-NDI was established relative to the severity of dyspeptic symptoms using the Mann-Whitney U test. For all 5 sub-scale scores and the total score of the SF-NDI, there was significant ($p < 0.001$) compromise of health-related quality of life for patients with severe relative to patients with mild dyspeptic symptoms (Table 3).

Discussion:

This study demonstrates that tools developed for the study of dyspepsia prevalence and its impact on health-related quality of life in Western populations can be successfully adapted for use in an African language and cultural context. Obtained results indicate that Kinyarwadan versions of both the SF LDQ and SF NDI are reliable and internally consistent and that the SF LDQ displays a high correlation with African physicians' clinical diagnoses, with 89% of patients correctly classified by a SF LDQ >16 (area under ROC curve 0.91). While objective proof of the quality of life impact measured by the SF NDI was more difficult to obtain, secondary markers suggest a high correlation between SF NDI and SF LDQ scores, as well as high internal consistency and reliability for the SF NDI. Finally, the SF LDQ was responsive to changes with treatment in patients likely to respond to acid suppression, with a clinically and statistically significant fall in both scores in patients with clinically diagnosed PUD following initiation of a PPI.

The strengths of this study lie in clear and rigorous validation methodology applied to a Sub-Saharan linguistic and cultural context with significant dyspepsia-associated disease burden but without clinical precedent for evaluative tools available to treating physicians. This study's administration of both tools in written, oral, and phone-based forms realistically reflects the modes of communication that are routinely and necessarily employed for clinical and research purposes in Rwanda, ensuring that clinicians can confidently employ these tools without concern for compromised results.. Both tools were chosen for their simplicity and ease of use, further reducing survey length and complexity, barriers which can otherwise prove insurmountable in real-world African settings, where clinical demands often compete with research for the limited health care worker resources available. Additionally, the simultaneous evaluation of dyspeptic symptom prevalence and health-related quality of life enables this study to demonstrate for the first time that these domains are closely correlated in an African population, a link that bears important clinical and healthcare policy implications as Rwanda adapts to treat this patient population.

Although this is the first validation of the SF LDQ and SF NDI in Africa, similar studies have been performed in Malaysia and China; (21,23) together with the initial validation studies of these tools in Western populations, (17-19,24) these global results serve as a benchmark for

the use of both long form and short form versions of the LDQ and NDI in multiple languages and varied populations.

Specifically, LDQ translations to Malay, Malaysian English and Mandarin (21,23) performed similar to the current study in terms of reliability (Spearman's coefficient 0.78-0.98), with a range of internal consistency (Cronbach alpha 0.74-0.80) lower than results reported for this study population. Critically, LDQ results in historical populations were less valid than those obtained in this study when compared with clinical diagnoses in a mixed primary care and secondary care population (area under the ROC curves ranging from 0.71 - 0.84), save for a single Italian version of the SF NDI (Cronbach's alpha 0.90, Pearson's correlation coefficient 0.92, sensitivity 80% and specificity 82%) (25) .

Therefore, within the context of these geographically and demographically comparable validation studies, the results of this initiative to develop tools to measure the prevalence of dyspepsia and its impact on health-related quality of life in Sub-Saharan Africa impress with their robust validity. This relative success may be attributed to a number of observations, including differences in patient presentation, as African patients tend to present later in the course of other diseases, (26) differences in patient population, as this study enrolled patients at a tertiary care center, or differences in the cultural expression of dyspeptic symptoms. (27) It is also possible that the tools developed by this study are more culturally intelligible than those deployed in prior research settings, given the meticulous, multidisciplinary methods by which they were translated.

All research initiatives are subject to limitations. In this study, no gold standard for dyspepsia-related quality of life has been developed in Kinyarwanda; therefore, the validity of the SF NDI was evaluated with surrogate SF LDQ scores and contemporaneous clinical diagnoses. As this study focused exclusively on patients seeking medical care at a tertiary healthcare center, it is possible that the Kinyarwanda version of the SF LDQ might prove less discriminatory in other populations; however, the wide range of SF LDQ and SF NDI scores and the significant prevalence of incidental dyspepsia in the medical outpatient population (which likely resembles "primary" dyspepsia) suggest a diversity of patient illness experience that is reassuring. Finally, the initial administration of these tools (verbal or written) depended upon the literacy of each enrolled patient; all patients completed the surveys by telephone on re-administration. Although this heterogeneity could potentially have reduced the test-retest reliability of these tools, in fact reliability remained encouragingly high in our final study analysis. Further investigation of dyspepsia in African populations, with attendant translations of these tools into other African languages, will prove instructive areas for future research

Conclusion

The Kinyarwanda versions of the SF LDQ and SF NDI developed by this study proved reliable and valid, particularly when compared to the gold standard of clinical diagnosis. These tools are recommended for use in clinical and research initiatives involving the prevalence of dyspepsia and its impact of health-related quality of life in Kinyarwanda-speaking patients of Sub-Saharan Africa.

