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DISSERTATION

IBADAN –BERLIN BICULTURAL COMPARATIVE STUDY OF QUALITY OF LIFE IN STROKE PATIENTS USING A NEW INSTRUMENT (HRQOLISP)

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LIST OF ABBREVIATIONS

ACE	Angiotensin Converting Enzyme
ADL	Activities of daily living
AF	Atrial Fibrillation
AHA	American Heart Association
ANOVA	Analysis of variance
ADC	Apparent Diffusion Coefficient
BOLD	Blood Oxygen Level Dependent imaging
CADASIL	Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarct and Leucoencephalopathy
CADASILM	Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarct and Leucoencephalopathy with hemiplegic Migraine.
CBF	Cerebral Blood Flow
CIND	Cerebral Infarction No Deficit
CITS	Cerebral Infarction with Transient Symptoms].
$CMRO_2$	Cerebral Metabolic Rate for Oxygen
CSF	Cerebrospinal Fluid
CT	Computerized Tomography
CTA	Computerized Tomography Angiography
DALYs	Disability Adjusted Life Years
ECG	Electrocardiography

EEG	Electroencephalography
EuroQol	Europe Quality of Life Scale
FLAIR	Fluid-Attenuated Inversion Recovery
GDS	Geriatric Depression Scale
HDL-C	High Density Lipoprotein Cholesterol
HOPES	Heart Outcome Prevention Evaluation Study
HRQOL	Health-Related Quality of Life
HRQOLISP	Health-Related Quality of Life in Stroke Patients
ICA	Internal Carotid Artery
ICIDH	International Classification of Impairments, Disabilities and Handicaps
IL-1	Interleukin 1
LDL-C	Low Density Lipoprotein Cholesterol
LIPID	Long-Term Intervention with Pravastatin in Ischaemic Disease
MELAS	Mitochondrial Myopathy, Encephalopathy, Lactic Acidosis and Stroke
MRI	Magnetic Resonance Imaging
MRA	Magnetic Resonance Angiography
MRS	Magnetic Resonance Spectroscopy
NEWSQOL	Newcastle Stroke-Specific Quality of Life Measure
PCA	Posterior Cerebral Artery

PET	Positron Emission Tomography
PON-1	Paraoxonase-1
PROGRESS	Perindopril Protection Against Recurrent Stroke Study
PSED	Post Stroke Emotional Disorders
QALYs	Quality Adjusted Life Years
QOL	Quality of Life
RIND	Reversible Ischemic Neurological Deficit
SAH	Subarachnoid Hemorrhage
SAQOL-39	Stroke and Aphasia Quality of Life Scale-39
SEC	Socioeconomic Class
SF-36	Medical outcome Scale, Short Form -36
SHEP	Systolic Hypertension in Elderly Program
SIP	Sickness Impact Profile
SPECT	Single- Photon Emission Computerized Tomography
SPSS	Statistical Package for the Social Sciences
SSS	Siriraj stroke score
STROKELE	Stroke Levity
SSQOL	Stroke-Specific Quality of Life Scale
TIA	Transient Ischemic Attack
TNFα	Tumour Necrosis Factor alpha
UCH	University College Hospital, Ibadan
WHO	World Health Organisation

WHOQOL World Health Organisation Quality Of Life

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CHAPTER ONE:

INTRODUCTION AND LITERATURE REVIEW

The topic - quality of life in stroke- unfolds two fundamental concepts: stroke which has a standard definition and quality of life which must be properly conceptualised and defined after a proper understanding of the meaning of life itself.

1.1 DEFINITION OF STROKE AND STROKE – RELATED DISORDERS

Stroke [Gk. *apoplexia*] is clinically defined as a syndrome of rapidly developing symptoms or signs of focal or global neurological dysfunction of which there is no other apparent cause than vascular, leading to death or lasting more than 24 hours.[1;2] It is a leading cause of neurological admissions and a major cause of disability, the presence of which affects health-related quality of life (HRQOL).[2;3] Stroke can be ischemic (thrombotic, embolic, lacunar, watershed, or cryptogenic: 80%) or hemorrhagic (intraparenchymal 15% or subarachnoid 5%).[2;4-7] However, secondary hemorrhagic infarcts can also occur.[2;4-7] On the average in black Africans, non-embolic cerebral infarction accounts for about 60%, embolic infarction 5%, cerebral hemorrhage 20%, subarachnoid hemorrhage10%, ill-defined stroke 5% or more.[8-10] Subarachnoid hemorrhage is due to aneurysms and arteriovenous malformations in a ratio of 3:1.[11-14]

In addition to clinical assessment (case definition), to diagnose stroke in developing countries, radiological assessment (computerized tomography scan or magnetic resonance imaging) is indicated where the clinical diagnosis is uncertain, the source of the disease is atypical, the stroke is in the cerebellum or thalamus, there is subarachnoid hemorrhage, the patient is young (age under 45 years), and intracranial hemorrhage has to be excluded (e.g. when anticoagulants / thrombolytic therapy is intended).[15;16] Where it is widely affordable and available, CT scan / MRI is essential for the definitive diagnosis and classification of stroke.[15;16] While stroke refers to any abrupt damage to the brain caused by an abnormality of the blood supply with persistent neurological deficit, it excludes subdural hemorrhage, epidural hemorrhage, cortical venous and dural venous sinus thromboses, transient ischemic attack (with only transient neurological deficit), and uncomplicated dissection of carotid and vertebral arteries.[13;17-19]

Transient ischemic attack [TIA] is defined as a neurological deficit lasting less than 24 hours attributed to focal cerebral or retinal ischemia.[17;20-22] However, the TIA working group has proposed a new definition: ‘ A TIA is a brief episode of neurological dysfunction caused by focal brain or retinal ischemia, with clinical symptoms clinically lasting less than 1 hour and without evidence of acute

infarction. The corollary is that persisting clinical signs or characteristic imaging abnormalities define infarction -- that is stroke'.[17;20-22]

The most recent definition of stroke [brain attack] for clinical trials requires symptoms lasting more than 24 hours or radiological evidence of a relevant vascular brain lesion with rapidly vanishing symptoms [**CITS – Cerebral Infarction with Transient Symptoms**].[22]

For symptoms that exceed 24 hours but resolve within 3 weeks the term reversible ischemic neurological deficit [**RIND**] is sometimes used even though a true infarction could have occurred. [22] **Completed stroke** implies maximal deficit within 6 hours while **stroke in evolution** means evolving/ deteriorating symptoms/signs during 24 hours from time of onset.[18]

Silent stroke [**CIND: Cerebral Infarction No Deficit**] may occur without clinical features because a silent area of the brain is involved or the patient/ family does not notice the symptoms.[22]

Therefore the definition of stroke excludes transient ischemic attacks, epidural and subdural hemorrhage/hematoma but includes RIND, CITS and CIND. [14;19;22]

1.2 STROKE: A BRIEF HISTORICAL PERSPECTIVE

Hippocrates [circa 400BC] observed that stroke was most common between the ages of 40 and 60. He recorded that occlusion of the 'stout' carotid [Gk. *karos*: deep sleep] arteries caused loss of consciousness. Galen [131-201AD] later described the vascular anatomy of the brain from animal dissections. However his findings were later challenged by Andreas Vesalius [1514-1564] in the *Fabrica*, based on human dissections.[17]

More light was shed on this in the later half of the seventeenth century. Wepfer JJ [1620-1695] described the course of the carotid siphon and the middle cerebral artery in the sylvian fissure. He showed that apoplexy resulted from obstruction of the carotid or vertebral artery; or bleeding into the brain. At about the same time, Thomas Willis [1621-1675] documented the anastomotic vessels at the base of the brain in his *Cerebri Anatome*.[17]

Morgagni GB [1682-1771] introduced the clinico-pathologic method which was later used by John Cheyne [1777-1836] to relate clinical presentations of stroke to morbid anatomical findings of brain softenings and intracerebral / subarachnoid hemorrhages. John Abercombie in 1828 classified apoplexy clinically into primary apoplexy [large intracerebral hemorrhages or infarcts with focal deficits and stupor], probable subarachnoid hemorrhage [with stupor and headache but no focal deficit] and small infarcts or hemorrhages [with focal deficit but no stupor or headache] .[17]

Hooper, Cruveilher, Carswell, Bright, Osler, Gowers, Wilson and Duret also worked on stroke in the nineteenth and early twentieth centuries. Foix, Miller Fisher, Kubik and Adams analyzed the

clinicopathologic correlates of syndromes resulting from infarction or hemorrhage of different cerebral and vertebrobasilar arteries and their branches.[17]

During the last half of the 20th century, tremendous explosion of knowledge, antemortem visualization of vascular lesions and discovery of new surgical and medical therapeutic and prophylactic strategies were made possible by the technological revolution.[17]

Angiography developed by Moniz and Seldinger and Computerized Tomographic [CT] scan by Hounsfield in Britain [in the 1970s] provided information about vascular anatomy and allowed definition of the site of brain infarction and haemorrhage, respectively. Newer and more advanced techniques include spiral CT scan, perfusion CT scan, Magnetic Resonance Imaging [MRI, in the 1980s], CT angiography, Magnetic Resonance Angiography [MRA], diffusion- and perfusion-weighted MRI, MRI with FLAIR [fluid attenuated inversion recovery], Magnetic Resonance Spectroscopy [MRS], carotid and transcranial B-mode, continuous mode, color, pulsed and power Doppler ultrasonograghy.[17] Radionuclide techniques like Positron [PET] and Single- Photon Emission Computerized Tomography [SPECT] are functional imaging procedures that allow the assessment of cerebral perfusion and metabolism and have led to the understanding of stroke pathophysiology and discovery of misery perfusion syndrome, diaschisis and luxury perfusion.[17]

Echocardiography [transthoracic and transoesophageal] and ambulatory electrocardiogram allowed assessment of cardiogenic embolism while new laboratory techniques emerged for the assessment of hemorrheological, hypercoagulable, thrombophilic and genetic factors.[17]

Computerized randomized multi-center studies and clinical trials have yielded new evidence on the efficacy of various medical treatments like antihypertensives, osmotherapy, antiplatelet, thrombolytic therapy and mechanical thrombectomy. Treatment guidelines for hemorrhage, infarction and TIA have been proposed by the American Heart Association and the Deutsche Gesellschaft für Neurologie.[17]

Microsurgery, stereotactic neurosurgery, carotid endarterectomy, stenting and bypass surgery and advancements in neuroanaesthesia and neurorehabilitation have contributed to better outcomes in stroke patients.

These developments culminated in the establishment of stroke units which provide timely and effective care for stroke patients.[17]

1.3 THE EPIDEMIOLOGY OF STROKE

The burden of stroke encompasses data on its prevalence, incidence, risk factors, mortality, morbidity and economics. Stroke is a major cause of morbidity and mortality worldwide. It is the second most common cause of death in developed countries like Germany[2] and low income countries like

Nigeria.[23;24] Due to ongoing epidemiological transition[25] stroke is a major cause of morbidity and mortality in Africa[1;5;23;24] where [1;5] it accounted for 0.9-4.0% of hospital admissions and 2.8-4.5% of total deaths.[1] In a 3-year review of adult neurological admissions in University College Hospital,[1] Ibadan, stroke constituted 50.4% of cases.[3] This is more than what was previously reported in Ibadan but similar to what was recently reported in Lagos.[3;26]

The prevalence of stroke survivors in a community depends on the incidence and case fatality, both of which have different determinants. The community prevalence of stroke varied from 58/100,000 to 400/100,000 with crude annual mortality rate of about 70/100,000 per year in Nigeria.[1;5;14;19] The age-specific mortality in the elderly was as high as the average of 100/100,000 per year reported in other races. The incidence rate of stroke in Ibadan, 26/100,000, was much less than the figures of 50-400/100,000 for western countries like Germany though the age-specific incidence rates in those above the age of 40 years were comparable to those in Caucasians.[1;5;14;19] However, these community-based epidemiological studies in Nigeria are over 3 decades old. Newer studies are warranted to show the current burden of stroke particularly with the adoption of western lifestyle and consequent epidemiological transition.[27]

Stroke occurs in all age groups even though the incidence of stroke rises exponentially with age establishing the fact that age is the strongest risk factor for stroke.[28] Hypertension, diabetes mellitus, cardiac disease and male gender are a few of the other multitude of established risk factors for stroke.[17;20-22] Case fatality rate averages about 35% but could be as low as 14.9% or as high as 77% when due to intracerebral hemorrhage. The stroke recurrence rate is about 5% per annum in those with previous stroke.[1;2;29]

The total estimable monetary lifetime cost of each stroke averaged $103,576 in the 1990s in the United States. Acute care costs in 2 years accounted for 45% while long-term ambulatory care and nursing home costs accounted for 35% and 17.5% of aggregate lifetime costs, respectively.[2;30] In 2008, Americans are expected to pay $448.5 billion for stroke and cardiovascular diseases.[31] There is no scientific data quantifying the direct and indirect economic cost of stroke in Nigeria.

1.4 TYPES OF STROKE

There are two main types of stroke: ischemic and hemorrhagic.

1.4.1 ISCHEMIC STROKE

The brain is a metabolically active organ requiring about 50ml/100g/min blood flow and with a metabolic rate for oxygen [$CMRO_2$] of 3.5cc/100g/min. The cerebral blood flow [CBF] remains relatively constant between mean arterial blood pressure of 50 and 150mmHg by autoregulation. At CBF of smaller than 20ml/100g/min, electroencephalographic abnormalities appear. The zone of dysfunctional but structurally viable brain tissue constitutes the salvageable ischemic penumbra [benign oligaemia] which surrounds the ischemic core. [17;22;32-35]

At levels below 10ml/100g/min, cell membranes and functions are severely affected while neurons

cannot survive long below 5ml/100g/min. When blood flow is interrupted for 30 seconds, brain metabolism is altered. After 1 minute, neuronal function may cease and after 5 minutes anoxia may lead to infarction if blood flow is not restored quickly.[17;22;32-35]

Ischemia results in hypoxia and hypoglycemia which sets up a vicious cycle [ischemic cascade] potentiated by Na+/K+ pump failure, membrane failure, inflammation , altered gene expression, Ca^{2+} influx, excitotoxicity [via N-Methyl D-Aspartate receptor], acidosis, free oxygen radical injury and apoptosis.[36] Secondary injury and dysfunction occurs from diaschisis, cytotoxic and/or vasogenic oedema, raised intracranial pressure and herniation syndromes.[17;22;32-35]

Factors affecting tissue survival include the adequacy of collateral flow, the state of the systemic circulation, microvascular resistance, changes within the obstructive vascular lesion, disorders of calcium and glucose metabolism. Capillaries or other vessels within the ischemic tissue may be injured such that reperfusion leads to leakage of blood into the ischemic tissue resulting in hemorrhagic infarction.[17;22;32-35]

Ischemic stroke may be sub-classified based on vascular territory involved within the brain. Such classification, utilizing the Oxfordshire Community Stroke Project (OCSP) criteria, may be established on the basis of clinical history and physical examination. Combined with basic neuroimaging (non-contrast CT of brain), categories include: total anterior circulation infarct (TACI), partial anterior circulation infarct (PACI), lacunar infarct (LACI) and posterior circulation infarct (POCI).[37;38] Ischemic stroke may be further subgrouped into large vessel, cardioembolic, small vessel (lacunar) or cryptogenic stroke based on the Trial of ORG 10172 in Acute Stroke Treatment (TOAST) criteria.[37;39]

1.4.1.1 Thrombotic/ Atherosclerotic Infarction

This accounts for 12 - 40% or strokes. Atherosclerotic plaques are common at the bifurcation of the common carotid, the origins of the middle and anterior cerebral arteries and the origins of the vertebral arteries. Plaques at the bifurcation or curves of the major vessels can lead to progressive stenosis, critical stenosis [> 70 - 80%] and total occlusion. This leads to ischemia from perfusion failure. It usually presents with stuttering or fluctuating symptoms that worsens over minutes or hours. Complicated and ulcerated plaques or thrombus can be propagated distally as emboli leading to embolic infarcts.[17;22;32-35]

1.4.1.2 Embolic Infarction

This accounts for up to 57% of strokes and it occurs when cardiac [cardioembolism] or arterial thrombi [artery-to-artery embolism] are propagated causing distal occlusion or stenosis. Neoplasm, air, nitrogen, fat and other foreign bodies can also embolize. [17;22;32-35]

Cardioembolism accounts for 20-57% of cerebral infarcts. It commonly results from high risk sources such as atrial fibrillation [AF, 5-fold increase in risk], congestive heart failure, valvular heart diseases [e.g. mitral stenosis], recent myocardiac infarction [<4 weeks], cardiomyopathies, akinetic left ventricular segment, mechanical prosthetic valve, sick sinus syndrome, left atrial appendage thrombus, atrial myxoma, and septic embolism [infective endocarditis].[17;22;32-35]

Medium risk sources include mitral valve prolapse, mitral annulus calcification, mitral stenosis without AF, paradoxical [transcardiac] embolism from patent foramen ovale or cyanotic congenital heart diseases, marantic endocarditis, Libmann – Sach's endocarditis, bioprosthetic cardiac valves, atrial flutter, lone atrial fibrillation, left atrial turbulence [smoke], hypokinetic left ventricular segment, myocardiac infarction [4-6weeks after] and atrial septal aneurysm. Thoracic aortic atherosclerosis can also cause embolic stroke.[17;22;32-35]

Embolic stroke usually presents with maximal deficit at onset. Embolism is inferred when the brain image demonstrates an infarction confined to the cerebral surface territory of a single branch, combinations of infarcts involving branches of different divisions of major cerebral arteries, or secondary transformation to hemorrhagic infarcts. Embolic obstruction is cleared most commonly by recanalisation and artificial thrombolysis. It is vital to detect the source.[17;22;32-35]

1.4.1.3 Small Vessel Lacunar Infarction

It accounts for about 18% of strokes and results from lipohyalinosis, atherosclerosis [microatheroma] and microembolisation of 100 -300µm diameter penetrating vessels causing 3mm-2cm (diameter) sized infarcts. Hypertension occurs in up to 65% of cases. Many are asymptomatic while others are frequently preceded by TIAs [e.g., capsular warning syndrome]. Some of the classical clinical syndromes are as presented below. Fisher described over 20 of them.[17;22;32-35]

Pure motor hemiparesis, the commonest type [57% of cases], results from infarction of the posterior limb of the internal capsule, basis pontis, cerebral peduncle and/or the crus cerebri. Sensorimotor type [20%] is due to infarction of posterior internal capsule and/or brainstem. Ataxic hemiparesis [10 %] presents with homolateral ataxia and crural paresis due to infarction of the posterior limb of the internal capsule or corona radiata, posteriolateral thalamus and cerebellothalamic fibres. Lacunar stroke can also present with hypesthetic ataxic hemiparesis or dysarthria-facioparesis due to infarction of the cerebral peduncle or basis pontis.[17;22;32-35]

Finally, the dysarthria-clumsy hand syndrome [6%] results from infarction of the basis pontis while pure sensory syndrome [7%] results from posterior ventral thalamic infarction.[17;22;32-35]

1.4.1.4 Cryptogenic Infarction

This group consists of infarcts of undetermined cause and accounts for up to 40% of ischemic infarcts. Usually there is no clinical, laboratory or radiological evidence of TIA, cardiac embolism, or lacunar infarct, though large vessel disease of unknown cause may be demonstrated angiographically. Postulated occult causes include hypercoagulable states, paradoxical emboli from patent foramen ovale and aortic arch atherosclerosis.[17;22;32-35]

1.4.2 HEMORRHAGIC STROKE

Hemorrhagic stroke is classified according to location [intracerebral/intraparenchymal, subarachnoid], according to the type of the ruptured vessel [arterial, capillary, venous] or according to the underlying cause [primary: hypertension and amyloid angiopathy, secondary: other causes].[17;22;32-35]

1.4.2.1 Spontaneous Intracerebral Hemorrhage

This is the most common type of nontraumatic intracranial hemorrhage. It accounts for 10-15% of strokes. Hypertension accounts for 26-77% of cases. Hypertensive hemorrhage results from rupture of Charcot – Bouchard microaneurysms caused by small vessel disease with lipohyalinosis, fibrinoid necrosis and subadventitial hemorrhage. Rupture leads to an avalanche type effect with breakage of nearby vessels resulting in hematoma expansion in up to 40% of cases. Mass effect ensues with neuronal damage resulting from excitotoxicity, free radicals, apoptosis, ischemia, diaschisis, neuropathic products and pressure necrosis.[17;22;32-35]

Ventricular or subarachnoid extension can occur with associated hydrocephalus. Cerebral oedema can be vasogenic resulting from destroyed blood-brain barrier, cytotoxic resulting from ischemia or interstitial resulting from hydrocephalus. The most common herniation syndromes are central transtentorial, uncal, subfalcine, upward transtentorial and tonsillar herniation. Duret's hemorrhage results from distortion of the upper brainstem.[17;22;32-35]

The most common sites of hypertensive bleed are deep gray matter [putamen, globus pallidus, caudate nucleus and thalamus (65%)], subcortical white matter [10-20%], pons [10-15%] and cerebellum [8-10%]. Each of these present with characteristic neurological syndromes of motor, sensory, visual, ocular and papillary signs. This occurs in addition to features of raised intracranial pressure with associated seizures, meningism, abulia, posturing and respiratory signs in some cases.

