**Title:**

Validation of EURO-D, a geriatric depression scale in South India: Findings from the Mysore Study of Natal effects on Ageing and Health (MYNAH).

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**Abstract (250 words)**

Introduction: Many of the assessment tools used to study depression among older people in low- and middle- income countries (LMICs) are adaptations of instruments developed in other cultural settings. There is a need to validate those instruments in LMICs.

Methods: 721 men and women aged 55-80 years from the Mysore Birth Records Cohort underwent standardised assessments for sociodemographic characteristics, cardiometabolic risk factors, cognitive function and mental health. Sensitivity, specificity and level of agreement of EURO-D diagnosis of depression with diagnosis of depression derived by the Geriatric Mental State (GMS) examination were calculated. To validate the EURO-D score against GMS depressive episode, we used maximum Youden’s index as the criterion for each cut-off point. Concurrent validity was assessed by measuring correlations with the WHO Disability Assessment Schedule (WHO DAS II).

Results: Of the 721 (408 men and 313 women) who participated in this study, 138 (54 men and 84 women) were diagnosed with depression. Women had higher depression scores on the EURO-D scale and disability on the WHO DAS II scale. A maximum Youden’s Index of 0.60 was observed at a EURO-D cut-off of 6, which corresponded to 95% sensitivity, 64% specificity, kappa value of 0.6 and area under the curve (AUC) of 80%. There was significant and positive correlation between EURO-D and WHO DAS II scores.

Limitations: Future independent validation studies in other settings are required.

Discussion: This study supports the use of the EURO-D scale for diagnosing depression among older adults in South India.

**Background**

Depression is a common and burdensome psychiatric disorder in older people (Mulsant and Ganguli.,1999; Beekman et al.,1995). In Low and Middle Income Countries (LMIC) it is difficult to assess its prevalence because of the lack of culturally adapted and validated assessments. Clinical diagnostic criteria for depression including DSM-5 (Blazer., 2003) and ICD-10 (American Psychiatric Association.,2013 are applied to adults of all ages. These may, however, miss clinically significant episodes among older people who do not meet these specific criteria. Some investigators have suggested a syndrome of depression without sadness, thought to be more common in older adults (Gallo et al., 1997; Gallo et al.,1999), and a depletion syndrome manifested by withdrawal, apathy, and lack of vigour (Adams et al., 2001; Newman.,1989).

Depression symptom scales have been widely used in population surveys to quantify depression burden as a continuum, or to screen for depression of clinical significance in the first phase of a two phase survey design (Yeswage et al., 1992l; Sheik et al., 1986; Prince et al., 1999; Radloff et al., 1997; Goldberg et al., 1998; Zung., 1965). However, only the Geriatric Depression Scale (Yeswage et al., 1992; Sheik et al., 1986) and the EURO-D (Radloff 1977; Guerra et al., 2015) were developed specifically for use in older people, and evidence for their validity comes mainly from high income countries [Wu et al.,1989; Meng et al., 2000; Pan et al., 2008; Zunzenugie et al.,2009; Alvarado et al., 2007; Chi et al., 2005; Castro et al., 2008; Prince et al., 1999).

There is limited evidence for the cross-cultural validity of the EURO-D scale in Latin American counties, India and China from the 10/66 Dementia Research Group (10/66 DRG) [n=17,852, 13 sites (Guerra et al., 2015). These population based studies confirmed the hierarchical structure of EURO-D and at the cut-off point of 4 or 5, sensitivity for ICD-10 depressive episode was 86% or higher and specificity 84% or higher in all sites, including rural and urban settings in South India. Good concurrent validity of EURO-D measured against WHO Disability Assessment Schedule II (WHO DAS II) was observed across all the sites. However, it is important to note that the EURO-D scale score and ICD-10 (International Classification of Diseases) diagnoses in these studies were derived from a single Geriatric Mental State (GMS) interview, administered by the same research worker, with some overlap in the symptoms ascertained. Therefore, this does not represent an independent validation of the EURO-D scale, but rather an attempt to compare its calibration with ICD-10 clinical diagnosis across the sites. Therefore, we carried out an independent validation study of EURO-D in the MYsore studies of Natal effect of Ageing ad Health (MYNAH) in Mysore, South India.