Funding

This study was partially funded by the Rwandan Ministry of Health, via a Masters of Medicine (Internal Medicine) Research Grant. The views expressed are those of the authors and not of the Rwandan Ministry of Health.

Competing Interests

Nil

Contributorship Statement

TDW conceived the study; AN, VD and TDW designed the study; AN and VD carried out and supervised the interviews; AN, VD, KE, SB and TDW interpreted the data; AN, KE, SB and TDW drafted the manuscript; AN, VD, KE, SB and TDW critically revised the manuscript for intellectual content. All authors read and approved the final manuscript. TDW and AN are guarantors of the paper.

Study Ethical Approval

The study was approved by the Kigali University Teaching Hospital Ethics Committee.

Acknowledgements:

Thanks to Professor Nick Talley and Professor Brendan Delaney for kind permission to translate the SF-NDI and SF-LDQ tools.

Data Sharing Statement

A database containing de-identified patient level data for all study participants' response to administered questionnaires at all time points is available from the corresponding author upon request.

List of Tables, Figures and Appendices

Table 1: Demographic characteristics of study population

Characteristic	Number (%)		
Dyspepsia	137 (68)	**Occupation**	
No dyspepsia	63 (32)	Jobless	37 (19)
Gender		Farmer	48 (24)
Female	123 (62)	Student	26 (13)
Male	77 (38)	Private	46 (26)
Residency		Public	34 (17)
Kigali	121 (60)	Retired	9 (4)
East	28 (14)	**Marital status**	
West	8 (4)	Single	69 (34)
South	18 (9)	Married	105 (53)
North	25 (13)	Window	15 (7)
Education		Divorced	6 (3)
None	18 (9)	Separated	5 (3)
Primary	70 (35)	**Having children**	
Secondary	63 (32)	Children	138 (69)
University	49 (25)	No children	62 (31)

Notes: Residency refers to province of residence.

Table 2: Time 1 response frequencies for the SF LDQ

		Frequency (%)	Severity (%)
Indigestion	Not at all	38 (19)	44 (22)
	Less than once a month	14 (7)	14 (7)
	Between once a month and once a week	23 (11.5)	21 (10.5)
	Between once a week and once a day	42 (21)	44 (22)
	Once a day and more	83 (41.5)	77 (38.5)
Heartburn	Not at all	65 (32.5)	74 (37)
	Less than once a month	18 (9)	19 (9.5)
	Between once a month and once a week	28 (14)	25 (12.5)
	Between once a week and once a day	37 (18.5)	34 (17)
	Once a day or more	52 (26)	48 (24)
Regurgitation	Not at all	80 (40)	80 (40)
	Less than once a month	22 (11)	25 (12.5)
	Between once a month and once a week	25 (12.5)	27 (13.5)
	Between once a week and once a day	38 (19)	36 (18)
	Once a day and more	35 (17.5)	32 (16)
Nausea	Not at all	69 (34.5)	73 (36.5)
	Less than once a month	15 (7.5)	20 (20)
	Between once a month and once a week	24 (12)	24 (12)
	Between once a week and once a day	40 (20)	35 (17.5)
	Once a day or more	52 (26)	48 (24)

Notes: SF LDQ: Short Form Leeds Dyspepsia Questionnaire

Table 3: Known groups construct validity of the Kinyrwanda version of the SF-NDI relative to the severity of dyspeptic symptoms*

SF-NDI Subscale Scores	Mild (n 14**)	Severe (n 152)	p#
Tension (median; range)	2 (2-6)	5 (2-10)	<0.001
Interference (median; range)	2 (2-4)	6 (2-10)	<0.001
Eating/Drinking (median; range)	3 (2-5)	6 (2-10)	<0.001
Knowledge/Control (median; range)	2 (2-4)	3 (2-10)	0.001
Work/Study (median; range)	2 (2-6)	6 (2-10)	<0.001
Total (median; range)	25 (20-44)	56 (20-92)	<0.001