For instance, putamenal bleed presents with contralateral hemiparesis, hemianaesthesia, hemianopia, ipsilateral conjugate gaze and aphasia or hemineglect while a pontine hemorrhage presents with hyperventilation, loss of oculocephalic reflex, hyperhydrosis, hyperthermia, hypertension, pinpoint pupil and quadriparesis.[17;22;32-35]

Other causes of ICH include amyloid angiopathy, bleeding disorders, arteriovenous malformations, cavernous angioma, low cholesterol [< 160-190mg/dl], arteritis, drugs [cocaine, amphetamine, phenylpropanolamine, pseudoephedrine], reperfusion, infections [e.g. HIV,] and neoplasm.[17;22;32-35]

1.4.2.2 Subarachnoid Hemorrhage [SAH]

This accounts for 5% of all strokes. Eighty percent are due to saccular aneurysms. Twelve percent of patients die before medical attention and another 20% after admission. Of the two-thirds that survive, half remain disabled primarily due to severe cognitive deficit.[17;22;32-35] They arise where the arterial elastic lamina are defective and tend to increase in size with age. The wall comprises thin tunica intima and adventitia which can rupture through the dome.

Up to 90% of aneurysms occur in the anterior circulation. They usually occur at the bifurcations of the major arteries in the circle of Willis. The most common sites of ruptured aneurysms are the junction of the internal carotid artery with the posterior communicating artery [41%], the junction of the anterior communicating artery with the anterior cerebral artery [34%] and the bifurcation of the middle cerebral artery [20%] and vertebrobasilar arteries [4%].[35] Giant aneurysms [25mm or more] account for 5% of cases and occur at the terminal carotid artery, the middle cerebral artery bifurcation and the top of the basilar artery.[17;22;32-35]

The prevalence of berry aneurysms increases with age and is higher in autosomal dominant polycystic kidney disease, pseudoxanthoma elasticum, fibromuscular dysplasia, Marfan's syndrome, coarctation of the aorta and Ehlers-Danlos syndrome. Risk factors for aneurysmal rupture include hypertension, cigarette smoking, excessive alcohol consumption and history of SAH in a first degree relative.[17;22;32-35] Other causes of SAH include mycotic aneurysm, trauma, arteriovenous malformations, benign perimesencephalic SAH, intracranial arterial dissection, cocaine and amphetamine use, pituitary hypoplexy, vasculitis, sickle cell disease, coagulation disorders and neoplasm.

Sentinel leaks may present with warning headaches. Bleeding is associated with thunderclap headache, features of raised intracranial pressure, absence of fever, meningeal signs, subhyaloid hemorrhage and loss of consciousness. Clinical severity is graded by the Hunt and Hess scale and the World Federation of Neurological Surgeons Scale while radiological severity on CT scan uses the Fisher scale.[17;22;32-35]

Focal signs may arise from hematoma or infarction, the latter resulting from vasospasm. Early complications include rebleeding, acute hydrocephalus, seizures, and neurogenic cardiac and pulmonary disturbances. Late complications include syndrome of inappropriate antidiuretic hormone secretion, intravascular volume contraction and vasospasm. Annual rebleed rate is 2-4%.[17;22;32-35]

1.5 RISK FACTORS FOR STROKE

Risk factors for stroke are important both for primary and secondary stroke prevention. These are modifiable and non-modifiable.[17;22;32-35]

1.5.1 Nonmodifiable Risk Factors

Age is the strongest determinant of stroke with incidence rising exponentially with age. There is at least a doubling of stroke risk in each decade above age 55. Age can be considered a marker for duration of exposure to other risk factors.[17;22;32-35]

Gender, Race, Ethnicity: Stroke is commoner in men, blacks, Hispanics and is the leading cause of death in the Japanese. There is predominance of intracranial atherosclerosis in these groups for unknown reasons.[17;22;32-35] However these data may be confounded by socioeconomic variables.

Family History of Stroke/TIA. The relative risk of stroke is 2.4 and 1.4 with paternal and maternal history respectively.[17;22;32-35]

1.5.2 Well-Documented Modifiable Risk Factors

Hypertension is the strongest risk factor after age. The Framingham Heart Study showed that relative risk of stroke for a 10mmHg increase in systolic blood pressure was 1.9 for men and 1.7 for women. Data from the Systolic Hypertension in Elderly Programme [SHEP], Perindopril Protection Against Recurrent Stroke Study [PROGRESS] and Heart Outcome Prevention Evaluation Study [HOPES] demonstrated significant reduction in stroke risk with blood pressure lowering. Hypertensives have reduced nitric oxide activity and increased endothelin activity.[17;22;32-35] The risk of stroke beginning at 115/75 mmHg doubles with each increment of 20/10mmHg.[40]

Diabetes Mellitus increases stroke risk with relative risk of 1.5 to 6.0 times depending on the type and severity. However there is no demonstrated reduction in stroke risk with tight glycemic control.[17;22;32-35]

Cigarette smoking is associated with a relative risk of brain infarction of 1.7. Overall the stroke risk due to smoking is greatest for subarachnoid hemorrhage, intermediate for atherosclerotic cerebral infarction and least for intracerebral hemorrhage.[17;22;32-35]

Hyperlipidemia [High triglyceride, total cholesterol, LDL –cholesterol, small dense LDL-C and oxidized LDL-C, low HDL-C, lipoprotein (a)] is a less well correlated risk factor for stroke. Nevertheless, statins [Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study, Simvastatin – Heart Protection Study] resulted in risk reduction in ischemic stroke in patients with concomitant coronary disease. Although it is generally thought that the risk reduction by Statins is not

due to a lowering of cholesterol or other lipid but due to other effects e.g. on nitric oxide synthase (NOS), the relative risk of stroke is 1.8 to 2.6 in hyperlipidemia. The risk is greater in patients younger than 55, with high LDL-C, low HDL and lipoprotein little a. Studies have shown increase in morbidity and mortality in ischemic stroke due to dyslipidemia.[17;22;32-35]

Cardiac risk factors are as discussed under embolic stroke.

Asymptomatic **carotid artery disease** which includes stenosing and non-stenosing plaques has been associated with up to 2.0 relative risk of stroke particularly among those with more than 75% stenosis.[17;22;32-35] A stenosis associated with previous TIA or minor stroke in the past six months is associated with a significantly higher risk than an asymptomatic carotid stenosis.

TIAs are associated with annual stroke risks of 1–15% with the greatest risk in the first year after and in hemispheric ischemic attacks compared to transient monocular blindness. TIAs could be due to an embolic or thrombotic phenomenon. Embolic TIAs are less frequent but last longer while thrombotic [low flow] TIAs are more frequent and briefer. Overall TIAs tend to be more associated with thrombotic stroke.[17;22;32-35]

Previous stroke also increases the risk of subsequent stroke with a recurrence rate of 5-25% in 1 year and 20-40% in 5 years.[17;22;32-35]

Sickle cell disease with a prevalence of 0.25% in blacks increases the risk of stroke by 200-400 fold.[17;22;32-35]

Peripheral vascular arterial occlusive disease is a strong predictor of extracranial cerebrovascular and coronary artery disease and is associated with high frequency of stroke.[17;22;32-35]

1.5.3 Less Well- Documented or Potentially Modifiable Risk Factors

These include obesity, physical inactivity, excessive alcohol consumption [J –curve relationship, more than 5 drinks per day], hyperhomocysteinemia, drug abuse and hypercoagualability [e.g. antiphospholipid antibody, factor V Leyden, prothrombin G20210A mutation, hereditary deficiency of protein C, protein S and antithrombin III, neoplasm, renal disease- nephrotic syndrome, drugs, infections and hematological diseases].[17;22;32-35]

Other risk factors are oral contraceptive use [4 -13 fold risk], hormonal replacement therapy, vasculitides, fibromuscular dysplasia, malaria, inflammatory processes, migraine, sleep apnea syndrome, elevated fibrinogen, prothrombin activator inhibitor complex deficiency, hypotension, high C-reactive protein, tuberculosis, neurocysticercosis, Chlamydia pneumonia, Helicobacter pylori, herpes zoster virus, Legionella pneumophilia, chronic bronchitis, periodontal disease, hyperviscosity, hyperuricemia and dietary factors.[17;22;32-35]

Infections can lead to elaboration of cytokines with procoagulant activity, TNF-α, IL-1, fibrinogen; reduction in protein C, S and antithrombin III; and fever with dehydration.[17;22;32-35]

Genetic factors include MELAS [mitochondrial myopathy, encephalopathy, lactic acidosis and stroke], CADASIL [Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarct and Leucoencephalopathy – Notch-3 gene mutation], CADASILM [CADASIL with hemiplegic migraine], ACE DD genotype, Paraoxonase-1 gene [PON-1], inherited thrombophilic states, STRK1 locus and apolipoprotein ϵ 2 and ϵ 4 [amyloid angiopathy -> intracerebral hemorrhage].[17;22;32-35]

Risk factors for hemorrhagic stroke and cardioembolic stroke are as discussed above.

1.5.4 Risk Factors For Stroke In The Young [< 45 years]

These include congenital heart disease, valvular heart disease, antiphospholipid syndrome, thrombophilic states, infective endocarditis, hypertension, and genetic risk factors earlier discussed.[17;22;32-35,41]

1.5.5 Precipitating Factors For Stroke

These include physical activity, physical and psychosocial stress, coitus, surgery, and Valsalva manouvre [e.g. coughing, sneezing, straining].[17]

1.6 DIAGNOSIS OF STROKE

The art of the skillful stroke physician is to obtain and process clinical data to arrive at a diagnosis of stroke and exclude other underlying diseases with stroke-like syndromes; to determine the type [pathology and pathophysiology] and site of stroke; and to establish the risk factors for stroke. He/she then selects laboratory and radiological tests to assist in confirming his/her findings.[17;22;32-35]

1.6.1 Clinical Evaluation

Other diseases presenting with stroke-like syndromes must first be ruled out. Examples are subdural hematoma, cerebral abscess, brain tumors, migraine, encephalitis, meningitis, metabolic and seizure disorders. They should be suspected when there are no risk factors for stroke, there is history of trauma or fever and when the onset of illness is insidious. The frequency of clinical misdiagnosis of stroke ranges from 1 to 34.6 % in various clinico-pathologic and clinicoradiological tests.[42]

On the other hand a stroke may be asymptomatic or masquerade as another illness. Examples are a small SAH with headaches only; a cerebellar hemorrhage not evident unless the patient is made to stand up and walk; a lateral medullary syndrome mimicking a gastrointestinal disorder, myocardial infarction, vestibular neuronitis or labyrinthitis.[43]

A thorough neurological and cardiovascular examination including auscultation for bruits is therefore required in all cases.[17;22;32-35]

The diagnosis of stroke is largely clinical in most developing countries because neuroimaging facilities are not readily available and affordable.[42;44] The clinical accuracy of distinction of stroke from other disorders has a sensitivity of up to 95% and a specificity of 66-97%. However, this accuracy drops significantly when stroke subtypes have to be distinguished, with sensitivity of up to 68% and specificity of 67% and is better when assessment is by a neurologist.[42]

The information used for clinical stroke diagnosis includes ecological factors [past and present family and personal illness of the patient], presence and nature of past strokes, temporal course of the illness, activity at onset and accompanying symptoms/signs such as headache, loss of consciousness, vomiting and meningism.[17] For instance matudinal [morning] embolism occurs on arising at night to urinate. This body of information has been organized into stroke scales for distinguishing ischemic and hemorrhagic types based on discriminant analysis techniques.[45-47]

The **Guy's Hospital score [Allen's score]** developed in 1984 is complex and difficult to apply at the bedside.[45-47]

The **Siriraj stroke score** [SSS] was developed in Siriraj medical school in Bangkok, Thailand. It is calculated as [2.5x level of consciousness] + [2x vomiting] + [2x headache] + [0.1 x diastolic blood pressure] – [3 x atheroma markers] – 12. A score above 1 indicates supratentorial intracerebral hemorrhage, while a score below -1 indicates infarction. A score between 1 and -1 is equivocal and requires CT scan.[45-47]

Level of consciousness is scored as alert [0], drowsy or stuporous [1], semicomatose or comatose [2]. History of headache within 2 hours of onset and vomiting are each scored as 1 point. Atheroma markers [diabetes, angina, intermittent claudication] are each scored as 1 point.

The SSS had a 90% predictive accuracy in Bangkok community, and sensitivity of 50% for cerebral hemorrhage and 58% for cerebral infarction with an accuracy of 54.2% in Nigerians.

The clinical score by Besson was validated in France, while the WHO criteria has been validated in Nigeria.[45-47]

In **the WHO criteria**, ischemic infarction is suggested by associated TIA, onset at rest, minimal or absent headache, focal neurological deficit without change in consciousness, moderate hypertension or normotension and clear CSF. Whereas intracerebral hemorrhage is diagnosed when there is activity at onset, headache, loss of consciousness, severe hypertension, bloody CSF and absence of TIA. The WHO criteria has a sensitivity of 73% for hemorrhage and 69% for infarction and an overall accuracy

of 71% and is therefore better than SSS in this environment.[46;48] However, a small bleed and a large infarct may be difficult to distinguish.

The use of clinical information in localization has been discussed above under the various types of stroke.

1.6.2 Computerised Tomography

Cranial CT scan is the most important and useful initial diagnostic test. Its sensitivity is nearly 100% for intracerebral hemorrhage and 95% for subarachnoid hemorrhage. It is positive in only 54% of cases of cerebral infarction by the second day, and 90% by the 4th day. Indirect signs of ischemia, which can be detected at a very early stage include focal flattening of the cortical sulci, effacement of the ventricle, loss of insular ribbon, blurring of the interface between the grey and white matter or basal ganglia and white matter, asymmetry of the sylvian fissure, hyperdense arterial sign and hypodense brain tissue. It can identify and localize subarachnoid hemorrhage and help in determining possible source and complications. However CT scan may miss lacunar infarcts, posterior cranial fossa lesions and lesions adjacent to bony surfaces [orbital, frontal and temporal bones].[17;42;44]

1.6.3 Magnetic Resonance Imaging [MRI]

MRI is more sensitive than CT in detecting early ischemic changes and lesions close to bone. MRI shows tomographic sections of the brain in multiple planes of proton distribution modified by spin-lattice [T1] and spin-spin [T2] relaxation times. Perfusion-weighted MRI (PWI) using gadolinium-diethylenetriamine pentaacetic acid (GdDTPA) provides qualitative maps of regional cerebral blood flow (CBF) and volume (CBV) while diffusion-weighted MRI (DWI) can show the core of a focal ischemia within 15 minutes of a stroke. Areas of mismatch between perfusion-weighted (“perfusion disturbance”) and diffusion-weighted MRI (“core”) identify the zone of salvageable ischemic penumbra.[4;17;42;44]

Diffusion weighted MRI using time-dependent variations in apparent diffusion coefficient [ADC] can be used to determine the age of infarcts. FLAIR images and DWI/PWI are very sensitive for acute brain infarcts. MRI spectroscopy may provide biochemical markers of the extent of ischemic injury. Elevated lactate is found soon after infarction; with decreased N-acetyl aspartate, choline and creatine. However, MRI is not practical in emergency situations and is contraindicated in claustrophobic patients, patients using pacemakers or with metals in the head and neck region. It is not readily available and is more expensive than CT scan.[4;17;42;44]

1.6.4 Ultrasound Techniques

Ultrasound is useful for rapid and accurate assessment of intracranial and extracranial vessels in acute

stroke. *Duplex imaging* with combined B-mode echotomography [brightness mode] and pulsed Doppler enables examination of the vessel wall and lumen and definition of plaque architecture. *Color flow Doppler imaging* simultaneously displays two-dimensional tissue structure and flow velocity profile in real time with resultant extremely high sensitivity for minor, moderate and severe stenosis. However, severe stenosis cannot always be differentiated from complete occlusion. Three dimensional display duplex system further increases accuracy.[17;35]

Power Doppler is a new technique which relies on the amplitude of echo from the density of red blood cells. The angle of insonation is not as critical. It shows the intravascular surface and tortuous vessels better. Calcification, and ulceration can also be displayed.[17;35]

Transcranial Doppler ultrasound through transorbital, temporal and suboccipital windows can accurately detect important atherostenotic lesions within the intracranial internal carotid arteries, MCAs, and the vertebrobasilar circulation, respectively. It is useful in assessing collateral flow patterns in patients with extracranial occlusive disease and serial assessment for vasospasm in SAH.[4;17;35;44]

1.6.5 Magnetic Resonance Angiography [MRA]

MRA is usually performed using two-dimensional and three-dimensional time-of-flight and phase contrast imaging. It is a functional process and not an anatomical display and may require gadolinium enhancement. However, patient positioning is critical and it requires longer examination times with resultant motion artifacts. Other demerits include poor demonstration of calcification and bony landmarks, pulsation artifacts, turbulent flow causing dephasing and overestimation of stenosis. It is nevertheless superior to Computerized Tomography Angiography [CTA] in imaging vessels in the posterior cranial fossa.[4;17;35;44]

1.6.6 CT Angiography [CTA]

CTA involves intravenous injection of a bolus of dye followed by helical scanning. It has an accuracy of approximately 90% when correlated with conventional angiography for the detection of ICA stenosis. Display modalities include multiplanar reconstructions, maximal intensity projection, shaded surface display, and volume rendering. The contrast dye infusion also enhances the brain CT image yielding a perfusion CT scan.[4;17;35;44]

1.6.7 Catheter Cerebral Angiography

This is invasive and more frequently associated with complications compared to CTA and MRA. It is indicated when the preliminary tests do not satisfactorily clarify the nature and severity of vascular lesions on which treatment depends. It can be combined with digital subtraction techniques to remove

nonvascular elements from the image.[4;17;35;44]