**Methods**

**Setting:** This study was carried out at the Epidemiology Research Unit, CSI Holdsworth Memorial Hospital (HMH), Mysore in South India. The study was approved by HMH Research and Ethics Committee.

**Participants:** HMH, Mysore, India has preserved obstetric records since 1934 till the present date. These include the birth weight, length and head circumference of all babies born in the hospital, as well as maternal weight and pelvic diameters. During 1993-2001, the records were used to trace people born in Holdsworth Memorial Hospital between 1934 and 1966. The tracing process resulted in 3,427 men and women being matched to their birth records. Between 2013-15, 721 of these were retraced and examined for the association of size at birth with cognitive function and depression in late life (Figure 1). The cohort profile including key findings from previous studies has been published elsewhere. (Krishna M et al., 2015)

**Figure 1 somewhere here**

**Assessments:** All participants underwent standardised assessments for sociodemographic characteristics, cardiometabolic risk factors, cognitive function and mental health, details of which have been published in a study protocol (Krishna M et al., 2017) and briefly summarised here:

Sociodemographic questionnaires collecting information on age, sex, marital status, level of education, income, living arrangements living circumstances (Prince et al., 2007) and Standard of Living Index (SLI) questionnaire (NFHS 2006).

EURO-D: The EURO-D symptom scale was originally developed to compare symptoms of late-life depression across 11 European countries in the EURODEP Concerted Action Programme (Prince et al., 1999). The 12 EURO-D items (depressed mood, pessimism, wishing death, guilt, sleep, interest, irritability, appetite, fatigue, concentration, enjoyment and tearfulness) were all taken from the Geriatric Mental State (Copeland et al., 1988); each item is scored 0 (symptom not present) or 1 (symptom present), generating a simple ordinal scale with a maximum score of 12. In the EURODEP study, internal consistency of the EURO-D, was moderately high with a Cronbach’s alpha ranging from 0.61 to 0.75. The optimum cut-point for the identification of DSM-IV major depression and GMS/AGECAT depression was ≥ 4. Evidence for internal consistency and construct validity of the EURO-D scale was strengthened following its use in the 10 nation European Survey of Health, Ageing, and Retirement in Europe (SHARE) (Castro-Costa et al., 2007). It was shown to be a hierarchical scale with similar rank ordering of item calibration values across countries. The Kannada version of EURO-D, which was previously translated and piloted by the 10/66 Dementia Research group in South India (Prince et al., 2003), was administered by a trained psychologist who was blind to the mental health diagnoses.

Geriatric Mental State Examination (GMS) was used for diagnosis of depression the previous four weeks (Copeland et al., 2002). Internationally, the GMS is the most widely used comprehensive clinical mental health assessment for diagnosis of mental disorders in older adults. A computerised diagnostic algorithm, the AGECAT (Automated Geriatric Examination for Computer Assisted Taxonomy), groups symptoms to form patterns recognised by a psychiatrist as illness, and identifies them as syndrome cases (Copeland et al., 1976). Items are later added together to generate affective disorder diagnoses according to ICD-10, and DSM-IV criteria (Copeland et al., 1988; Livingston et al.,1990). The reliability and validity of the GMS has been demonstrated for in-patient, out-patient and community samples, and in various languages and cultures including Kannada (Collighan et al., 1997; Prince et al., 2003). The GMS was administered by trained psychiatrist (MK) who was blind to the EURO-D scores.

Cognitive assessments: The 10/66 Dementia Research Battery in local language was administered by a trained clinical psychologist that comprises: Community Screening Instrument for Dementia (CSID), a 32 item test assessing orientation, comprehension, memory, naming and language.(Hall et al., 2000); Animal naming task and Word List Memory recall test (Hall et al., 2000; Morris et al.,1989) adapted from the CERAD and used in the Indo-US Ballabgarh study(Ganguli et al., 1996; Prince et al., 2003).