* Mild SF-LDQ < 15 ; Severe SF LDQ ≥15
**Patients who reported "non-applicable" on the SF-NDI were excluded from this analysis
Mann-Whitney U test

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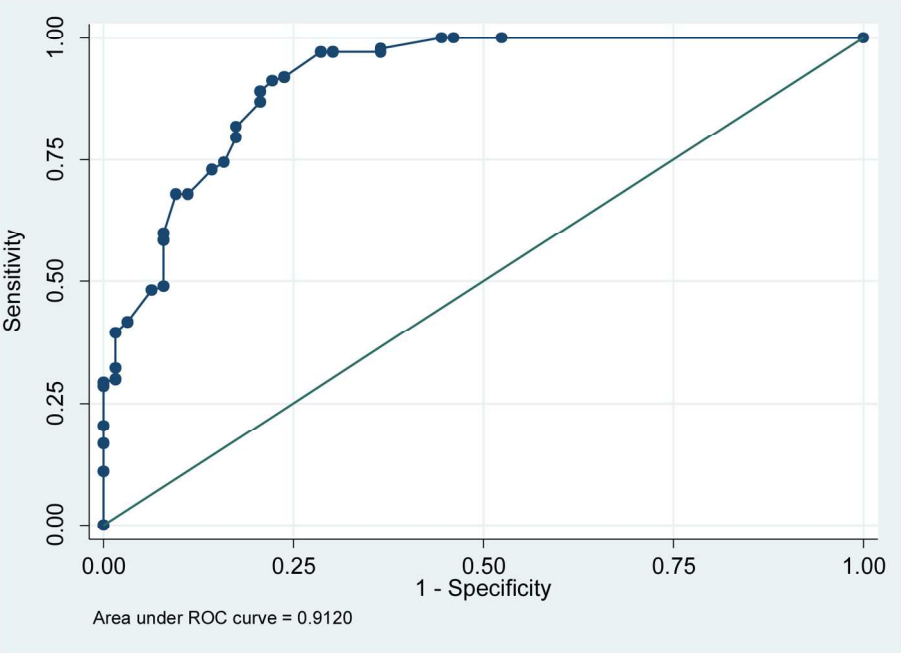
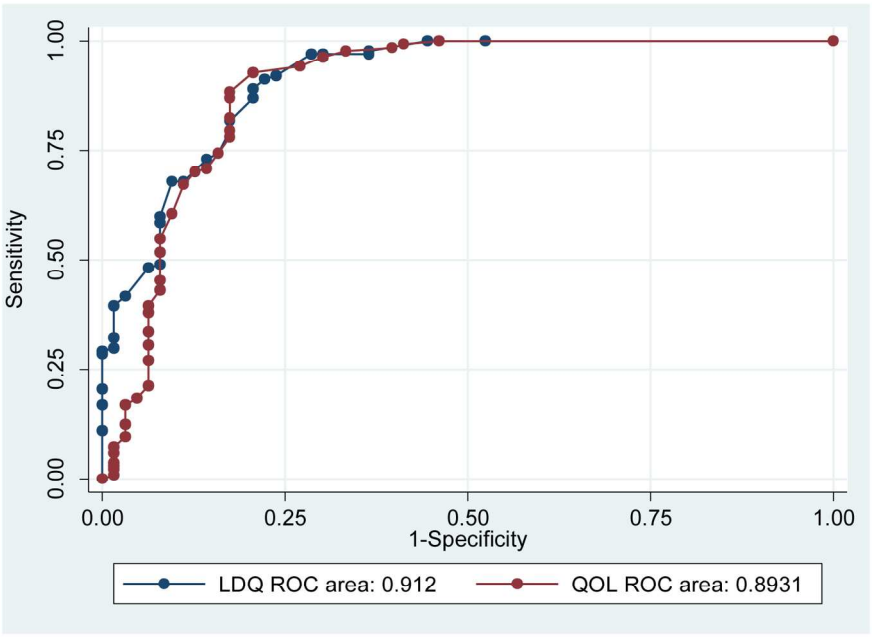
Figure 1: ROC curve for SF LDQ total score at Time 1, plotted against clinical diagnosis