1.6.8 Other Investigations

Other neuroradiologic techniques include xenon-enhanced CT scan, positron emission tomography [PET], and single photon emission CT which allow assessment of regional cerebral blood flow. PET assesses cerebral metabolic rate for oxygen and oxygen extraction fraction in addition.[4;17;35;44]

Cardiac evaluation by roentgenography, ECG, Holter monitoring and echocardiography [preferably transesophageal echocardiography] are required when cardioembolic stroke is suspected. Electroencephalography [EEG], magnetoEEG, computerized frequency analysis and topographical EEG are used to detect electrical abnormalities in stroke.[4;17;35;44]

Lumbar puncture is important in SAH. Risk factors for stroke can be identified by performing the full blood count, serum protein electrophoresis, clotting profile, antiphospholipid factor assay, immunological studies, fasting lipid profile, blood sugar measurement, serum biochemistry, homocysteine assay and genetic studies.[4;17;35;44]

1.7 THE CONCEPTS OF HEALTH AND HROOL

The International Classification of Impairments, Disabilities and Handicaps [ICIDH] defined **impairment** as any loss or abnormality of psychological, physiological or anatomical structure or function. **Disability** is defined as any restriction or lack [resulting from an impairment] of ability to perform an *activity* within the range considered normal for a human being. **Handicap** is defined as a disadvantage of a given individual resulting from an impairment or disability that limits or prevents the fulfillment of a *role* that is normal [depending upon age, sex and social and cultural factors] for that individual. Recent modifications being proposed include the replacement of handicap with participation and disabilities with activities.[49]

WHO [World Health Organization] defined **health** [***hal*** in old English = whole] in 1948 as '**a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.**' In 1984, the WHO advanced a revised statement that any measure of health must take into account 'the extent to which an individual or a group is able to realize aspirations and satisfy needs and to change or cope with the environment'. [50] Pursuant to this the WHOQOL group in 1993 defined **'quality of life'** as **'an individual's perception of his/her position in life in the context of the culture and value systems in which he/she lives, and in relation to his/her goals, expectations, standards and concerns'.** [51;52]

Health related quality of life [HRQOL] measures are useful in the assessment of the multifaceted impact of disease on the patient's life and determination of the utility and disability associated with

various health states. They can be used in identifying and prioritizing areas of need of individual patients and patients with special needs. They are particularly useful in the assessment of the effectiveness, cost-benefit and cost-utility of various old and emerging prophylactic, therapeutic and rehabilitative interventions. Moreover, outcome measures are important in the identification of determinants of good and poor prognosis in stroke patients. These instruments facilitate patient-caregiver communication, clinical decision making, and uncover hidden problems.[52-55]

Yet, in spite of several previous works on quality of life, there is no universally accepted standard health-related quality of life measure for stroke.[56] This could be because there are no generally accepted definitions of quality of life, life, and the essence and purpose of life.[52-55;57-64]

1.8 THE FEATURES OF A GOOD HROOL MEASURE FOR STROKE

The WHOQOL [WHO Quality of Life] facet definitions include 29 items in 6 domains [physical, psychological, dependence, social, environment and spiritual / personal].[52] There are many generic and stroke-specific measures. Some have as few as 6 items while others test for as many as 136 items. A good stroke-specific HRQOL measure must be rigorous, valid, reliable, individualized, patient-centered, patient-perceived, responsive, precise, acceptable, appropriate, proxy-suitable and interpretable, and must cover all measurable domains of life and functioning.[7;52;53;55;65-70]

An ideal HRQOL instrument must be psychometrically robust and possess the following qualities.

1. 8 .1 Validity is the extent to which an instrument measures what it is meant to measure.[7;52;53;55;65-70]

Face validity involves a subjective assessment of the extent to which an instrument measures what it is intended to measure. *Content validity* is a subjective assessment of how well the domain of interest is sampled. Ware recommends including physical, mental, social and perceptual health as the basic minimum standard for content in any comprehensive generic measure of health related quality of life. [52] Aday suggests reviewing the literature and ensuring that at least one item is represented on the questionnaire for each domain identified.[52]

Duncan and colleagues in the United States identified 8 key important areas [strength, hand function, activities of daily living, mobility, communication, memory, emotion and social participation] from the patients' perspectives.[53;71] Similarly, Williams et al. reported that patients identified 12 key domains [mobility, energy, upper extremity function, work/productivity, mood, self-care, social roles, family roles, vision, language, thinking and personality].[53]

Moreover, since perceptual, spiritual and cultural issues are involved in understanding the concepts of life, essence of life and purpose of life and in determining quality of life, extensive literature and scriptural search and analysis on these concepts is paramount to generating an all–embracing HRQOL measure.[52]

Absence of *floor and ceiling effects* improves validity. The measure would be able to assess the worst and the best health state possible and detect small improvements and deterioration.[52;53]

Criterion validity involves comparison of the results of a proposed measure with that of an existing gold standard. However, since there is no gold standard this is not practicable.[52;56;72]

Construct validity connotes the use of theory in guiding the comparison of groups or measures. This involves specifying the constructs or factors that account for variance in the proposed/reference measures as well as the hypothesized relationships among them. Hypotheses are stated regarding the direction and possibly the strength of relations that might be expected. Validity is supported when the associations are consistent with prior hypotheses.[7;52;65;68;72;73]

Convergent [concurrent] validity, which is a form of construct validity is achieved if different measures of the same construct are logically related and highly correlated. Conversely, discriminant validity, another type of construct validity is evident when logically different measures/domains are not as highly correlated as a more related measure/domain. An example is 'known groups' validity which demonstrates that a measure can differentiate members of one group from another.

1.8.2 Reliability is a generic term that refers to stability and equivalence of repeated measures of the same concept.[7;52;53;65;68;70;72-74]

Internal consistency reliability is the correlation among items in an instrument. Cronbach's coefficient 'alpha' is used to estimate the degree of equivalence and correlation between responses to items/questions tapping the same concept. Coefficient alpha is directly proportional to the number of and the correlation between items tapping the same concept. An acceptable level [Nunnaly's] of alpha has been defined as 0.70 or above.[52; 65]

Reproducibility or test-retest reliability refers to the correlation between responses to the same items administered to the same respondent at different times. The difficulties are in determining whether observed changes are due to chance or improvement/deterioration over time.[52; 65; 68; 74]

Inter-observer/inter-rater reliability refers to the degree of correlation obtained between responses to the same items administered to the same respondent by different observers.[52; 65; 68; 74]

1.8.3 Responsiveness is sometimes called sensitivity or referred to as validity for assessment of change. It is the ability of a measure to detect small but clinically important changes within an individual over time. This is important in determining the effect of intervention on the patient's health. Responsiveness can be determined by using the paired t-test statistic for within-subject changes. It can also be calculated as effect size, which is the changes in mean score from baseline to follow - up divided by the standard deviation of baseline scores.[7;52;53;65;70;73;74]

It is important to note that population- or condition-specific measures can be more responsive than generic measures, because they assess domains of particular interest to the persons with the condition,

whereby small changes may be more easily detected.[7;52;53;65;70;73;74]

1.8.4 Precision is concerned with the number and accuracy of distinctions made by a measure, that is, precision of response categories or of numerical values.[53] Also important is the capacity of the measure to report the most favourable or poorest health states i.e. the paucity of floor or ceiling effects.

1.8.5 Appropriateness is the suitability of a measure for its intended use.[53;70] The content of a measure used to assess QOL in stroke should reflect the aims of the study and the patient group involved.

1.8.6 Acceptability which is indicated by high response rates to the measure overall and individual items is best determined by pretesting with patients in terms of wording, response options and general layout.[53; 70] Instruments with few items and thus short completion times facilitate acceptability but may compromise content validity, precision and responsiveness.[53; 70; 74] Simplicity and brevity of items also promote acceptability.

1.8.7 Proxy suitability/validity is present when there is good correlation between responses obtained from patients and their caregivers/close relations. The use of proxies is necessary if patients with communication and cognitive deficits are to be included in QOL assessment. Proxies – close relations, health professionals, lay caregivers – can give useful information particularly on the more concrete, observable aspects of life. To limit selection bias, the use of proxies is preferable to outright exclusion of severe cases from trials. It is precisely in these patients that information is required in making clinical decisions.[53;71;75;76]

1.8.8 Interpretability is the extent to which results are clinically relevant and applicable.[70]

1.8.9 Duality of administration mode: While self-administered questionnaires may be less resource-intensive, patients with reading and writing difficulties may have problems with them. Conversely, interviewer-administration may be problematic in patients with dysphasia. Hence it is desirable for HRQOL measures to be both self and interviewer administrable. Self-administration is facilitated by simplicity and brevity.[53]

1.9 REVIEW OF EXISTING HRQOL MEASURES

Measures of HRQOL could be generic or disease-specific.[56] While *generic measures* assess and compare HRQOL across populations or different diseases, *disease-specific [population-specific] measures* are more valid, patient-centered, responsive and sensitive in assessing HRQOL in specific diseases and/or populations.[7;56]

Examples of **generic measures** are the 36-item SF-36, the 6-item EuroQol, and the 136-item sickness

impact profile [SIP]. While both the SF-36 and EuroQol correlate closely in the physical domain, their poor correlation in the psychological domain may be due to difference in content, validity or reliability of one or both of these instruments in these domains. The SF-36 correlates well with measures of the physical and mental domains but poorly with measures of social functioning suggesting that a supplemental measure may be required for this domain.[49;53;71;72;77-79]

The SF-36 correlates poorly with the Stroke-Specific QOL measure [SSQOL].[7;15;53;67;70;76;77;80] Generic measures fail to assess condition-specific domains.[56] Though they are useful for comparing HRQOL across disease states they have poor responsiveness[56] and questionable validity and reliability for specific disease states.[7;15;53;67;70;76;77;80] Hence the development of the stroke-specific version of the SIP [SA-SIP 30] which however remains poorly responsive and lacks questions on personal wellbeing, happiness and satisfaction.[49;53;56] It also does not reflect the subjective construct of HRQOL.[56]

Stroke-specific measures include the Niemi QOL scale which is designed for use four years after stroke and assesses working conditions, activities at home, family relationships, and leisure activities. However it was not developed with patient-centered methods. The Ferrans and Power QOL Index, Stroke Version is a 38-item measure of health and functioning, socioeconomic, psychological, spiritual and family functioning. [53]

Other examples of stroke-specific measures are the Stroke Impact Scale (SIS), Stroke and Aphasia Quality of Life Scale -39 (SAQOL-39), Newcastle Stroke-Specific Quality of Life Measure (NEWSQOL) and the Stroke-Specific Quality of Life Scale (SSQOL).[7;53;56;79;81-85] The CQOL (change in quality of life scale for stroke) and the ECVI-38 are also stroke specific measures recently developed in Taiwan and Cuba respectively.[7; 53;56;79;81-85] These measures have been preliminarily evaluated in stroke patients but require further studies to ascertain their psychometric suitability particularly in multicultural settings.[7;53;56;79;81-85] So far, none of them represents a fully reasonable and complete operationalisation of the concept of HRQOL.[56;85]

Though there are several valid **dimension-specific instruments** for the measurement of single aspects of psychological, social or physical outcome after stroke, the use of a series of such instruments may subject patients to an unacceptable burden and so reduce the overall frequency and reliability of response.[86]

These measures are exemplified by **impairment scales** [e.g. National Institutes of Health Stroke Scale-NIHSS, Stroke levity scale (SLS),[87] European Stroke Scale, Glasgow Coma Scale, Folstein Mini Mental State Test] which assess various aspects of physical activity such as motor function, speech, consciousness, cognition, visual and gaze disorders and sensory function. These measures oftentimes can only be administered by trained medical staff.[49; 81]

Disability measures [e.g. modified Rankin Scale, Barthel Index, AHA Stroke Outcome Scale,] assess basic and instrumental daily functioning. Basic activities of daily living include feeding, swallowing, grooming, dressing, bathing, continence, toileting and mobility while instrumental/extended activities include using the telephone, handling money, shopping, using transportation, maintaining a household, working, participating in leisure activities, etc. The challenge of ADL measures is that considering the wide ranges and settings of daily functioning and individual priorities and idiosyncrasies, no ADL measure can sufficiently represent these factors in each person. Hence a single case design has been proposed.[49; 81]

Other dimension-specific measures include Ryff Measure of Psychological Wellbeing for the psychological domain, and Geriatric Depression Scale [GDS] for depression. The Ryff measure assesses self-acceptance, self-determination and independence, environmental mastery, purpose in life, positive relations and personal growth.[15; 81;86;88]

Utility measures are developed for economic evaluation. They incorporate preferences for health states and produce single numerical indices. The utility of a health state is rated between 0 [death] and 1 [perfect health], though some health states are opined by some to be worse than death. Utility is determined directly using the standard gamble method, time trade-off model, category-rating scale or visual analogue scale. Indirect methods of elicitation include the use of established weighted multidimensional scales from the general public for cost-effectiveness analysis and from patients for clinical decision making. The third method of assessment is judgment by expert[s] opinion. Quality Adjusted Life Years [QALY] is determined by finding the product of expected lifespan and utility.[49;53;55;89-91]

Individualized measures allow the respondents to include and weigh the importance of aspects of their own life. While they could be useful for the assessment of response shifts, they are complex and difficult to complete, interpret and use for inter-individual comparisons. Examples are the SEIQoL-DW (Schedule for the Evaluation of Individual Quality of Life-Direct Weight and the PGI (Patient Generated Index).[92;93]

Health related quality of life [HRQOL] measures are useful in the assessment of the multidimensional impact of disease on the patient's life and determination of the utility and disability associated with various health states. Yet, in spite of extensive previous work on quality of life and many generic and stroke-specific measures, there is no gold standard.[56] This could be because there are no generally accepted definitions of quality of life, life, and the essence and purpose of life.[16;52-56;59-64]

What seems required now is a rigorous, valid, reliable, individualized, patient-centred, responsive, precise, acceptable, appropriate, proxy-suitable and interpretable HRQOL measure that covers all measurable domains of life and functioning.[52;53;55;66;67;70]

1.10 EFFECT OF STROKE ON HRQOL

1.10.1 What Is Known

In the western world, the number of people who survive stroke and live with its consequences is increasing possibly due to new therapies. The case fatality rate for stroke has declined over the past few decades, and 85% of the people who experience stroke in the United States now survive. There are nearly four million people in the United States alone, living with the sequelae of stroke.[15;32;91;94-97] This increase in survival has necessitated a new approach to the measurement of the health outcomes associated with stroke prevention, treatment and rehabilitation. In developing countries like Nigeria, stroke is not only a major cause of mortality but also a major cause of disability and morbidity.[20;30;42;98]

Previously published studies on stroke in developed countries, mainly focussed on affected physical [mobility, speech, hand function, activities of daily living, vision, self-care, occupation] and cognitive functioning [communication, memory, emotion, thinking, personality] which led to dependency in patients with the major types of stroke.[2;15;53;79;88;91;94;99-101] This is because the motor and sensory systems, and/or the higher centers/association areas (e.g. in vascular dementia) are primarily affected in most cases. Social and family roles may be consequently impaired.

However, in a study of stroke survivors in Auckland using the SF-36, HRQOL was found to be relatively good for stroke survivors compared to normal individuals. Despite significant ongoing physical disability, survivors of stroke appeared to adjust well psychologically to their illness.[15;99 ;100] Conversely a Canadian study showed multidimensional impairment of all domains except for the autonomy and purpose of life dimensions.[88] This is corroborated by the Kansas city study[88] which demonstrated that even in stroke patients deemed to have recovered by the Barthel index, stroke still affected hand function, activities of daily living and participation.[79]

Previous work done on health-related quality of life after stroke reported highly variable estimates with considerable overlap in the distribution of HRQOL measured for major and minor stroke. In a systematic review, HRQOL weights for major stroke ranged from -0.02 up to 0.71; moderate stroke from 0.12 to 0.81 and minor stroke from 0.45 to 0.92.[94] The Pearson correlation between stroke severity [using the Rankin Scale] and assessed HRQOL weight was -0.74.[94] However, in a recent meta-analysis by the same author, a utility weight of 0.52 for major stroke, 0.68 for moderate stroke and 0.87 for minor stroke was reported.[91] Another systematic review observed a utility of 0.25 for major stroke and 0.55 for minor stroke.[90]

The profile and determinants of HRQOL in stroke varies from study to study. These enormous variations in assessed HRQOL for the same health state (major/ moderate/ minor/ general stroke) may be due to considerable variations in the rigor and outcome of the methods used.[90;94] This may in turn be due to arbitrariness of definition of minor/ moderate/ major stroke and presumptiveness of both qualitative and quantitative HRQOL assessment measures.[56;59;62-64]

Depression, social support, caregiver characteristics [age, burden, HRQOL], social class, functional status, age and co-morbidity [e.g. diabetes mellitus] have been identified as predictors of overall HRQOL.[15;79;80;102] Personal priorities and resources for compensatory manoeuvres are also important determinants of outcome.[49] The time which has elapsed after the stroke ("time after stroke") may also influence HRQOL. A study reported worsening in HRQOL over time, despite stable neurological function.[103] The effect of rehabilitation on HRQOL was studied by Hopman et al. Substantial gains during in-patient care were followed by significant declines after discharge.[86]

1.10.2 What Needs To Be Known

A new stroke-specific instrument, the HRQOLISP (Health-Related Quality of Life in Stroke Patients questionnaire), which was modelled after a complete concept of life and quality of life[59; 63;64] was developed and applied by the author in Nigeria. It showed good face, content and construct validity and internal consistency reliability. It was observed that stroke, even in mild cases, had a multidimensional effect on quality of life. The physical and social interaction domains were the most affected while the spiritual domain which was rated as most important by the respondents was most preserved. Stroke levity (the reciprocal of stroke severity) was found to correlate significantly with the physically-based domains whereas it did not correlate well with the spiritually based domain. The predictors of HRQOL in stroke survivors were social support, stroke levity, negative emotions, laughter frequency and duration of stroke.

A study in Berlin using a generic measure, the SF 12, found predictors of HRQOL in stroke and TIA sufferers after 12 months to be age, cardiac arrhythmias, diabetes, symptom severity and pre-event HRQOL.[104] However, generic measures which have less content validity are less sensitive and responsive than specific measures as demonstrated by Williams et al. who recorded a standardized effect size (SES) score of > 0.5 for the SSQOL (Stroke Specific Quality of Life) measure compared to Becks Depression Inventory and SF36 mental health subscale with SES scores of < 0.2.[7]

Prior to this study, there was no stroke-specific measure that was developed in Germany nor published studies with such measures in Germany. In addition, there is currently no published transnational multicultural study of HRQOL in stroke patients using stroke-specific measures. Therefore it would be of interest to compare the profile and determinants of HRQOL in stroke patients using a psychometrically robust HRQOL instrument for stroke jointly generated and applied in both Nigeria (a developing country) and Germany (an industrialized country) by the same author.

This will provide information which could be used to improve the HRQOL of increasing numbers of stroke survivors and plan rehabilitative care in both settings. This is important because stroke is a common cause of morbidity and mortality in both industrialized and developing countries. It is the most common indication for neurological admissions in Nigeria and in Berlin teaching hospitals.