Disability assessments (WHO Disability Schedule-II): The degree of global disability was measured by administering the WHO Disability Schedule-II (WHO DAS II)-Kannada version (Rehm et al., 2000 ; Prince et al., 2003; Sousa et al., 2010). It was developed by the WHO as a culture-fair assessment tool for use in cross-cultural comparative epidemiological and health services research to measure activity limitation and participation restriction. The 12-items assess five activity limitation domains (communication, physical mobility, self-care, interpersonal interaction, life activities and social participation). Each domain is covered by two questions, with scores ranging from 0 (no difficulty) to 4 (extreme difficulty or cannot do) and yielding a total score between 0 to 48. This was administered independently by a trained research assistant.

Health status and physical health assessments included:

Self-reported global health, diagnoses and treatments for these conditions (Prince et al., 2007)

A self-reported list of 12 commonly occurring physical impairments (Duke University.,1978)

Rose Angina Questionnaire (Cook et al., 1989)

Direct physical assessments: pulse rate, systolic and diastolic resting blood pressure, weight, height, leg length, head circumference, waist circumference, waist:hip ratio, skin fold thickness (subscapular, triceps and abdominal), calf circumference, 12-lead ECG for Minnesota coding (Macfarlane., 2000), 5 m walking test and a brief structured neurological examination (Prince et al., 2007)

Blood tests: Glucose tolerance tests and lipid profile

**Definitions**

Diagnosis of depression was derived from the Geriatric Mental State Examination with its computerised algorithm (GMS) (Copeland et al., 1988).

Diabetes mellitus was diagnosed if fasting plasma glucose ≥ 7 or 2 hr plasma glucose ≥ 11.1 mmol/l, or if the participant was known to have diabetes and taking medication for diabetes. (WHO., 2006)

Hypertension was defined as systolic blood pressure ≥ 130 mm Hg or diastolic blood pressure ≥ 85 mm Hg us (International Diabetes Federation criteria- (Alberti et al., 2006) and if they were known to have hypertension and taking antihypertensive medication.

Metabolic syndrome was diagnosed using International Diabetes Federation criteria (Alberti et al., 2006) for South Asians: defined as central obesity (waist circumference ≥ 90 cms for men and ≥ 80 cms for women) plus any two of the following four factors: raised triglycerides level (≥ 1.7 mmol/l), reduced HDL cholesterol (<1.03 mmol/l in males and <1.29 mmol/l in females), raised blood pressure: systolic blood pressure ≥ 130 or diastolic blood pressure ≥ 85 mm Hg, or treatment of previously diagnosed hypertension or raised fasting plasma glucose 5.6 mmol/l, or previously diagnosed type-2 diabetes.

Coronary heart disease (CHD) was diagnosed if there was typical angina on Rose chest pain questionnaire, or a history of cardiac revascularisation procedures or the presence of Minnesota codes 1-1 or 1-2 (major Q waves) on the ECG.

**Analyses**

Differences in means and medians between the groups (those with and without depression) were examined by t-tests and Mann Whitney U tests respectively. Differences in proportions between the groups were examined by chi-square tests. The associations of an exposure (e.g BMI) with depression were examined by employing mixed logistic regression models adjusted for age, sex and sibship.

Sensitivity, specificity and level of agreement (kappa-value) of EURO-D diagnosis of depression (at different cut-offs and for each individual item) with ICD-10 diagnosis of depression derived by GMS-AGECAT were derived. To calibrate the EURO-D score against ICD-10 depressive episode diagnosis, we used maximum Youden’s index [(sensitivity + specificity)-1] as the criterion for each cut-off point. Youden’s index is a single statistic that captures the performance of a dichotomous diagnostic test. (Schisterman and Perkins., 2007)

We conducted receiver operating characteristic (ROC) curve analyses using ICD-10 depressive episode as the reference criterion, plotting sensitivity against false positive rate (1-sensitivity) and estimated the area under the ROC curve (AUROC). The ROC curve for a parameter is a plot of sensitivity (true positive rate) against specificity (True negative rate).The cut-off points on the AUC (Area Under the Curve) will indicate how accurately a given EURO-D score separates participants with depression from those without.