Notes: ROC: Receiver Operator Characteristic, SF LDQ: Short Form Leeds Dyspepsia Questionnaire

Figure 1 - ROC curve for SF LDQ total score at time 1, plotted against clinical diagnosis.
155x152mm (300 x 300 DPI)

Figure 2: ROC curves for SF NDI and SF LDQ at Time 1, plotted against clinical diagnosis

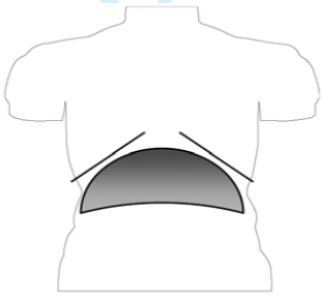


Notes: ROC: Receiver Operator Characteristic, SF NDI (and "QOL" in key): Short Form Nepean Dyspepsia Index, SF LDQ (and "LDQ" in key): Short Form Leeds Dyspepsia Questionnaire

Figure 2 - ROC curve for SF LDQ and SF NDI at time 1, plotted against clinical diagnosis.
161x152mm (300 x 300 DPI)

Appendix 1: Short Form Leeds Dyspepsia Questionnaire in Kinyarwanda

I. Incamake y'ibibazo by'urwaye igifu.

Ibimenyetso by 'uburwayi bw'igifu	Ikibazo cya mbere gisubizwa kuri buri kimenyetso.	Ikibazo cya kabiri gisubizwa kuri buri kimenyetso.
1. **Kugugara mu gifu**: kumva uribwa cyangwa ubangamiwe mu gifu. 	**Mu mezi abiri ashize wagaragaje ibi bimenyetso incuro zingahe?** **Hitamo igisubizo kimwe gusa kuri buri kibazo, ushyire V mu kazu bijyanye.** ☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(**Incuro imwe mu mezi abiri)** ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cyumweru. ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi. ☐ Incuro imwe cyangwa nyinshi ku munsi	**Mu mezi abiri ashize, ni kangahe ibi bimenyetso byabangamiye imibereho yawe (kurya, gusinzira, gukora, kwidagadura.)** **Hitamo igisubizo kimwe gusa kuri buri kibazo, ushyire V mu kazu bijyanye.** ☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(incuro imwe mu mezi abiri) ☐ Hagati y'incuro imwe mu kwezi n'inshuro imwe mu cyumweru ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi

2. **Ikirungurira**; ni ukumva wokerwa hagati mu gituza. 	☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(**incuro imwe mu mezi abiri)** ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cyumweru ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi	☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(**incuro imwe mu mezi abiri)** ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cyumweru ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi
3. **Kugarura mu kanwa ibiri mu gifu bisharira.**	☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(incuro imwe mu mezi abiri) ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cy'umweru ☐ Hagati y' incuro imwe mu cy'umweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi	☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(incuro imwe mu mezi abiri) ☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cy'umweru ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi
4. **Iseseme**: kumva ushaka kuruka.	☐ Nta na rimwe ☐Munsi y'incuro imwe mu kwezi(incuro imwe mu mezi abiri)	☐ Nta na rimwe ☐ Munsi y'incuro imwe mu kwezi(incuro imwe mu mezi abiri)

	☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cyumweru ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi	☐ Hagati y'incuro imwe mu kwezi n'incuro imwe mu cyumweru ☐ Hagati y' incuro imwe mu cyumweru n' incuro imwe ku munsi ☐ Incuro imwe cyangwa nyinshi ku munsi

Muri ibi bimenyetso bikurikira ni ikihe cyakuzahaje kurusha ibindi?

0. Ntibindeba ☐

1. Kugugara mu gifu ☐

2. Kugarura mu kanwa ibiri mu gifu bisharira ☐

3. Ikirungurira ☐

4. Iseseme ☐

Appendix 2: Short Form Nepean Dyspepsia Index in Kinyarwanda

1. **Uburwayi bwawe bw'igifu bwaba bwarahungabanije amarangamutima yawe mu byumweru bibiri bishize?**

0. Ntibindeba ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

2. **Uburwayi bwawe bw'igifu bwaguteye kugira umunabi, umushiha, cyangwa ishavu mu byumweru bibiri bishize?**

0. Ntibindeba ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

KUBANGAMIRWA MU MIRIMO YA BURI MUNSI

3. **Uburwayi bwawe bw'igifu bwaba bwarabangamiye gahunda zawe zo kwidagadura (nko gutembera, gukina, siporo n' ibindi nk'ibyo) mu byumweru bibiri bishize?**

0. Ntibindeba ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

4. Uburwayi bwawe bw'igifu bwaba bwarahungabanije uburyo ushimishwa no kwidagadura (gutembera, gukina, siporo n'ibindi nkibyo) mu byumweru bibiri bishize?