This study, probably the first of its kind, will serve as a model for cross-cultural generation and

utilisation of HRQOL measures. It could also bring out the differences in HRQOL profile and predictors between stroke patients in developing and developed countries. Predictors of better QOL in stroke patients in both populations may be incorporated into the rehabilitation programmes for stroke patients in order to improve their QOL. It could also help to identify factors that predict worse QOL which need to be minimised during secondary and tertiary stroke prevention. It will be especially useful in the assessment of the effectiveness, cost-benefit and cost-utility of various old and emerging prophylactic, therapeutic and rehabilitative interventions.[52-55]

Furthermore, the results of this study would form the basis for further research including longitudinal studies to determine the inter-rater reliability, responsiveness to change, factorial validity and effect-size interpretation of this and other HRQOL measures including research to determine utilities, disability adjusted life years [DALYs] and quality adjusted life years [QALYs] of stroke states.

CHAPTER TWO: METHODOLOGY

2.1 OBJECTIVES OF THE STUDY

2.1.1 General Objective

To assess the profile and predictors of HRQOL in German stroke patients and compare them with the profile and predictors of HRQOL in Nigerian stroke patients using a new instrument, the HRQOLISP.

2.1.2 Specific Objectives

1. To translate the HRQOLISP into German while maintaining semantic and conceptual equivalence and validity.
2. To pretest the measure in German stroke patients in order to ensure understanding and clarity and allow for possible patient-centred additional items.
3. To determine the validity and reliability of the instrument in German stroke patients.
4. To determine the profile and predictors of HRQOL in German stroke patients using the instrument; potential predictors are sought among independent variables such as sociodemographic data, duration, side, type and number of strokes, co-morbid factors and neurological impairments.
5. To compare the profile and predictors of quality of life in stroke patients in Nigeria and Germany.

2.2 PARTICIPANTS AND METHODS

2.2.1 Study Sites

The Ibadan arm of the study was carried out at the University College Hospital, a quaternary referral hospital in Ibadan Nigeria. Ibadan is a city in south-western Nigeria with a population of 3.8 million. One hundred stroke patients were recruited from the outpatient clinic of the hospital between 2002 and 2004.

The Berlin arm was carried out in the department of neurological rehabilitation of the Charité, Median Klinik, Berlin (62 patients); and the in-patient (12 patients) and out-patient units (28 patients) of the Evangelisches Geriatrisches Zentrum, Berlin. One stroke patient was also recruited from the local stroke patient association in Berlin (LSVB e.V.). Berlin is the capital city of Germany with a population of 3.4 million. The 103 patients were recruited in 2005.

2.2.2 Sample Size

The study population for the Ibadan arm of the study was 100 consecutive stroke patients seen in the clinic who satisfied the inclusion criteria.[80; 82;88;90 ;105] The sample size of 100 was chosen because most published studies on the subject used sample sizes of less than 100 which were considered acceptable and appropriate.[7;15;73;79;86 ;90] With this sample size the precision limit was 9.67% using the formula $d^2 = z^2pq/n$, [106] where n = sample size = 100, p = prevalence = 0.58 per thousand in Ibadan in1977 [2, 15, 21], q = 1-p = 0.42 per thousand, z = constant = 1.96 and d = [desired] precision limit; domain/personal difference to be detected.

Similarly, the study population for the Berlin arm of the study was 103 stroke patients recruited consecutively from the rehabilitation centres. One hundred (Ibadan) and 50 controls (Berlin) were recruited.

2.2.3 Study Design

This project is a cross-sectional study. [15; 107] One hundred stroke patients in Ibadan and 103 in Berlin served as the cases while healthy age and sex matched adults (100 in Ibadan, 50 in Berlin) with no known somatic or psychiatric disease formed the control group. Apparently healthy adults were used as is the practice because any other group of individuals would have conditions interfering with HRQOL.[15; 99] HRQOL was assessed in stroke patients using the new instrument: HRQOLISP [Appendix I], while HRQOL was assessed in the control group using a modified version of the same questionnaire. [Appendix II which is exactly the same as Appendix I with the absence of disease data]. The Ibadan arm of the study was concluded in 2004.

2.2.4 Inclusion Criteria For The Study Population

Those included in the study were:

1. Patients with definite clinical and/or radiological diagnosis of stroke.[1; 15; 16; 42; 108]
2. Patients who had stroke one or more months prior to time of contact with the investigator.[1; 54] The absence of a cut-off point for maximum duration is to permit the determination of the influence of duration after stroke on HRQOL while the one –month minimum duration was chosen to exclude acute cases of stroke with rapidly remitting symptoms.
3. Patients who consented to be included.
4. Patients who could not communicate reliably and validly because of severe cognitive deficits but had close, suitable and reliable proxies who could respond surely and firmly to the questions asked.[75] Their inclusion was to prevent the exclusion of severe cases (in which there may be communication difficulties) thereby reducing selection bias and enabling us to get useful information for planning rehabilitation across the full spectrum of stroke severity.[75; 76]

2.2.5 Exclusion Criteria For The Study Population

Patients excluded from the study were:

1. Patients who did not fulfil the inclusion criteria. For instance, patients with questionable clinical /radiological diagnosis of stroke, patients with severe aphasia, aphonia, tracheostomy, severe dysarthria or dementia without appropriate proxies were excluded.

2. Patients with other medical conditions that are neither risk factors for, nor complications of stroke, but could interfere with HRQOL. Patients who were acutely ill and could not withstand the rigour of an interview were also excluded.

2.3 HYPOTHESES

1. Patients with stroke should have HRQOL profiles different from those of individuals without stroke.
2. The HRQOL in patients with different severities of stroke should be proportional to stroke severity especially in the physically based domains.
3. HRQOL may not be proportional to stroke severity in the spiritually-oriented domains because of the disability paradox.
4. Physically-oriented domains are expected to correlate more with each other than spiritually-based domains.
5. Provided HRQOL does not really vary with culture, the HRQOL difference between patients and controls should be greater than the difference in HRQOL between patients with identical stroke characteristics (including severity) who are from different countries. Also the difference in HRQOL between the control populations in the different countries should be less than the difference between the control population and the stroke patients in that country.

2.4 ASSUMPTION

It was assumed that the respondents answered all the questions honestly, giving the nearest most appropriate response, while keeping in mind their standards, hopes, pleasures and concerns compared to their life in the previous two weeks.

2.5 ETHICAL CLEARANCE

The ethical permission for the Ibadan arm was obtained from the joint ethical committee of the University College Hospital and College of Medicine, Ibadan. That for the Berlin arm was obtained from the institutional ethical committee of the Charité – Universitätsmedizin Berlin.

2.6 THE PROTOCOL (ADMINISTERED SCALES AND ADMINISTRATION PROCEDURE)

2.6.1 The Stroke-specific HRQOL Questionnaire

Patients and their records were evaluated to make the diagnosis of stroke and record cognitive deficits and other illness and demographic characteristics. In Ibadan, using the WHO stroke scale and/or CT scan, the type of stroke was classified into ischemic, hemorrhagic and undetermined[46;48]. A stroke-specific HRQOL questionnaire (the HRQOLISP), generated by patient involvement [structured and open interviews], multidisciplinary consultation, extensive literature and scriptural review, and adherence to WHO criteria [Appendices I and II] was used. After reviewing the literature on stroke-specific domains and facets of life, interviews were held with individual patients in the Ibadan pretesting phase to identify other relevant facets and aspects.

The HRQOLISP encompasses two dimensions and seven domains. The physical dimension includes physical, psychological, cognitive/intellectual and eco-social domains while the spiritual dimension comprises soul, spirit and spiritual interaction domains.Three levels of questions were generated in each domain, namely: perceived objective [global evaluation of health states], self-report subjective [perceived satisfaction/dissatisfaction] and domain importance ratings.[52] The self-report subjective questions assess individual adaptation.[52]

Most items were placed on a 5-unit scale. Aphasia was coded as present or absent because severity data were skewed in literature.[15] The WHO criteria for WHOQOL questions were followed [e.g. avoidance of double negatives and ambiguities].[52] Open questions were added at the end for patients' comments and patients' suggestions on uncovered aspects.

The instrument which was earlier used for the Ibadan arm of the study was found to have face, content and construct validity, and internal consistency reliability. The new measure was used because of the inadequacies of pre-existing measures which this measure was developed to address;[56] and because its psychometric suitability could only be assessed by fielding it.[7; 82;90,;94]

It was translated into German, back-translated into English (by a bilinguist who had no prior knowledge of the original English version) and pretested in 5 German stroke patients for possible expansion of domain and facet coverage and to ascertain appropriateness of wording and understanding. Whereas no new domain or questions were suggested by the patients, adjustments in wording were made without altering its conceptual equivalence. The process of translation and back-translation with preservation of the conceptual and semantic equivalence was made easier by the participation of the author, who is the original developer of the instrument.

The instrument was applied by interviewer- or self- administration to the respondents [consecutive patients /reliable proxies].[7;15;52;53;72] The preferred mode of administration was self-administration to ensure honest responses. However, it was applied by the interviewer to the patient/proxy when this

was not possible due to reading and writing difficulties. The dual mode of administration to the respondents also made it possible to assess the influence of the mode of administration on the HRQOL score. A health assessment version of the instrument [Appendix II] was given to healthy age and sex matched controls who completed the questionnaire themselves.[79] Socioeconomic class was assessed using level of education and income.

The Ibadan arm of the study was completed earlier by the same investigator using an identical protocol.

2.6.2 Further Assessment Instruments

The WHO stroke scale was administered to the Nigerian stroke patients for stroke classification.[46; 48] The National Institute of Health Stroke Scale (NIHSS) was applied by the investigator to all the Berlin stroke patients to determine the severity of stroke. Stroke levity [the reciprocal of stroke severity] was applied in both Ibadan and Berlin. Stroke levity was calculated based on the presence of speech deficit, objective MRC motor power in the dexterous (dominant) upper limb, objective MRC motor power in the affected lower limb and mobility.[87 ;73]

2.6.3 Procedure of Test Administration

Stroke patients:

In Ibadan, the instrument was applied to people of various tribes in the language they understood while maintaining conceptual and semantic equivalence. Where this was not possible, the subject was excluded. However, it was possible in most cases because most respondents were either Yoruba or English speaking; and the instrument was conceptualized by the investigator who speaks both Yoruba and English and who consulted other authorities to translate and back-translate concepts in the instrument. [52; 109] The WHO stroke scale was also administered to the stroke population in Ibadan. After having obtained informed consent from the patients, the new questionnaire, and the NIHSS (scales) were administered once to all the patients studied in Berlin, while stroke severity was determined in both stroke populations using the SLS.[87] The same interviewer applied the instruments in both countries.

Healthy respondents*:*

In Ibadan, the control instrument was administered by the interviewer to healthy elderly clinic clients who visited the clinic for health checks and screening for hypertension. However, in order not to obtain dishonest or biased response to personal questions [e.g. age, family life, income, sexual life], absolute secrecy and honesty were maintained through self-completion of the questionnaire by participating UCH workers.[88] The self-administration mode reduces assessment bias by the unblinded

interviewer.[99] This dual mode of administration in the control group also made it possible to assess the influence of mode of administration on HRQOL.

In Berlin, healthy hospital workers and clients of the Sport Gesundheit Park were included in the control group. After participant information and informed consent, a health assessment version of the instrument [Appendix II] was administered to healthy age and sex matched controls. They completed the questionnaire themselves. However, a subset of 5 healthy volunteers who completed the questionnaire themselves had the instrument re-applied to them by the interviewer a day later in order to determine influence of mode of administration on HRQOL in the control group.

2.7 DATA ANALYSIS

Data analysis was carried out using methods widely reported in HRQOL literature.[15;65;78-80;88 ;99 ;110] Demographic variables in both study populations were collated, summarized and compared with the control [normal] population using the Student's t-test for numeric variables and chi square tests for categorical variables. Other illness characteristics such as side of the body affected and stroke risk factors were also summarized.

Missing values were minimised by asking respondents to choose the approximate best response (for instance by utilising the corresponding domain average or response to mirror question). The remaining missing values were not replaced and varied between 1 and 3% in different domains. The quality of life scores for each domain were generated by the Likert's method, i.e. item responses were summed without weighting or standardization. This was done after recalibrating the items such that a high score always indicate better quality of life.[77] Furthermore the domain scores were transformed into a scale with a maximum score of 100 [best health] each. The importance ratings for the different domains were collated. The overall quality of life score was generated by finding the arithmetic mean of the domain scores.

The domain scores, overall scores and importance ratings were compared between the study and control populations. The discriminant validity was tested by examining and comparing responses from patients with various severities of stroke, using analysis of variance (ANOVA); and between the test and control population of normal individuals using student's t-test and correlation statistics.[73]

In Ibadan, the effect of mode of questionnaire administration on HRQOL [domain and sum] was tested in the control group using the generalized linear model [univariate ANOVA] and adjusting for age and socioeconomic class. Discriminant validity for domain and sum HRQOL was further assessed in all subjects and in the interviewer-administered groups [stroke versus control subjects] using the generalized linear model [univariate ANOVA] and adjusting for age and socioeconomic class. In Berlin, the effect of mode of questionnaire administration on HRQOL [domain and sum] was assessed using correlation statistics in the test-retest sample.

Internal consistency reliability was determined by calculating the Cronbach's coefficients, an inter-

item correlation statistic. Stroke levity [the reciprocal of stroke severity] was calculated based on the presence of speech deficit, objective motor power in the dexterous upper limb, objective motor power in the affected lower limb and mobility.[73]

Stroke levity was determined according to this formula: Stroke levity = maximum power in the dexterous hand + maximum power in the affected lower limb + mobility score (i.e. item 1.1.1.1. iv of Appendix II) – 1[if aphasia present]. Min. = 0, Max = 15. The scores were then stratified as follows for ease of analysis: Mild Stroke [11-15], Moderate Stroke [6-10], Severe Stroke [0-5].

Socioeconomic class (SEC) was assessed using occupation [Appendix III], level of education and income in Nigeria. Whereas in Berlin SEC was assessed using only income and level of education because most respondents were pensioners.

Social support score was computed using items 2.1.iii [support from relations], 2.1.vi [support from friends], 2.1.xi [access to social support], and 2.1.xviii [satisfaction with support from friends].

Relationships score was calculated by adding the scores in items on satisfaction with personal relationships and satisfaction with relationship to God. Physical means aggregate was generated by adding the scores in items on adequacy of financial resources, access to optimal health care services and access to social support.

The effects of gender, side, type, number and duration of stroke on quality of life were determined by using the Student's t-test, and ANOVA. The predictors of domain and overall HRQOL using the HRQOLISP was determined by stepwise multiple regression analysis. The statistically significant two-tailed p value [alpha] was set at < 0.05.

Data was analyzed using the SPSS software [SPSS Inc.© 2003] and Intercoded Stata 7.0. In order not to interfere with the results, missing values were not replaced.

2.8 LIMITATIONS

Time was the greatest limitation to obtaining an accurately age and sex matched control population.[88;99]

2.9 DECLARATION OF INTERESTS

The investigator has no conflicting interests or bias**.**

2.10 LEVEL OF INVOLVEMENT

The questionnaire (HRQOLISP) was conceptualised, developed and fielded in Ibadan and Berlin by the author (candidate) who also carried out most of the analysis using statistical software.

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CHAPTER THREE: RESULTS

3.1 DEMOGRAPHIC CHARACTERISTICS

In Ibadan, one hundred patients comprising 41 males, 59 females; and 100 controls comprising 41 males, 59 females were studied. The age characteristics of control and stroke subjects are represented in Table 1A. The mean age was 59.4 years for the stroke subjects and 57.6 years for the controls. Student's t-test for equality of means with equal variances assumed showed no statistically significant difference in age between the control and study populations. [t = 1.138, 95% CI -1.319 to 4.919, p =0.256].

In Berlin, one hundred and three patients comprising 61 males, 42 females; and 50 controls comprising 11 males, 39 females were studied. The age characteristics of control and stroke subjects are represented in Table 1B. The mean age was 66.9 years for the stroke subjects and 65.7 years for the controls. Student's t-test for equality of means with equal variances assumed showed no statistically significant difference in age between the control and study populations. [t = 0.676, 95% CI – 2.258 to 4.606, p (two-tailed) =0.500]. However, there was statistically significant difference in gender between the stroke and control populations, with χ^2 =18.720 and p < 0.0001.

Other socio-demographic characteristics are represented in Tables 2 to 5. In Ibadan, fifty-one percent of the stroke cases were unskilled workers, while 23% were non-academic professionals. Other occupational groups were manual skilled workers [10%], academic professionals [7%], housewives [4%], non-manual skilled workers [3%], and semi-skilled [1%]. In Berlin, 68 of the stroke patients were pensioners while 19 were professionals. Other occupational groups are as shown in Table 2B. The occupational groups of the control populations in Ibadan and Berlin are as shown in Tables 2A and 2B, respectively.

In Ibadan, as shown in Table 3A, more than half of the study and control populations earned below 25,001 Naira every month. The highest levels of formal education attained are displayed in Table 4A. Half of the subjects had no education or only primary education, while half of the control group had tertiary education. There was a statistically significant difference between the study and control populations in level of education, income and occupation [p = 0.001 to 0.021]. Mean socioeconomic class score [using level of education, income and occupation] was 41.2 $\pm$ 22.9% in stroke patients and 53.3$\pm$ 25.7 % in the control group. There was statistically significant difference in socioeconomic class between the study

and control populations [t = -2.949, p=0.004].

In Berlin, as shown in Table 3B, 80 % and 74% of the study and control populations had a monthly income of less than 2,001 euro respectively. The highest levels of formal education attained are displayed in Table 4B. Fifty-nine percent and eighty percent of the stroke patients and control population respectively, had secondary or tertiary education. There was statistically significant difference between the study and control populations in income [p = 0.021]. Conversely, there was no statistically significant difference in the level of education and occupation between the study and control populations.

Table 5A shows no statistically significant difference in marital status between the study and control populations in Ibadan [p = 0.640]. In the study subjects 78% were married while 16% were widows. In the control group, 80 % were married while 17% were widows.

Likewise in Berlin, Table 5B shows no statistically significant difference in marital status between the study and control populations [p = 0.829]. In the study population 51% were married, while 17% were widows. In the control group, 58 % were married, while 20% were widows. Fourteen and ten percent of the stroke and control subjects respectively were divorced.

In Ibadan, in the stroke group, the tribes of origin were Yoruba [88%], Igbo [4%], Hausa [2%] and others [6%]. 69% were Christians whereas 31% were Muslims. 100% believed in God while 94% believed in life after death [53% extremely, 36% very much]. In the control group in Ibadan, the tribes of origin were Yoruba [93%], Igbo [3%] and others [4%]. 72% were Christians whereas 28% were Muslims. 100% believed in God while 89% believed in life after death [57% extremely, 25% very much].

In Berlin, 92 of the stroke patients were Germans, 3 were Turkish while the remainder were Russian, Beninese/German, Nigerian/German, Spanish, Thai, Korean and American. Sixty-five percent were Christians while 4.9% were Muslims. There was one Buddhist while the remainder had no religion. Ninety-six percent of the control population were Germans, with one Iranian and one Austrian; while 74% were Christian with 1 Muslim and the remainder had no religion. There was no statistically significant difference between the study and control populations in religion (χ^2 = 4.723, p= 0.580) or tribe/race (χ^2 = 2.633, p= 0.621). Sixty-three percent of the stroke patients believed in God while 37% believed in afterlife.