The concurrent validity of the EURO-D was assessed by measuring Spearman rank correlations (ρ) with WHO-DAS 2.0 disability scores (positive correlation hypothesised).

**Results**

Of the 721 (408 men and 313 women) who participated in this study, 138 [(19%) 54 men and 84 women] were diagnosed with ICD-10 depression. Their characteristics are provided in Table 1. Depression was more common among older participants, women (compared to men), those widowed or separated (compared to those who were married), and those with lower attained educational level, lower Standard of Living Index and those who were not in paid employment. Those with depression had higher levels of disability and lower composite cognitive score.

**Table 1 somewhere here**

Women had higher scores of depression on EURO-D scale and disability on the WHO DAS II scale. [median (IQR) EURO-D score 0 (0,1) for men versus 1 (0,6) for women p<0.001; median (IQR) WHO DAS II score (0,0) for men vs 0(0,3) for women p<0.001]

**Table 2 somewhere here**

Sensitivity, specificity, Kappa value and Younden index at different cut-offs of EURO-D against the GMS AGECAT derived ICD-10 depression as a gold criterion are provided in Table 2 and the corresponding AUCs are illustrated in Figure 2. We have provided Receiver Operating Characteristic curves for total EURO-D scores with ICD-10 depression as supplementary figures (Supplementary Figure 1 ). AUCs for a maximum Youden Index of 0.60 was observed at a EURO-D cut-off of 6 which corresponded to 95% sensitivity, 64% specificity, kappa value of 0.6 and area under the curve (AUC) of 80%. On conducting subgroup analyses, there was no difference across these measures between those with higher and lower levels of attained education (less than 10 years of schooling vs greater than 10 years in education).

**Figure 2 somewhere here**

Severity of depression as measured by EURO-D was positively and significantly correlated with severity of disability as measured by WHO DAS II (Spearman coefficient ρ=0.38 and p=0.01 value for men; Spearman coefficient ρ=0.45 and p<0.001 for women; Spearman coefficient ρ= 0.4 and p<0.001 for the combined).

All participants completed the assessments for depression and disability. It took approximately 7 minutes to administer the EURO-D scale by the psychologist

**Discussion**

This study has evaluated the psychometric properties of the EURO-D scale and confirms its cross-cultural and education-fair properties among community dwelling older adults in an urban setting in South India. In addition, this study contributes to the growing body of evidence in response to an urgent need for developing culturally appropriate instruments for diagnoses of mental disorders in resource poor settings with low literacy levels, as prioritised by mhGAP programme (https://apps.who.int/iris/handle/10665/43809) and the most recent WHO guidelines on Integrated Care for Older People (ICOPE) in LMICs ( https://www.who.int/ageing/publications/guidelines-icope/en/ ref)

The psychometric properties of the EURO-D (Kannada version) in our study are broadly similar to those observed earlier in population-based validation studies conducted by the 10/66 DRG in LMIC settings in Latin American countries, India and China (Guerra et al., 2015). Findings from this study have further strengthened the evidence base for use of EURO-D in LMIC settings, as this was an independent validation study where investigators administering the EURO-D, GMS and WHO DAS II were blind to each other’s findings. Sensitivity and specificity of EURO-D at a cut-off of 6 in our study is similar to that of the 10/66 DRG studies in India and other LMIC settings. However, the level of concurrent validity of EURO-D with WHO DAS II was slightly lower (Spearman correlation 0.6 in the 10/66 DRG vs 0.4 in our study), but as hypothesised the correlation was positive and significant. This may be in-part because the EURO-D and WHO-DAS II were administered independently and those examined in the 10/66 DRG studies were much older, with higher levels of disability and lower levels of literacy: mean (SD) age of the participants in our study for men was 63.4 (6.0) years and for women was 62.1 (5.1) years while in 10/66 DRG it was 71.2 years (SD not provided); median (IQR) WHO DAS II score was 0 (0,0) for men and 0 (0,3) for women participants while in the 10/66 DRG it was 3 (1,5); and 80% of our study participants had completed secondary school and the corresponding value in the 10/66 DRG study was only 35% (Guerra et al., 2015). Nevertheless, the findings from this study, complemented by the findings from 10/66 DRG studies in India indicate that EURO-scale can help accurately identify older adults with higher disability levels in this study population.