0. Ntibindeba ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

KURYA NO KUNYWA.

5. Uko wabashaga gufungura cyangwa kunywa (amasaha yo gufungura, ibyo ufungura n'ingano yabyo), byaba byarahungabanijwe n'uburwayi bwawe bw'igifu muri ibi byumweru bibiri bishize?

0. Ntibindeba ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

6. Kuryoherwa n'ibiribwa(apetit) cyangwa ibinyobwa n'uko wiyumva umaze kurya cyangwa kunywa, byaba byarahungabanijwe n'uburwayi bwawe bw'igifu muri ibi byumweru bibiri bishize?

0. Ntibindeba ☐
1. Oya, ntanabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

UBUMENYI-IGENZURA.

7. Waba warigeze kwibaza ko uzahorana uburwayi bw'igifu mu byumweru bibiri bishize?

0. Ntibindeba ☐
1. Nta na rimwe ☐
2. Rimwe na rimwe ☐
3. Kenshi ☐
4. Kenshi cyane ☐
5. Buri gihe ☐

8. Waba waratekereje ko uburwayi bwawe bw'igifu bushobora kuba buturuka ku burwayi bukomeye (urugero: kanseri, uburwayi bw' umutima) mu byumweru bibiri bishize?

0. Ntibindeba ☐
1. Nta na rimwe ☐
2. Rimwe na rimwe ☐
3. Kenshi ☐
4. Kenshi cyane ☐
5. Buri gihe ☐

AKAZI- AMASOMO.

9. Uko wabashaga gukora cyangwa kwiga byaba byarahungabanijwe n'uburwayi bwawe bw'igifu muri ibi byumweru bibiri bishize?

0. Ntibindeba (sinkora, siniga) ☐
1. Oya, ntanabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

10. Uko ushimishwa n'akazi cyangwa amasomo, byaba byarahungabanijwe n'uburwayi bwawe bw'igifu mu byumweru bibiri bishize?

0. Ntibindeba (sinigeze nkora cyangwa ngo nige muri ibi byumweru bibiri bishize) ☐
1. Oya, nta nabusa ☐
2. Gakeya ☐
3. Biringaniye ☐
4. Cyane ☐
5. Bikabije ☐

STARD checklist for reporting of studies of diagnostic accuracy

(version January 2003)

Section and Topic	Item #		On page #
TITLE/ABSTRACT/ KEYWORDS	1	Identify the article as a study of diagnostic accuracy (recommend MeSH heading 'sensitivity and specificity').	1
INTRODUCTION	2	State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.	5
METHODS			
Participants	3	The study population: The inclusion and exclusion criteria, setting and locations where data were collected.	5-6
	4	Participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?	5-6
	5	Participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected.	5-6
	6	Data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?	5
Test methods	7	The reference standard and its rationale.	6-7
	8	Technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.	5-7
	9	Definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.	4-5, 8
	10	The number, training and expertise of the persons executing and reading the index tests and the reference standard.	5-6
	11	Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.	6
Statistical methods	12	Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).	6-7
	13	Methods for calculating test reproducibility, if done.	6-7
RESULTS			
Participants	14	When study was performed, including beginning and end dates of recruitment.	6
	15	Clinical and demographic characteristics of the study population (at least information on age, gender, spectrum of presenting symptoms).	8, 14
	16	The number of participants satisfying the criteria for inclusion who did or did not undergo the index tests and/or the reference standard; describe why participants failed to undergo either test (a flow diagram is strongly recommended).	8
Test results	17	Time-interval between the index tests and the reference standard, and any treatment administered in between.	6
	18	Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.	8
	19	A cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.	ROC curve: 16
	20	Any adverse events from performing the index tests or the reference standard.	NA
Estimates	21	Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).	8
	22	How indeterminate results, missing data and outliers of the index tests were handled.	8
	23	Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.	NA
	24	Estimates of test reproducibility, if done.	8
DISCUSSION	25	Discuss the clinical applicability of the study findings.	9-10