TABLE 1A : AGE AND GENDER DISTRIBUTION (IBADAN)

Age in years	Stroke subjects *n =100*		Control Subjects *n = 100*	
	Male	Female	Male	Female
30- 39	1	2	3	0
40- 49	3	9	11	13
50- 59	8	17	10	21
60 -69	21	25	5	12
70- 79	7	6	8	11
80- 89	1	0	4	2
Total	41	59	41	59
Mean$\pm$ SD	59.4 $\pm$ 9.9		57.6 $\pm$ 12.4	
Age Range	31 - 80		30 - 81	
Mode	63		63	

Student's t = 1.138, 95% CI -1.319 to 4.919, p =0.256

TABLE 1B : AGE AND GENDER DISTRIBUTION (BERLIN)

Age in years	Stroke Subjects *n = 103*		Control Subjects *n = 50*	
	Male	Female	Male	Female
40- 49	6	6	0	1
50- 59	13	0	1	3
60 -69	19	10	6	29
70- 79	18	20	4	6
80- 89	5	5	0	0
90-99	0	1	0	0
Total	61	42	11	39
Mean$\pm$ SD	66.9 $\pm$ 11.6		65.7 $\pm$ 5.9	
Age Range	40 - 92		47 - 78	
Mode	64		63	

AGE: Student's t = 0.676 , 95% CI -2.258 to 4.606, p =0.500 (2-tailed)

GENDER: χ^2 = 18.720 p < 0.0001

TABLE 2A . OCCUPATION (IBADAN)

Occupation	Stroke Subjects Frequency/ Percent	Control Subjects Frequency / Percent
Academic Professionals	7	5
Non-academic Professionals	23	42
Non-manual Skilled Workers	3	4
Manual skilled Workers	10	18
Semi-skilled Workers	1	3
Unskilled Workers	51	27
Housewife	4	0
Students	0	1
None	1	0
Total	100	100

χ^2 = 18.06, p = 0.021

TABLE 2B . OCCUPATION (BERLIN)

Occupation	Stroke Subjects Frequency	Control Subjects Frequency
Academic Professionals	5	1
Non-academic Professionals	14	2
Non-manual Skilled Workers	9	2
Manual skilled Workers	2	2
Semi-skilled Workers	3	0
Unskilled Workers	2	0
Pensioner	68	43
Total	103	50

χ^2 = 9.042 p = 0.171

TABLE 3A : AVERAGE MONTHLY INCOME (IBADAN)

Income in Naira	Stroke Subjects Frequency /Percent	Control Subjects Frequency / Percent
0 - 10,000	62	36
10,001 - 25,000	23	20
25,001 - 50,000	9	22
50,001 - 100,000	3	17
100,001 - 150,000	2	3
150,001 and above	1	2
Total	100	100

χ^2 = 20.08, p = 0.001

TABLE 3B : AVERAGE MONTHLY INCOME (BERLIN)

Income in Euro	Stroke Subjects Frequency	Control Subjects Frequency
0 - 1,000	43	14
1,001 - 2,000	40	23
2,001 - 3,000	7	11
3,001 - 5,000	8	1
5,001 - 10,000	2	0
Total	100	49
Not declared	3	1

$\chi^2 = 11.575, \quad p = 0.021$

TABLE 4A : LEVEL OF EDUCATION (IBADAN)

Highest Formal Education	Stroke Subjects Frequency/ Percent	Control Subjects Frequency / Percent
None	35	21
Primary	15	10
Secondary	30	19
Tertiary	20	50
Total	100	100

$\chi^2 = 19.4, p = 0.001$

TABLE 4B : LEVEL OF EDUCATION (BERLIN)

Highest Formal Education	Stroke Subjects Frequency	Control Subjects Frequency
None	3	0
Primary	39	10
Secondary	31	23
Tertiary	30	17
Total	103	50

χ^2 = 7.483, p = 0.058

TABLE 5 A : MARITAL STATUS (IBADAN)

	Stroke Subjects Frequency/Percent	Control Subjects Frequency / Percent
Married	78	80
Widowed	16	17
Single	3	1
Cohabiting	2	1
Separated	1	0
Divorced	0	1
Total	100	100

χ^2 = 3.389, p = 0.640

TABLE 5 B : MARITAL STATUS (BERLIN)

	Stroke Subjects	Control Subjects
	Frequency	Frequency
Married	53	29
Widowed	18	10
Single	12	3
Cohabiting	3	2
Separated	2	1
Divorced	15	5
Total	103	50

χ^2 = 2.141, p = 0.829

3.2 CLINICAL CHARACTERISTICS

In Ibadan, hemiparesis was on the left side in 47% and right side in 49%. Three patients were quadriparetic with equal powers on both sides while 1 patient was quadriparetic with worse power on the right side. Eighty-four percent had only one stroke while 14 % had two strokes and 2 % had three episodes.

In Berlin 74 patients were on admission while 29 received care at a day clinic. Hemiparesis was on the left side in 49 and right side in 48 patients. Three patients were quadriparetic with worse Motor Research Council power grades on the right side and 3 patients were quadriparetic with worse power on the left side. Eighty patients had only one stroke while 15 had two strokes and 7 had three episodes. One 62 year old hypertensive patient with history of ventricular tachycardia reportedly had 6 strokes.

In Ibadan, risk factors reported in the case notes [Table 6A] were hypertension [99%], age $\geq$45 [84%], diabetes mellitus [16%], previous stroke [16%], excessive alcohol consumption [14%], obesity – body mass index $\geq$ 30kg/m^2 [10%], hypertensive heart disease [9%], hyperlipidemia [1%], Transient Ischemic Attack [1%], and cocaine [1%].

In Berlin, the documented risk factors as well as the clinicoradiological categorization are as displayed in Tables 6A and 6B. Ninety-nine of the patients were at least 45 years old while 86 were hypertensive; 28 had carotid and/ vertebral artery disease while 27 had ischemic

heart disease. Forty had hyperlipidemia while 24 patients smoked and 24 had atrial fibrillation.

In Berlin, radiologically (using cranial CT scan and/ or MRI) 80 % had infarcts while 11 % had hemorrhagic stroke. Six percent had hemorrhagic infarcts while 3 percent had concurrent ischemic and hemorrhagic strokes at various sites. 52 patients had middle cerebral artery territorial infarcts while only two had thrombolytic therapy.

In Ibadan, based on the WHO clinical criteria, 30% had ischemic stroke, 23% had hemorrhagic, while clinical type was indeterminate in 47% due to poor recall of the ictus by the patients and / or insufficient data in the case notes. Because of poor availability and affordability, only 16% had brain CT scan. Of those who had CT scan, stroke was ischemic in 10 [63%] and hemorrhagic in 6 [37%] subjects. [Figure 3] The CT scan did not show any other lesion apart from stroke in any of the patients. There was no significant correlation between CT type and WHO type [p=0.631].

In Ibadan, the time elapsed since the stroke was 1 to 348 months [29 years], with a median value of 28.5 months. In Berlin, the time elapsed since the stroke event ranged between 1 and 324 months, with a median value of 1.5 months.

The NIHSS score in Berlin (Table 7A) ranged between 0 and 16 with a mean value of 5. More than 80% of the patients had a NIHSS score of less than 11. Hence the majority had mild stroke. Using stroke levity which had a correlation of -0.802 with NIHSS (two-tailed p = 0.000), 68 % and 80% respectively in Ibadan and Berlin had mild stroke. As shown in Table 7B, there was no statistically significant difference in stroke levity between the Ibadan and Berlin stroke populations (p = 0.065).

Aphasia was reported in 31% of cases in Ibadan and 38 % of cases in Berlin. As shown in Table 8, sixty-eight percent of the Ibadan stroke patients walked unaided while in Berlin 60 percent walked with or without aids.

Sexual dysfunction was reported in 45% of cases in Ibadan while in Berlin only 21 patients reported little or no sexual dysfunction. Negative feelings [e.g. fear, anxiety, depression, anger, despair] were present in 75% of cases in Ibadan and 68% of cases in Berlin. Only 20% were reportedly back to work; 26% were independent but not back to work, while 54% were dependent [Table 9]. The corresponding figures in Berlin are as shown with only 5 patients back to work.

TABLE 6A: DOCUMENTED RISK FACTORS FOR STROKE

Risk factors	Percentage Occurrence IBADAN, n =100*	Frequency, Percentage BERLIN, n =103
Hypertension	99	86, 83.5
Age ≥ 45	84	99, 96.1
Diabetes mellitus	16	25, 24.3
Previous stroke	16	23, 22.3
Excessive alcohol consumption	14	10, 9.7
Cigarette smoking	0	24, 23.3
Obesity – body mass index ≥ 30kg/m^2	10	14, 13.6
Congestive heart failure (excluding hypertensive heart failure)	0	14, 13.6
Atrial fibrillation	0	24, 23.3
Carotid/ vertebral plaque/ stenosis	0	28, 27.2
Ischemic heart disease	0	27, 26.2
Valvular heart disease	0	12, 11.7
Hypertensive heart disease/failure	9	0
Hyperlipidemia	1	40, 38.8
Transient Ischemic Attack	1	3, 2.9
Cocaine abuse	1	0
Others (CADASIL, dissection, PFO, homocysteine, VSD, HIT, HZ-oph)	0	8, 7.8

*Whereas all patients were assessed for hypertension, diabetes, smoking, alcohol consumption, and history of TIA, not all patients in Ibadan were comprehensively assessed for the remaining parameters. Carotid Doppler ultrasound was performed in 22% of the Ibadan cohort in which it was normal. Fasting lipid profiles were performed in 43%, ECG in 72%, and echocardiography in 38% of the Ibadan cohort.

TABLE 6B : CLINICORADIOLOGICAL CHARACTERISTICS OF THE STROKE PATIENTS IN BERLIN (n = 103)

CHARACTERISTIC	PERCENTAGE
CT/MRI Type of Stroke	
Ischemic	80
Hemorrhagic	11
Hemorrhagic infarct	6
Ischemic and hemorrhagic	3
Location	
Anterior circulation	78
Posterior circulation	18
Both	4
Aetiopathogenesis	
Large artery atherothrombotic	41
Small vessel/lacunar	10
Cardioembolic	8
Cryptogenic	24
Hemorrhagic	12
Both small and large vessel disease	5

TABLE 7A NIHSS (BERLIN)

NIHSS	Frequency	Percent
0 - 5	66	64.1
6 - 10	20	19.4
11 – 15	15	14.6
16 - 42	2	1.9
TOTAL	103	100

Mean = 5.04, Standard deviation = 4.35 Median = 3.00

TABLE 7B : STROKE LEVITY

Stroke levity score	Class of stroke	Frequency Percent IBADAN	Frequency, Percent BERLIN
0 - 5	Severe Stroke	6	6 , 5.8
6 - 10	Moderate Stroke	14	27, 26.2
11 - 15	Mild Stroke	80	70, 68.0
TOTAL		100	103, 100
Mean $\pm$ SD		12.2 $\pm$ 3.4	11.3 $\pm$ 3.4

t = - 1.85, p = 0.065 (2-tailed), C.I. = -1.84 to 0.056

Stroke levity = maximum MRC power grade in the dexterous hand + maximum power in the affected lower limb + mobility score – 1[if aphasia present]. Min. =0, Max =15

Pearson´s correlation (Berlin) Stroke levity and NIHSS, N =103, R = -0.802, p < 0.00001 (2-tailed).

TABLE 8 : MOTOR DISABILITY

	Frequency Percent IBADAN	Frequency Percent BERLIN
Bedbound	1	0, 0
Chairbound	8	35, 34.0
Needs Helpers	10	3, 2.9
Needs Aids	13	36, 35.0
Walks Unaided	68	29, 28.1
TOTAL	100	103, 100

TABLE 9 : LEVEL OF DEPENDENCE IN PERFORMING ACTIVITIES OF DAILY LIVING

	Frequency Percent IBADAN	Frequency Percent BERLIN
Fully dependent	18	2, 1.9
Requires substantial help	14	30, 29.1
Requires minimal help	22	26, 25.3
Requires no help but not back to work	26	40, 38.8
Back to work	20	5, 4.9
TOTAL	100	103, 100

3.3 INSTRUMENT'S PSYCHOMETRIC PARAMETERS AND HRQOL PROFILE

3.3.1 Administration of HRQOLISP

In Ibadan, the instrument [102 items in 7 domains] was administered to 96 subjects directly by an interviewer, and to 4 proxy respondents. The questionnaire was self-completed by 60 control subjects [UCH workers] and administered by interview to 40 subjects [geriatric clinic visitors]. After adjusting for age and socioeconomic class, the mode of administration in the control group had no statistically significant effect on the HRQOL sum [$p = 0.790$], spiritual interaction domain [$p = 0.097$], social interaction domain [$p = 0.547$], spirit domain [$p = 0.883$], soul domain [$p = 0.936$], intellectual domain [$p = 0.909$] and physical domain [$p = 0.055$]. However the psychological domain score was slightly higher in the self-administered group [$p = 0.005$].

In Berlin, the instrument was administered by the same interviewer (that developed and applied the instrument in Ibadan) to 84 patients, while 17 completed the questionnaire themselves and 2 had the instrument completed by the proxy and interviewer. The 50 control participants completed the questionnaire themselves. However, the questionnaire was administered consecutively (one day apart) by both interviewer and self-completion in five control volunteers. There was strong correlation between the HRQOL (domain and sum) obtained by interviewer and self administration ($0.96 < r < 0.99$, $0.000 < p < 0.036$). Similarly, there was no statistically significant difference between HRQOL (domain and sum) in in-patients and out-patients in Berlin ($0.239 < p < 0.948$).

The mean completion time was 26.5 ± 7.1 minutes in Ibadan and 28.2 ± 7.2 minutes in Berlin. No new additional item was suggested by respondents in both Ibadan and Berlin. However some patients in Berlin wanted a repeat assessment in order to know if their HRQOL has improved. The instrument was generally acceptable to them. They described it as "helpful", "good", "uplifting", "thought-provoking", "alright" and "interesting" despite being lengthy partly repetitive and partly difficult to answer. No additional item was suggested by the respondents.

3.3.2 Importance Rating and Reliability of HRQOLISP

In Ibadan, the spirit domain was rated most important by both stroke and control subjects whereas in Berlin the physical domain was generally rated as most important. However, a few Berlin stroke respondents described the spiritual aspect of their life as most pivotal and more important than their professional and financial life. Moreover, the soul and ecosocial interactional domains were rated higher by stroke patients than by the control respondents ($p < 0.00001$ and 0.001 respectively).

Cronbach's alpha, an inter-item correlation statistic and a measure of internal consistency reliability, varied from 0.721 to 0.849 in Ibadan (Table 10A) and from 0.772 to 0.924 in Berlin (Table 10B). The inter-domain alpha coefficient in Berlin was 0.724 and 0.885 in Ibadan. Analysis of the HRQOLISP for floor and ceiling effects in both cities is displayed in Table 10C.

3.3.3 HRQOLISP Validity and HRQOL Profile

In Ibadan, the instrument was able to discriminate between the stroke and control groups in all domains except spiritual interaction domain [Table 11A, Figure 1A]. Similarly, after adjusting for age and socioeconomic class, it was still able to discriminate between the stroke and control groups in all but one domain [Table 11A]. Moreover, after adjusting for age and socioeconomic class, it retained its discriminant validity for domain and sum HRQOL between the stroke and control subjects in the interviewer-administered only group [$p < 0.00001$ to 0.011] except in the spirit [$p = 0.181$] and spiritual interaction [$p = 0.063$] domains.

In Berlin, the instrument was able to discriminate between the stroke and control groups in all domains except the spirit and spiritual interaction domains [Table 11B, Figure 1B]. This was sustained in all domains in the physical dimension after adjusting for age and socioeconomic class. Although there was no statistically significant difference in HRQOL (domain and sum) between the male and female control respondents ($0.051 < p < 0.994$), the HRQOL was compared between the male stroke and control respondents. The same operation was carried out between the female stroke and control participants.

In Berlin, in the male-only respondents subgroup, the questionnaire was able to discriminate between the test and control cases in HRQOL sum and in all domains ($p < 0.00001$ to $p < 0.003$) except the soul domain ($p = 0.114$), spirit domain ($p = 0.489$) and spiritual interaction domain ($p = 0.723$). In the female-only respondents subgroup, the questionnaire was able to discriminate between the test and control cases in HRQOL sum and in all domains ($p < 0.00001$ to $p < 0.002$) except the intellectual domain ($p = 0.095$), soul domain ($p = 0.186$), spirit domain ($p = 0.555$) and spiritual interaction domain ($p = 0.275$). Furthermore, after controlling for gender, occupation and socioeconomic class (highest formal education obtained and reported average monthly income) the instrument was able to discriminate between control and stroke patients in all domains ($p < 0.00001$ to $p < 0.031$) except spirit domain ($p = 0.646$) and spiritual interaction domain ($p = 0.603$). In a univariate ANOVA, adjusting for socioeconomic class, the HRQOL (sum) still differed significantly between the stroke and control populations ($p = 0.035$, $F = 274.313$.)

In summary, in both Ibadan and Berlin, the questionnaire exhibited its discriminant validity between stroke and normal respondents more robustly in the physical dimension comprising the physical, psychological (emotional), ecosocial, and intellectual (cognitive) domains as well as HRQOLsum.

The mean HRQOL in control volunteers in Ibadan and Berlin were similar in the physical domain (91.1 Ibadan, 92.7 Berlin), psychological domain (84.7 Ibadan, 84.6 Berlin), ecosocial (76.8 Ibadan, 76.8 Berlin), and intellectual domain (85.0 Ibadan and 81.5 Berlin) as shown in Tables 11A and 11B. However the mean control HRQOL scores were higher in Ibadan than in Berlin in the remaining domains (soul, spirit, spirit interaction) and in HRQOL-sum. This is also true in the stroke patients in whom the HRQOL sum and in soul, spirit, and spirit interaction domains were higher in Ibadan compared to Berlin.

In Ibadan, 74.4% scored below cut-off point in the physical domain, while only 3.1 % scored below cut-off point in the spiritual interaction domain. [Table 12A]

In Berlin, the physical domain was also most affected [97.1 % scoring below cut-off point] while the most preserved was the soul domain [with 29.1% scoring below the cut-off point) as shown in Table12B. As shown in Fig 1C, the HRQOL was significantly higher in female stroke patients in the spirit and spiritual interaction domains (p= 0.011 and 0.029, respectively).

3.3.4 Construct Validity

In Ibadan, stroke levity discriminated domain scores except in spirit, social interaction and soul domains [Table 13A]. Hence the instrument had its best discriminant validity between various severities of stroke in the physical, psychological, intellectual and spiritual interaction domains. However, stroke levity correlated with physical domain, psychological domain, intellectual domain and social interaction domains which have similar constructs [Table 14 A, Figure 2A]. There was no significant correlation between stroke levity and the soul, spirit and spiritual interaction domains [Table 14A, Figure 3A].

In Berlin stroke levity and NIHSS discriminated HRQOL (domain and total scores) except in intellectual/cognitive, spirit, soul and spiritual interaction domains [Table 13 B and 13C]. Hence the instrument had its best discriminant validity between various severities of stroke in the physical, psychological, and ecosocial interaction domains. Similarly, NIHSS and stroke levity correlated with physical domain, psychological domain, intellectual domain and ecosocial interaction domains which have similar constructs [Table 14 B, Figures 2B and 2C]. There was no significant correlation between NIHSS and the soul, spirit and spiritual interaction domains [Table 14B, Figure 3B]; and between stroke levity and the spirit and

spiritual interaction domains (Table 14 B).