The prevalence of depression in our study was slightly lower for men and higher for women than those reported by the WHO SAGE ( WHO Study on Global Ageing and Adult Health) study (13% vs 17% for men and 28% vs 21% for women in India), but comparable to that reported in a meta-analysis of rates of depression among older adults (>60 years) in India [median (IQR) 21.9% (11.6%–31.1%)] (Barua et al., 2011; SAGE India National Report., 2013). The prevalence of depression was higher compared to high income settings [median (IQR) 10.3% (4.6%-16.0%), n=487,275] but within the range (15% to 48%) reported for LMIC settings by the 10/66 dementia research group (Barua et al.,2011; Prince M et al.,2009). As expected depression was more common among women and the widowed, and in those with lower levels of attained education and socioeconomic position, a finding that is universal. (WHO SAGE India National Report.,2013; Barua et al., 2011; Lorant et al.,2013; Colman and Ataullahjan.,2010; Grover and Malhotra et al.,2015; Chang-Quan et al.,2010). In this study BMI, diabetes, hypertension and coronary heart disease were unrelated to depression, while metabolic syndrome was inversely related to depression in late life. Studies examining the contemporaneous associations of BMI and other cardiometabolic disorders with depression in late life have reported inconsistent findings: while some studies have reported direct associations of these with depression, in several studies these were unrelated to depression (Valkanova and Embierer.,2013; Nouwen et al 2010; Pan et al., 2012)

**Limitations**

To the best of our knowledge this is the first independent validation study of EURO-D in a LMIC setting. GMS was administered by only one trained psychiatrist and EURO-D was administered by only one trained clinical psychologist. Diagnosis of depression was derived from AGECAT, the standardised computerised algorithm accompanying GMS. All participants completed the assessments, and there were no missing data. We examined the concurrent validity of the EURO-D scale with scores on WHO DAS II, an indicator of activity limitation and not with any other indicators of global health. We did not examine the test-retest reliability of EURO-D. All participants were community dwelling older adults from a birth cohort from one urban setting and therefore caution should be exerted before generalising the findings beyond the study settings and applying same cut-offs for diagnosing depression in clinical environment.

Despite the above limitations, this study supports the use of EURO-D scale for diagnosis of depression among older adults in our setting. Higher cut-off may have to applied in clinical settings where more specific diagnosis of depression is warranted. Future independent validation studies are required in other settings (e.g. clinical and rural areas) and in which EURO-D instrument is administered by non-specialists, to provide further evidence of task-shifting and scaling up, as a primary strategy as recommended by the WHO mhGAP amd ICOPE programmes.

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**Author Contributions**

The study was conceptualised and designed by MK, KGV, and CHDF. RH and MK administered EURO-D and GMS AGECAT respectively. SN administered WHO DAS scale, assessments for sociodemographics and conducted anthropometry. PM and VA conducted the analyses and prepared the manuscript. All authors have read and approved the manuscript.

**Conflicts of Interest**

The authors declare no competing interests.

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**Legend**

Table 1 Characteristics of study participants according to depression status

Table 2 Psychometric properties of EURO-D with ICD-10 Depression

Figure 1 The Mysore Birth Records Cohort studies

Figure 2 Receiver Operator Characteristic curves at different cut-offs on EURO-D scale with ICD-10 depression.