Furthermore, in Ibadan as shown in Table 14A, there was significant correlation among all physically-based domains [physical domain, psychological domain, intellectual domain, and social interaction domain] on the one hand [r= 0.449 to 0.703], and the spiritually-based domains [soul domain, spirit domain, spiritual interaction domain] on the other hand (r = 0.417 to 0.551). This demonstrates convergent validity within the physical dimension and the spiritual dimension; as well as discriminant validity between the two dimensions.

Similarly, in Berlin as shown in Table 14B, there was significant correlation among all physically-based domains [physical domain, psychological domain, intellectual domain, and social interaction domain] on the one hand [r= 0.394 to 0.645], and the spiritually-based domains [soul domain, spirit domain, spiritual interaction domain] on the other hand (r = 0.699 to 0.897). This further confirms convergent validity within the physically-based domains and spiritually-based domains; and discriminant validity between the two groups of domains.

TABLE 10A:DOMAIN RELIABILITY AND IMPORTANCE RATING (IBADAN)

Domains	Number of items	mean ± SD stroke[n=100]	mean ± SD control [n=100]	Cronbach's Alpha
Physical	16(items 1.1.v – xiv)	3.95 ± 0.77	3.88 ± 0.84	0.807
Psychological	12	4.01 ± 0.64	3.99 ± 0.68	0.835
Intellectual/Cognitive	12	4.09 ± 0.64	4.04 ± 0.61	0.849
Soul	26	4.15 ± 0.63	3.99 ± 0.61	0.771
Spirit	7	4.24 ± 0.56	4.17 ± 0.57	0.767
Ecosocial	23	4.04 ± 0.64	3.90 ± 0.53	0.843
Spiritual interaction	6	4.19 ± 0.63	4.03± 0.64	0.721
HRQOLsum	102, 7 domains			0.885

Maximum rating = 5 = extreme importance, 4= very important, 3= moderately important. [See appendix II]

TABLE 10B:DOMAIN RELIABILITY AND IMPORTANCE RATING (BERLIN)

Domains	Number of items	mean ± SD Stroke [n=103]	mean ± SD control [n=50]	Cronbach's alpha (Stroke)
Physical	16 (items1.1. :v – xiv)	4.03 ± 0.27	4.06 ± 0.75	0.810
Psychological	12	3.99 ± 0.25	3.94 ± 0.63	0.772
Intellectual/Cognitive	12	3.96 ± 0.24	4.04 ± 0.58	0.882
Soul	26	3.81 ± 0.56	3.33 ± 0.61	0.786
Spirit	7	3.09 ± 1.06	2.73 ± 1.01	0.873
Ecosocial	23	4.00 ± 0.27	3.75 ± 0.63	0.811
Spiritual interaction	6	2.52 ± 1.38	2.59± 1.16	0.924
HRQOLsum	102, 7 domains			0.724

TABLE 10 C : ANALYSIS FOR FLOOR AND CEILING EFFECTS

Domain	Floor effect		Ceiling effect	
	Ibadan	Berlin	Ibadan	Berlin
Physical	0	0	10	1
Psychological	0	0	11	6.9
Cognitive	0	0	10	5.8
Soul	0	0	3	1
Spiritual	0	0	16	0
Ecosocial	0	0	6	2
Spiritual interaction	0	0	13	2.9
HRQOLsum	0	0	8	0

Floor effect analysis: Percentage of respondents scoring below 10%.

Ceiling effect analysis: Percentage of respondents scoring above 90%.

TABLE 11A:HRQOL PROFILE IN STROKE AND CONTROL GROUPS (IBADAN)

Domains	Stroke patients Mean ± SD	Control group Mean± SD	*t*	*p* (two-tailed)	*F (adjusted for age and SEC)*	*p (adjusted for age and SEC)*
Physical	73.9 ± 14.1	91.1 ± 7.0	-7.937	<0.00001*	9.953	<0.00001*
Psychological	74.4± 13.5	84.7 ± 8.8	-5.553	<0.00001*	5.345	0.002*
Cognitive	71.9 ± 13.1	85.0 ± 17.0	-5.481	<0.00001*	8.461	<0.00001*
Soul	76.8 ± 6.9	84.2 ± 6.0	-5.179	<0.00001*	7.281	<0.00001*
Spirit	78.9 ± 10.8	84.8 ± 9.2	-4.028	<0.00001*	4.763	0.003*
Ecosocial	69.9 ± 12.7	76.8 ±10.4	-3.430	0.001*	6.620	<0.00001*
Spiritual interaction	76.8 ± 13.0	82.0 ± 26.2	-1.726	0.087	1.454	0.230
HRQOL Sum	73.5 ± 9.1	84.4 ± 6.9	-3.496	0.002*	3.883	0.027*

* Statistically significant.

TABLE 11B:HRQOL PROFILE IN STROKE AND CONTROL GROUPS (BERLIN)

Domains	Stroke Patients Mean ± SD	Normal adults Mean± SD	*t*-value	*P* [two-tailed]	*F (adjusted for age and SEC)*	*p (adjusted for age and SEC)*
Physical	65.1 ± 13.0	92.7 ± 5.1	-14.365	<0.00001*	73.96	<0.00001*
Psychological	74.1± 12.3	84.6 ± 9.6	-5.237	<0.00001*	10.163	<0.00001*
Cognitive	75.5 ± 13.0	81.5 ± 8.9	-2.927	0.004*	4.328	0.006*
Soul	65.4 ± 9.7	69.7 ± 9.1	-2.645	0.009*	2.460	0.065
Spirit	46.6 ± 18.3	49.1 ± 17.5	-0.817	0.416	0.912	0.437
Ecosocial	68.3 ± 9.1	76.8 ± 7.9	-5.835	<0.00001*	20.481	<0.00001*
Spiritual interaction	45.3 ± 22.0	45.6 ± 17.6	-0.073	0.942	0.495	0.686
HRQOL Sum	62.8 ± 8.9	71.4 ± 7.7	-6.075	0.000*	11.387	<0.00001*

* Statistically significant.

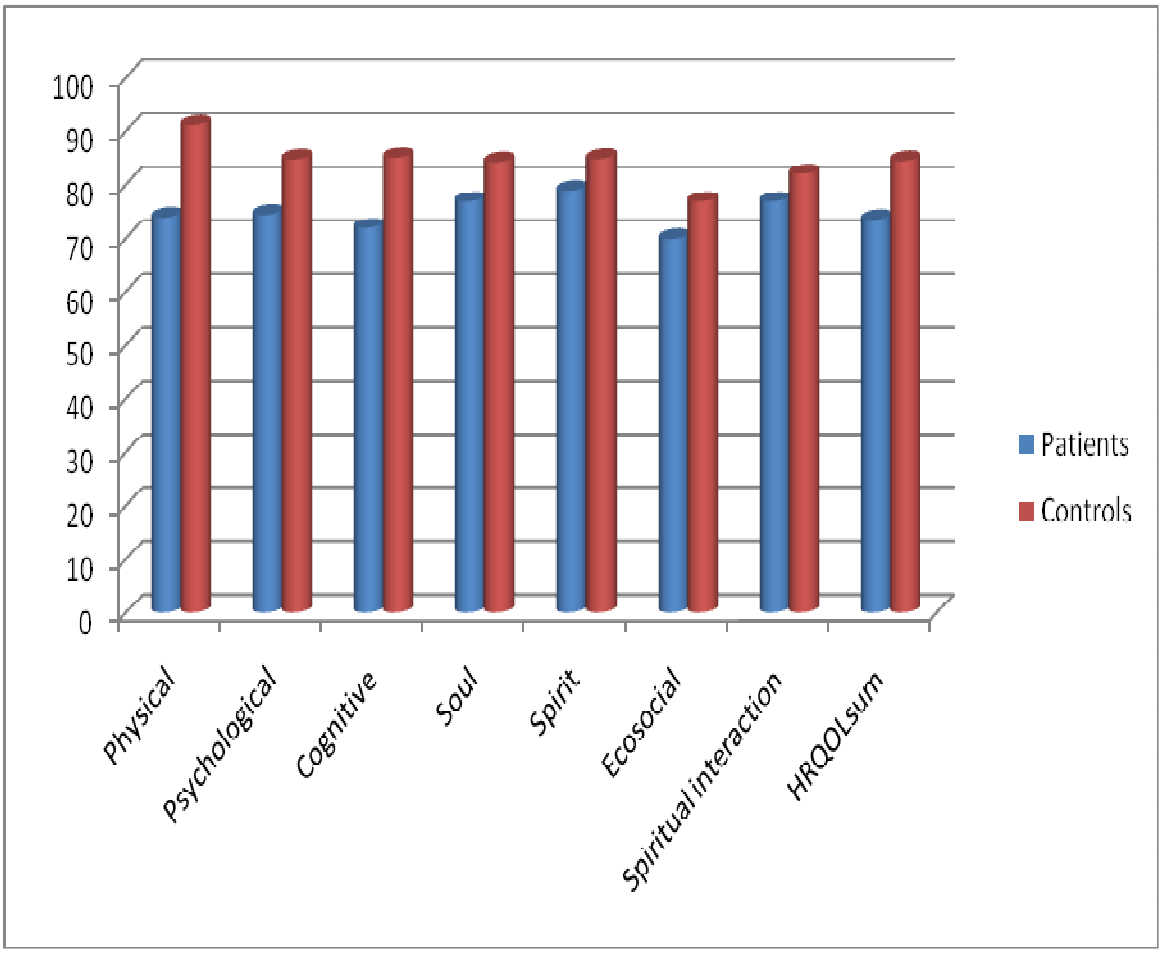


FIGURE 1A : COLUMN CHART SHOWING HRQOL PROFILE (IBADAN)

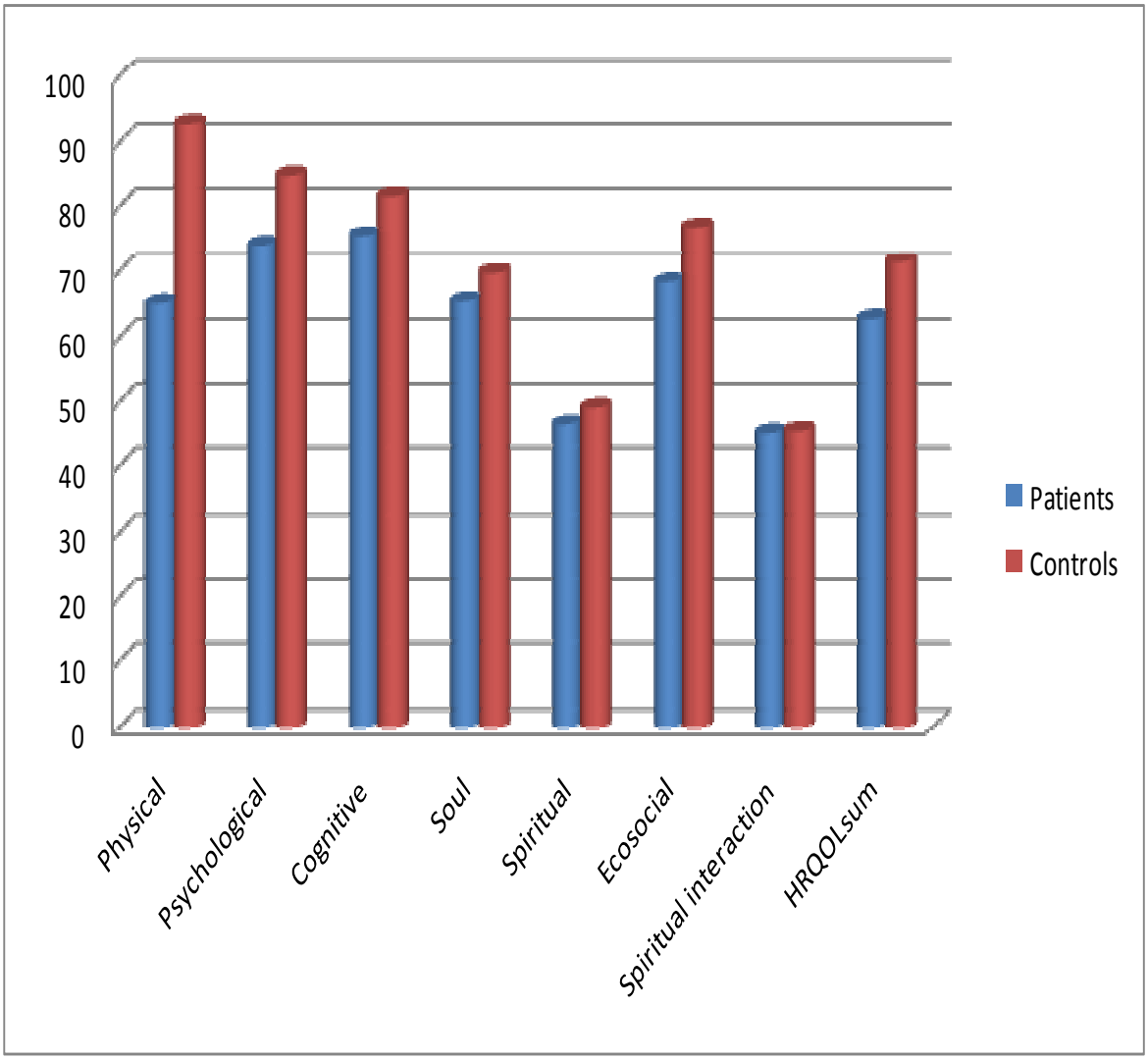


FIGURE 1B: COLUMN CHART SHOWING HRQOL PROFILE (BERLIN)

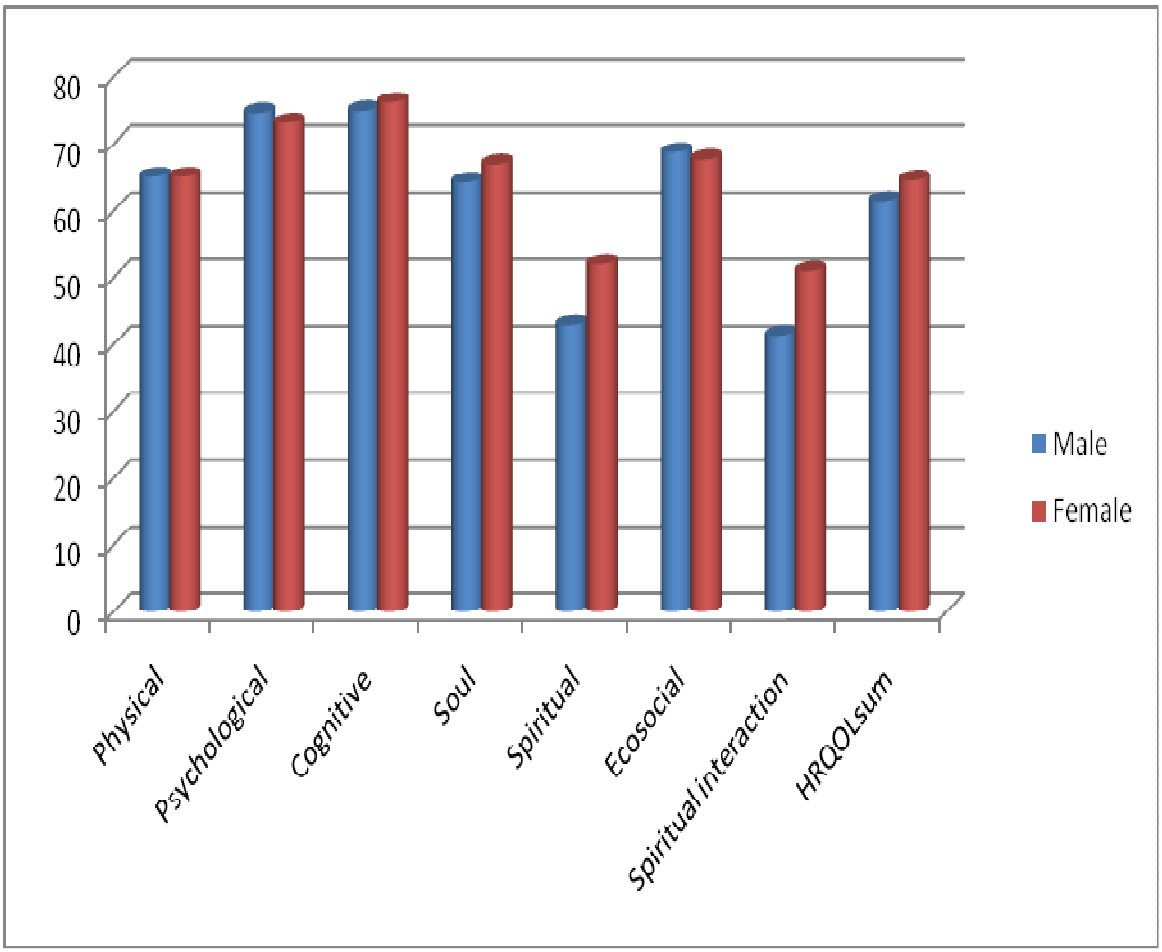


FIG 1C HRQOL PROFILE IN BERLIN- MALE VERSUS FEMALE STROKE PATIENTS

The HRQOL was significantly higher in female stroke patients in the spiritual and spiritual interaction domains (p= 0.011 and 0.029 respectively).

TABLE 12A : FREQUENCY OF DOMAIN INVOLVEMENT (IBADAN)

Domains	Cut-off point [$Mean_{normal}$ +1 S.D.]	% patient below cut-off point
Physical	84.1	74.4
Psychological	75.9	50.6
Intellectual /Cognitive	68.0	38.6
Soul	78.2	61.1
Spirit	75.6	40.8
Ecosocial	66.4	38.1
Spiritual interaction domain	55.8	3.1
HRQOL Sum	77.5	66.7

TABLE 12B : FREQUENCY OF DOMAIN INVOLVEMENT (BERLIN)

	Cut-off point [$Mean_{normal}$ +1 S.D.]	% patient below cut-off point
Physical domain	87.6	97.1
Psychological domain	75.0	46.1
Intellectual domain	72.6	32.0
Soul domain	60.6	29.1
Spirit domain	31.6	33.0
Social interaction domain	68.9	51.0
Spiritual interaction domain	28.0	32.0
HRQOL Sum	63.7	51.0

TABLE 13 A : ONE WAY ANOVA SHOWING THE EFFECT OF STROKE LEVITY ON HRQOL (IBADAN)

Domains	F	p-value
Physical	2.801	0.019*
Psychological	3.696	<0.0001*
Intellectual/Cognitive	3.229	0.002*
Soul	0.165	0.984
Spirit	1.036	0 .424
Ecosocial	1.534	0.151
Spiritual interaction	2.009	0.038*

* Statistically significant

TABLE 13 B : ONE WAY ANOVA SHOWING THE EFFECT OF STROKE LEVITY ON HRQOL (BERLIN)

Domains	F	Two-tailed p
Physical domain	10.322	<0.0001*
Psychological domain	1.949	0.021*
Intellectual domain	1.076	0.390
Soul domain	1.233	0.253
Spirit domain	0.877	0.612
Ecosocial interaction domain	2.364	0.004*
Spiritual interaction domain	0.945	0.532
HRQOL sum	2.630	0.001*

* Statistically significant

TABLE 13 C : ONE WAY ANOVA SHOWING THE EFFECT OF NIHSS (STROKE SEVERITY) ON HRQOL (BERLIN)

Domains	F	Two-tailed p
Physical domain	9.277	<0.0001*
Psychological domain	1.775	0.040*
Intellectual domain	1.168	0.305
Soul domain	1.088	0.378
Spirit domain	0.498	0.957
Ecosocial interaction domain	2.200	0.008*
Spirit interaction domain	0.852	0.641
HRQOL sum	1.928	0.022*

* Statistically significant

TABLE 14 A : HRQOL INTERDOMAIN CORRELATION MATRIX (IBADAN)

		Stroke levity	Physic. domain	Psycho domain	Intellectual domain	Soul domain	Spirit domain	Social Interact.	Spiritu. Inter.	HRQOL sum
Stroke levity	**r**	1	***.527(**)***	***.399(**)***	***.400(**)***	.073	.047	***.269(*)***	.075	.419
	p	.	.001	<0.0001	<.00001	.690	.661	.040	.479	.228
Physic.domain	**r**	***.527(**)***	***1***	***.703(**)***	***.634(**)***	.450(*)	.319(*)	***.495(*)***	.312	.875(**)
	p	.001	.	<0.0001	<0.0001	.024	.048	.019	.056	<0.0001
Psychol domain	**r**	***.399(**)***	***.703(**)***	***1***	***.695(**)***	.451(**)	.189	***.449(**)***	.087	.863(**)
	p	<0.0001	<0.0001	.	<0.0001	.008	.077	.001	.424	<0.0001
Intellect. domain	**r**	***.400(**)***	***.634(**)***	***.695(**)***	***1***	.513(**)	.147	***.496(**)***	.134	.868(**)
	p	<0.0001	<0.0001	<0.0001	.	.002	.173	<0.0001	.219	<0.0001
Soul domain	**r**	.073	.450(*)	.451(**)	.513(**)	***1***	***.551(**)***	.386	***.417(*)***	.586(*)
	p	.690	.024	.008	.002	.	<0.0001	.076	.013	.045
Spirit domain	**r**	.047	.319(*)	.189	.147	***.551(**)***	***1***	.402(**)	***.472(**)***	.683(*)
	p	.661	.048	.077	.173	<0.0001	.	.001	<0.0001	.014
Social interaction	**r**	***.269(*)***	***.495(*)***	***.449(**)***	***.496(**)***	.386	.402(**)	***1***	.350(**)	.829(**)
	p	.040	.019	.001	.000	.076	.001	.	.005	.001
Spiritu. interaction	**r**	.075	.312	.087	.134	***.417(*)***	***.472(**)***	.350(**)	***1***	.778(**)
	p	.479	.056	.424	.219	.013	<0.0001	.005	.	.003
HRQOLsum	**r**	.419	.875(**)	.863(**)	.868(**)	.586(*)	.683(*)	.829(**)	.778(**)	1
	p	.228	<0.0001	<0.0001	<0.0001	.045	.014	.001	.003	.

* Correlation is significant at the 0.05 level (2-tailed).

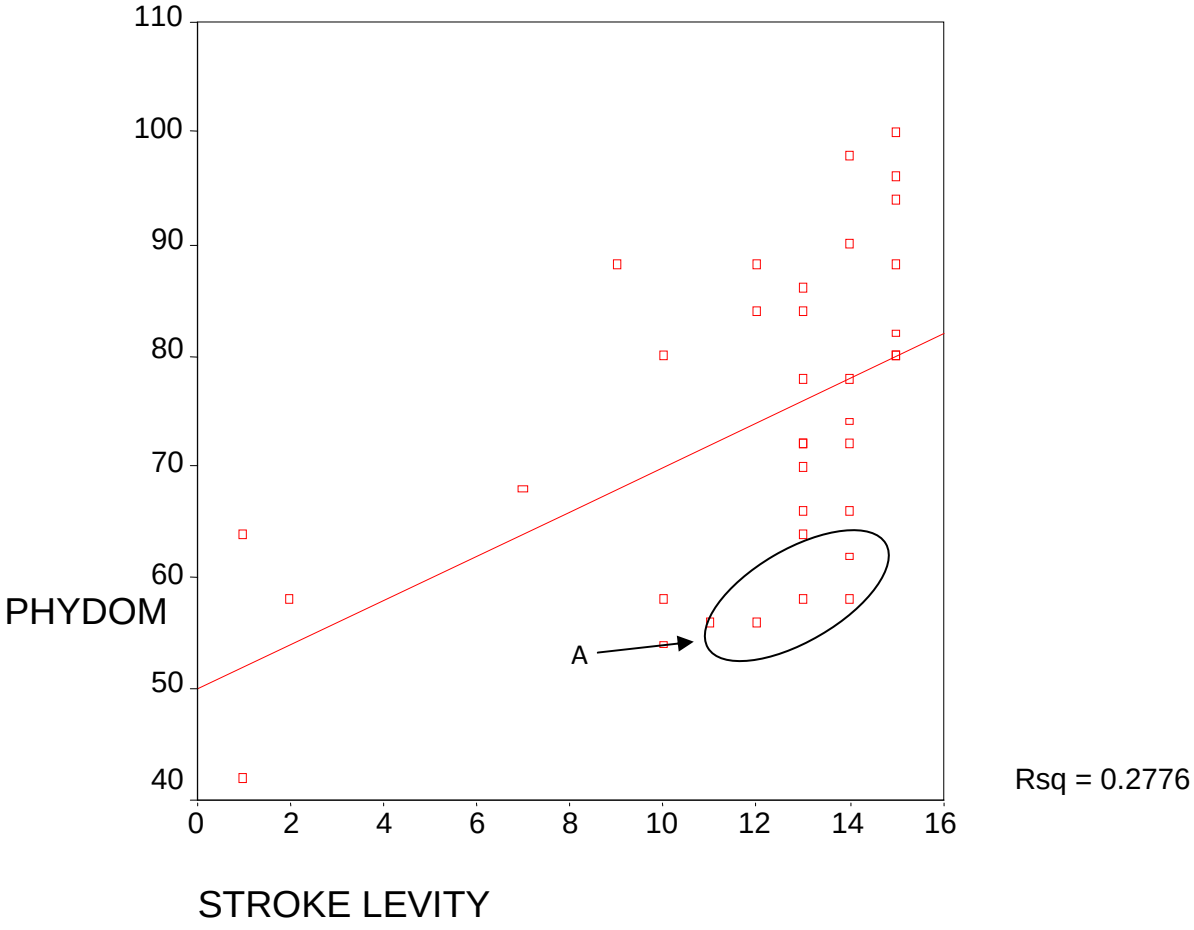
** Correlation is significant at the 0.01 level (2-tailed).

TABLE 14 B : HRQOL INTERDOMAIN CORRELATION MATRIX (BERLIN)

		NIHSS	Physical domain	Psych .dom.	Intell. dom.	Soul dom.	Spirit dom.	Social inter. dom.	Spirit inter. dom.	HRQOL sum	Stroke levity
NIHSS	r	1	**-0.777****	**-.422****	**-.285****	-,157	,036	**-.437****	,018	**-.378****	**-.802****
	p		,000	,000	,004	,113	,718	,000	,855	,000	,000
Physical domain	r	**-.777****	1	**.573****	**.394****	.291******	-,031	**.645****	,002	**.534****	**.727****
	p	,000		,000	,000	,003	,758	,000	,985	,000	,000
Psychological domain	r	**-.422****	**.573****	1	**.576****	,421**	,047	**.579****	,108	**.638****	.**378****
	p	,000	,000		,000	,000	,638	,000	,278	,000	,000
Intellectual domain	r	**-.285****	**.394****	**.576****	1	,245*	-,088	**.454****	-,085	**.453****	**.266****
	p	,004	,000	,000		,013	,379	,000	,396	,000	,007
Soul domain	r	-,157	,291**	,421**	,245*	1	**.729****	,307**	**.699****	**.848****	,232*
	p	,113	,003	,000	,013		,000	,002	,000	,000	,018
Spirit domain	r	,036	-,031	,047	-,088	**.729****	1	-,029	**.897****	**.697****	,055
	p	,718	,758	,638	,379	,000		,771	,000	,000	,580
Ecosocial interaction domain	r	**-.437****	**.645****	**.579****	**.454****	,307**	-,029	1	,032	**.539****	**.429****
	p	,000	,000	,000	,000	,002	,771		,750	,000	,000
Spirit interaction domain	r	,018	,002	,108	-,085	**.699****	**.897****	,032	1	**.728****	,068
	p	,855	,985	,278	,396	,000	,000	,750		,000	,496
HRQOL sum	r	-,378**	,534**	,638**	,453**	,848**	,697**	,539**	,728**	1	,422**
	p	,000	,000	,000	,000	,000	,000	,000	,000		,000
Stroke levity	r	**-0.802****	**0.727****	**.378****	**.266****	,232*	,055	**.429****	,068	**.422****	1
	p	,000	,000	,000	,007	,018	,580	,000	,496	,000	

* Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).



PHYDOM Physical domain

A = co-morbidity

p = 0.001, r = 0.527.

FIGURE 2A : SCATTERPLOT OF PHYSICAL DOMAIN VERSUS STROKE LEVITY (IBADAN).

Figure 2A shows the correlation between stroke levity and the physical domain scores. Some individuals with high stroke levity [mild stroke] had low physical functioning.

BERLIN

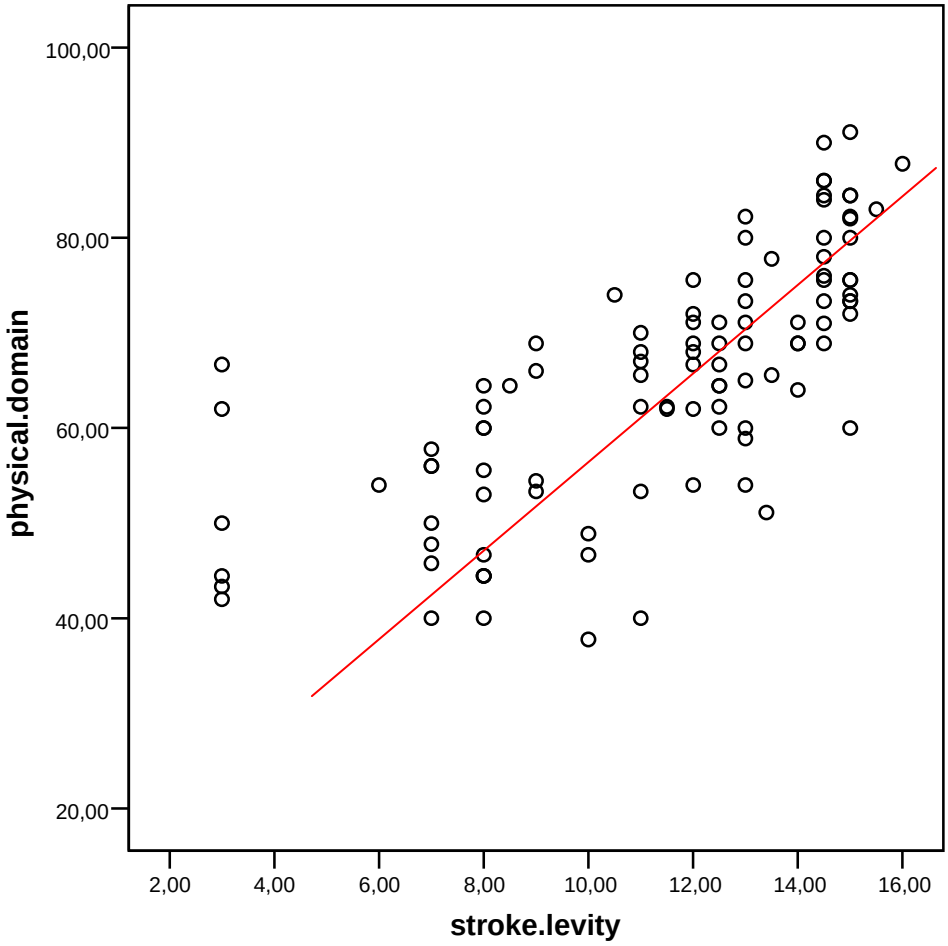
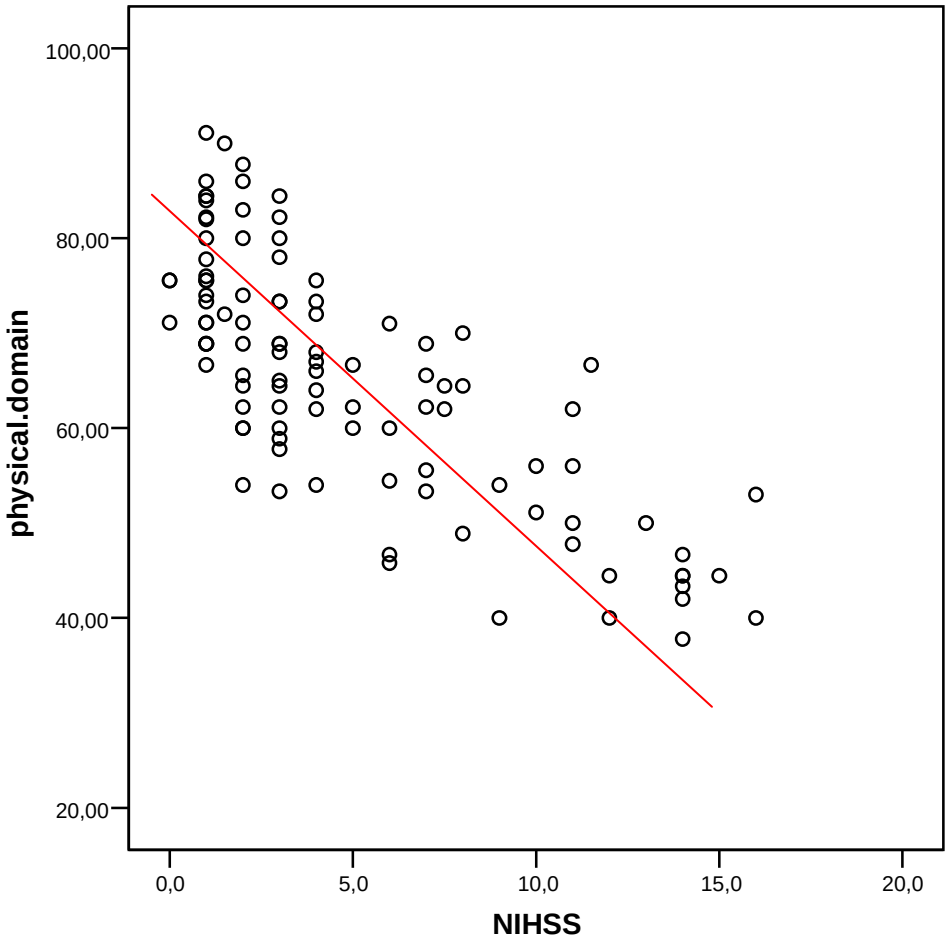


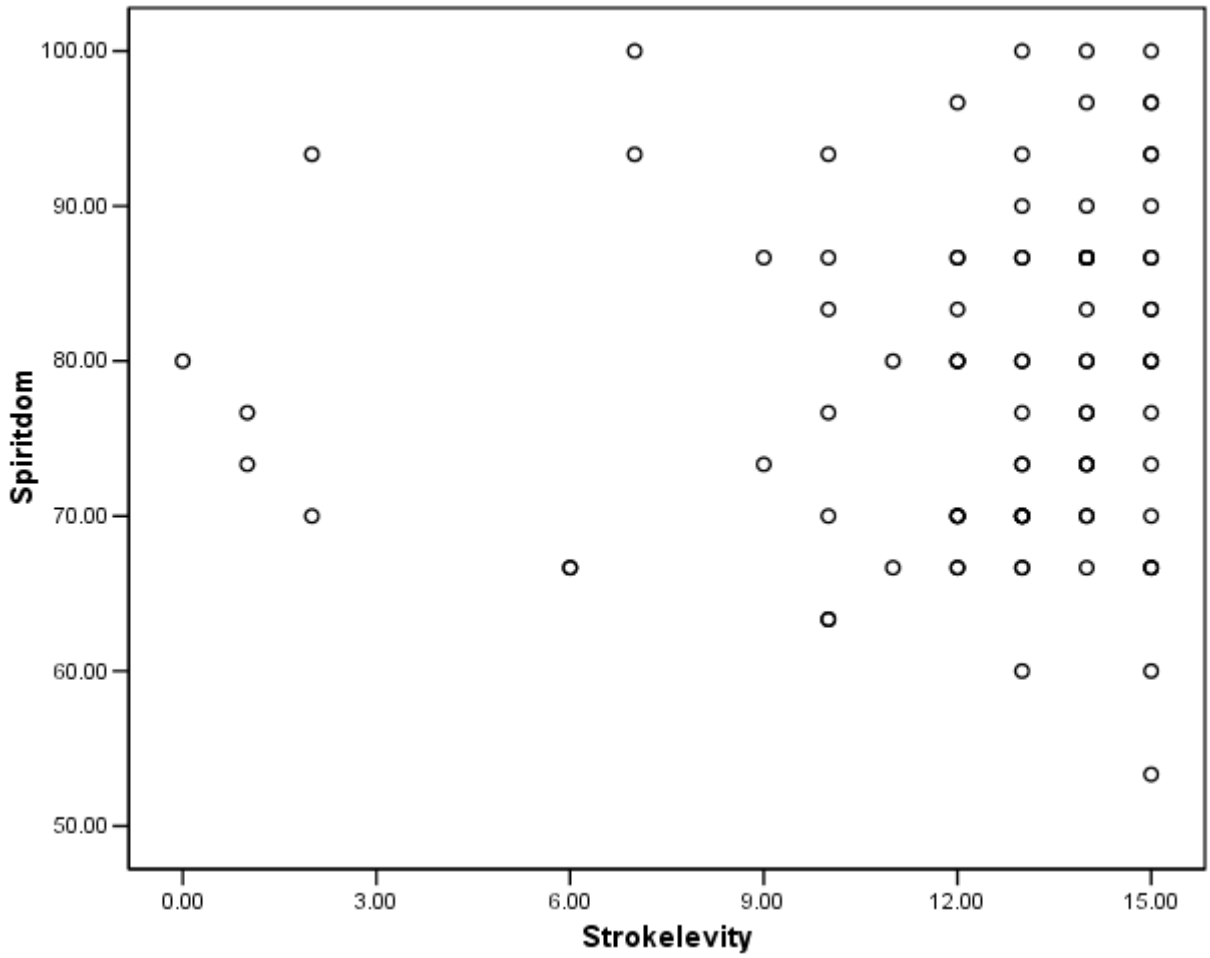
FIGURE 2B : SCATTERPLOT OF PHYSICAL DOMAIN VERSUS STROKE LEVITY (BERLIN)

p (two-tailed)< 0.0001, r =0.727 n = 103



SCATTERPLOT OF PHYSICAL DOMAIN VERSUS NIHSS SCORE (BERLIN)

p (two-tailed) = 0.000, r = -0.777 n = 103



B = Disability Paradox, Spiritdom = Spiritual domain, Strokelevity = Stroke levity

p = 0.661, r = 0 .047

FIGURE 3A: SCATTERPLOT OF SPIRIT DOMAIN VERSUS STROKE LEVITY.

(IBADAN)

Conversely, in Figure 3A, some individuals with low stroke levity [severe stroke] had good spiritual functioning. This is the phenomenon of **disability paradox**. In a cross-tabulation of spiritual domain and stroke levity, 5 patients had a stroke levity score of less than 50% and a spirit domain score of more than 75%.

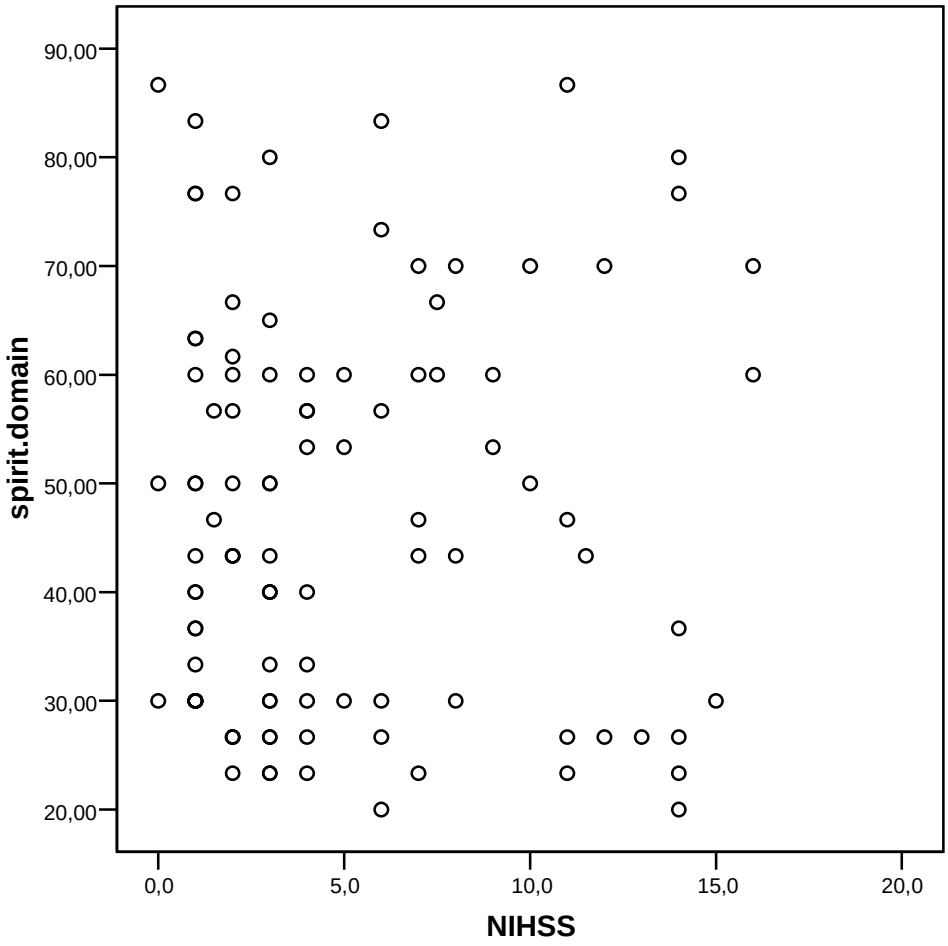


FIGURE 3B: SCATTERPLOT OF SPIRIT DOMAIN VERSUS STROKE LEVITY.

(BERLIN)

p (two-tailed) = 0.718, r = 0.036

3.4 DETERMINANTS OF HRQOL

In Ibadan, age correlated only with psychological domain [p =0.043, r = -0.215] and stroke levity [p=0.000, r = - 0.369]. Gender and aphasia had no significant effect on HRQOL. There was no statistically significant difference in HRQOL (sum and domain) and stroke levity, between the male and female stroke patients ($0.199 < p < 0.733$; $-1.298 < t < 1.270$). Type of stroke [by CT scan], side of body affected by stroke and number of strokes had no significant effect on HRQOL domains or HRQOL sum when subjected to Spearman's rank correlation, Student's t-test, and one-way ANOVA, respectively. Duration of stroke correlated only with spiritual domain [r = 0.358, p=0.001] and intellectual domain [r = 0.224, p = 0.047].

Predictors of domain HRQOL determined by stepwise multiple regression analysis are shown in Table 15A. Independent variables included in the model used for the analysis were age, gender, socio-economic class, negative feelings frequency, laughter frequency, stroke levity, social support, number of strokes and duration of stroke.

Stroke levity predicted both physical and intellectual HRQOL with higher scores occurring in milder stroke. Less frequent negative emotions predicted higher physical and psychological HRQOL whereas higher laughter frequency predicted better psychological, intellectual and spiritual HRQOL. A longer time period elapsed since the stroke event predicted better spiritual and social interaction HRQOL.

Social support was the strongest predictor of social interaction HRQOL. Socio economic class correlated with social support [p= 0.003, r= - 0.350] but had no significant effect on HRQOL.

In Berlin, handedness, admission status, side of the body affected, duration of first stroke, radiological extent of stroke and age had no statistically significant correlation to HRQOL (sum and domain), stroke levity and NIHSS score. However aphasia correlated with NIHSS (r = 0.359, p <0.0001), stroke levity (r = -0.273, p = 0.005), HRQOL-physical (r = -0.296, p =0.003) and HRQOL-intellectual (r = - 0.216, p =0.028). Neither atrial fibrillation nor diabetes mellitus correlated with HRQOL (sum and domain). Furthermore, diabetes mellitus did not correlate with stroke levity or NIHSS. The effect of gender is as previously mentioned and illustrated (Figure 1C).

Predictors of HRQOL determined by stepwise multiple regression analysis are shown in Table 15B. Independent variables included in the model used for the analysis were gender, age in years, occupation, marital status, tribe or race, stroke type, number of strokes developed, admission status, duration of first stroke in months, aphasia, negative feelings frequency, laughter frequency, physical means aggregate (adequacy of financial resources,

access to optimal medical services and social support), stroke levity, social support, socioeconomic class and relationship score (satisfaction with spiritual and personal relationships).

Although socioeconomic class correlated with the ecosocial domain ($p<0.00001$, $r = 0.381$), it had no significant impact on other domains nor HRQOL sum ($r = 0.041$, $p = 0.686$). The predictors of HRQOL-sum were relationships score, stroke levity, laughter frequency and number of strokes developed. Stroke levity predicted physical, psychological and ecosocial HRQOL, while laughter frequency predicted physical, intellectual and ecosocial HRQOL. Other predictors of domain-HRQOL are as shown in Table 15B.

TABLE 15 A : PREDICTORS OF DOMAIN HRQOL (IBADAN)

Domains	Predictors	T	p	Beta
Physical	Stroke levity*	3.18	0.005	0.52
	Negative emotions*	2.29	0.033	0.37
Psychological	Laughter frequency	4.82	0.000	0.48
	Negative emotions	3.80	0.000	0.38
Intellectual	Laughter frequency*	3.90	0.000	0.44
	Stroke levity*	2.52	0.015	0.28
Spirit	Laughter frequency*	2.05	0.045	0.25
	Duration of stroke*	2.18	0.033	0.26
Social Interaction	Duration of stroke*	3.29	0.002	0.42
	Social support	4.18	0.000	0.54

TABLE 15 B : PREDICTORS OF HRQOL (BERLIN)

HRQOL	Predictors	T	p	Beta
HRQOL sum	**Relationships score**	**10.52**	**<0.0001**	**0.640**
R =0.829	**Stroke levity***	**4.60**	**<0.0001**	**0.276**
R^2=0.678	**Laughter frequency**	**3.00**	**0.003**	**0.188**
Adjusted R^2 =0.674				
F=51.584				
p=0.000	**Number of strokes developed***	**-2.94**	**0.004**	**-0.176**
Physical	Stroke levity*	10.997	<0.0001	0.,689
	Laughter frequency*	3.344	0.001	0.215
	Number of strokes developed*	-3.357	0.001	-0.212
	Physical means aggregate*	2.649	0.009	0.164
Psychological	Negative feelings frequency	-6.014	<0.0001	-0.376
	Laughter frequency	6.898	<0.0001	0.416
	Stroke levity*	3.109	0.003	0.163
	Physical means aggregate*	3.139	0.002	0.162
	Tribe or race*(*non-German worse*)	-2.202	0.030	-0.120
	Relationships score*	2.713	0.008	0.148
	Gender* (*female worse*)	-2.431	0.017	-0.125
	Occupation*	2.197	0.031	0.119
Intellectual/Cognitive	Laughter frequency*	5.567	<0.0001	0.469
	Tribe or race* (*non-German worse*)	-2.660	0.009	-0.227
	Physical means aggregate*	2.424	0.017	0.208
Soul	Relationships score*	8.959	<0.0001	0.671
Spirit	Relationships score*	7.840	<0.0001	0.634
	Gender* (*female better*)	2.393	0.019	0.185
Ecosocial Interaction	Social support	5.502	<0.0001	0.339
	Stroke levity*	4.994	<0.0001	0.282
	Physical means aggregate	4.776	<0.0001	0.305
	Negative feelings frequency*	-2.747	0.007	-0.176
	Laughter frequency*	2.261	0.026	0.153
	Relationships score	3.063	0.003	0.178
	Number of strokes developed*	-2.096	0.039	-0.121
	Socioeconomic class*	2.016	0.047	0.126
Spiritual interaction	Relationships score	9.520	<0.0001	0.707
	Gender*(*female better*)	2.124	0.036	0.153

* Independent determinants

CHAPTER FOUR: DISCUSSION

4.1 DEMOGRAPHIC CHARACTERISTICS

The mean age of the Berlin stroke population of 67± 12 years is comparable to that of 68 ± 13 years obtained in a similar study of 405 stroke patients in Berlin.[104] The study population may therefore be regarded as representative of the Berlin stroke population. The Ibadan stroke population (age 60 ± 10 years) is however younger than that in Berlin but of similar age to the stroke population in London (62 ± 15 years). [105] While there were more females in the Ibadan stroke population (similar to that in a Polish study [91]), there were more males in the Berlin stroke population (similar to the previous Berlin [104] and Dutch studies.[111]These studies are hospital-based and may suffer selection bias. Because women tend to live longer (at least in Germany) and age is the strongest risk factor for stroke, if all stroke patients of all age strata are considered, overall there may be more females than males. Community-based studies are required to resolve this issue.

The project is a case control study with comparable age and sex between the Ibadan cases and the control population. There is no statistically significant difference between the ages of the two populations while the male to female ratios were equal to 2:3 in both populations. It is similar to the Auckland stroke study which was regarded as an age and sex matched case control study despite differences in age range and mean age between the stroke group and control group of normal adults.[98] Even though there is significant socioeconomic class [SEC] difference between the Ibadan stroke and control populations, SEC had no significant effect on HRQOL in the Ibadan stroke population. It was therefore appropriate to compare HRQOL among the normal population and patients with different severities [or levities] of stroke without necessarily adjusting for SEC differences.

In Berlin the matching of the age of the control and stroke populations was satisfactory as there is no statistically significant difference in age between the two populations. However the male to female ratios in the stroke and control populations were approximately 3:2 and 1:4, respectively. While gender had no statistically significant effect on HRQOL in the control group, it affected HRQOL in the study population. It was therefore necessary to adjust for gender differences while comparing HRQOL in the two populations. This was done firstly by using univariate ANOVA and secondly by comparing male patients directly with male controls only and female patients with female controls only. In addition the difference in monthly income, with the stroke population earning less (because less than 5% were working as against 12% of the control population) necessitated adjustment for SEC during comparison of the stroke and control populations in Berlin.

Whereas there were more unskilled workers in Ibadan, there were more pensioners in the Berlin populations. Half of the Ibadan stroke population had at least 12 years of education while about 60%

of the Berlin stroke population had at least 13 years education. While none of the stroke patients in Ibadan was a divorcee, 15 of the Berlin stroke patients were divorced. This is comparable to a 20% divorce rate in a London stroke population.[105] However whereas polygamy is practiced in Nigeria, monogamy is the rule in Western societies. While all the participants in Ibadan had religious affiliations, one quarter of the Berlin study group had no religious affiliation.

All the Ibadan stroke respondents were believers in God while most of them also believed in life after life. It was therefore necessary to assess this dimension of life in them; especially in this evolving era of patient-centered medicine and medical humanities.[52;57;112-115] In Berlin 63% of the stroke patients believed in God while 37% believed in afterlife and the spiritual dimensions (soul and spirit domains) assumed more importance in stroke patients compared to the control group (Table 10B). In a similar study in Chicago, faith in God was ranked the 2nd most important among 20 items by stroke patients.[15] This justifies the inclusion of these domains (as stipulated by the WHO and exemplified by the WHOQOL) in the HRQOLISP for use in both African and Western cultures.[52]

4.2 CLINICAL CHARACTERISTICS.

In Berlin 74 patients were in-patient while 29 received care at a day clinic. However, the status "in-patient" versus "day care" did not show any statistically significant effect on NIHSS, stroke levity, HRQOL-domain or HRQOL-sum (0.205 <two-tailed p < 0.948). In both stroke populations, the sides of the body involved were almost equal. This confirms that no side of the body is more prone than the other as shown in previous studies.[116] Stroke was recurrent in 16 % and 20% of the Ibadan and Berlin cases, respectively. A rate of 20% was also previously reported in a study of 405 stroke patients in Berlin.[104] This supports the fact that recurrent stroke (stroke a risk factor for stroke) is common in stroke survivors.[13; 14; 17]

As previously documented worldwide, hypertension and age were the commonest risk factors.[13-15; 17; 117] Ninety-nine percent of the Ibadan subjects were hypertensive with a blood pressure of $\geq$ 140/90 mmHg. Hypertension was found in 58-80% of stroke patients in 1973-75 in Ibadan, using a higher cut-off point of 160/100mmHg.[13] Hypertension was also documented in 79% of stroke cases in a retrospective study in Maiduguri (in Nigeria) using a cut-off value of 160/95mmHg.[118] Even in those below 45 years of age with stroke, hypertension was documented in agreement with a study on stroke in young Nigerians.[41] In Berlin 83% of the patients were hypertensive and 99% were at least 45 years old.

In Nigeria, age was also a very strong risk factor as up to 84% of cases were more than 44 years old. This is similar to what is reported in literature.[17; 28] In both males and females, stroke was commonest in the 7th decade of life followed by the 6th decade in agreement with previous documentation of 7th and 6th decades in Ibadan.[14] In Berlin, stroke was commonest in the 8th decade followed by the 7th

decade. In the Auckland and Swedish stroke studies, the mean ages of stroke cases were 71 and 74.3 years respectively, both within the 8th decade.[99;119] The higher decade of occurrence may be due to the facts that age is a strong risk factor for stroke and life expectancy is longer in Europe with people living longer enough to experience stroke!

In the Ibadan study, male to female ratio was 2:3 in contradistinction to 3:2 to 3: 1 earlier reported in Nigeria.[14;98]. However, female predominance has been reported in stroke survivors in Chicago and Melbourne.[15; 120] Furthermore, there was male predominance in the Berlin study group. It is therefore difficult to conclude that there is gender predilection for stroke occurrence.

Other risk factors identified were diabetes mellitus [16%], excessive alcohol consumption [14%], obesity [10%], hypertensive heart disease [9%], hyperlipidemia [1%], Transient Ischemic Attack [1%], and cocaine [1%]. The frequencies of these risk factors are similar to earlier studies in Nigeria.[14; 28; 98] However cigarette smoking (23% versus nil), hyperlipidemia (38.8% versus1%), atrial fibrillation, ischemic heart disease and arterial disease were strikingly commoner in Berlin than in Ibadan (Table 6). While it may be argued that not all the stroke patients in Ibadan were screened for hyperlipidemia, the higher frequencies of these risk factors is compatible with what has been reported in Western communities.[104 ;121] The difference in the risk factorology of stroke between the two countries may be accounted for by genetic, dietary and cultural (eg smoking) variables.

In Ibadan, using the WHO criteria for classification (with a sensitivity of about 70% in Nigeria[46]), 30% had ischemic stroke, 23% had hemorrhagic, while the stroke type was indeterminate in 47% due to poor recall of peri-ictal details by the patients and / or insufficient data in the case notes. The unclassified group in the Ibadan study was 24.2%.[13] Taking the classified group alone, ischemic stroke formed 56.6% which is different from previously reported values of 63% in Maiduguri and Ibadan.[19;118] However brain CT scan showed cerebral infarction in 10 [63%] and hemorrhage in 6 [37%] subjects. The CT scan did not show any other lesion apart from stroke in any of the patients. This means that there were no cases of misdiagnosed stroke in the CT scan group, and by extrapolation, the study group. There was no significant correlation between CT type and WHO type [p=0.631]. This may be due to poor recall of peri-ictal details. Therefore, the WHO stroke scale has reduced ability for sub-typing stroke in retrospective assessments. Considering the agreement of demographic parameters of the stroke patients with previous records in the Nigerian environment, the study population can be said to be representative.

On the other hand, in Berlin, all the patients had radiological assessment (MRI and/or CT) which showed primary ischemic stroke in 80% and infarcts with secondary hemorrhagic transformation in 6%.Whereas 3% had both hemorrhage and infarct at different sites, the remaining 11% had primary hemorrhagic stroke only. A previous study in Berlin showed ischemic stroke in 93% of 405 stroke patients with 7% having hemorrhagic stroke.[104] Other western studies have shown hemorrhagic

stroke proportions ranging between 10.6 and 15%.[116; 119,120] It is therefore clear that hemorrhagic stroke is commoner in Nigerians and probably in blacks.[11-14; 19] This may be due to the higher frequency of hypertension which is commonly undiagnosed and uncontrolled due to lack of resources (manpower and materials).

The fact that only 2 patients in Berlin had thrombolytic therapy is compatible with findings in other industrialized countries.[95] None of the Ibadan patients had thrombolytic therapy.

Majority [80% in Ibadan, 68% in Berlin] of the subjects had mild stroke [Table 6]. This was determined using the stroke levity score which was designed in 2004 by the author as a time-saving reciprocal measure of stroke severity. It is based on the Motor Research Council power scale in the dominant arm and affected leg, mobility and presence of aphasia. The importance of concordance (dominant hand = paretic arm) has been pointed out in a recent (2005) publication.[116] The high correlation of stroke levity (n =103, R = -0.802, 2-tailed p = 0.000) to the NIHSS attests to its validity. The mean NIHSS score of 5 .0 $\pm$ 4.4 in Berlin in this study, is similar to a mean NIHSS score of 6.1 $\pm$ 4.9 earlier reported in stroke patients in the city.[104] In the Kansas City study, 33 of 91 subjects had minor stroke while the remaining 58 subjects had moderate stroke. However, the criteria for classification were not stated.[73] The absence of statistically significant difference in stroke levity between the Ibadan and Berlin stroke populations would make it easier to compare the two.

Aphasia was reported in 31% of cases in Ibadan and 38% in Berlin. This is similar to a rate of 35% reported in Melbourne.[120] Language disorder was reported in 37% of 72 cases studied in Indianapolis.[7] Aphasia (in Ibadan ad Berlin) was mild in most cases as the interview could be conducted meaningfully with most patients without the need for a proxy. Post-stroke sexual dysfunction was common in both cities in agreement with reports elsewhere.[122]

Thirty-two percent of the Ibadan patients had mobility problems. This is similar to 31% reported in the Indianapolis study.[7] However only 60% of the Berlin stroke patients could walk alone with or without aids. Sexual dysfunction (or absence of sex) was disclosed in 45% of cases in Ibadan and 79% in Berlin. This is similar to earlier reports in literature, even in the elderly.[15; 123] Negative feelings [e.g. fear, anxiety, depression, anger, despair] were present in 75% of cases in Ibadan and 68% in Berlin. Up to 19 -30% of stroke patients have been found to present with clinical depression alone.[7; 15; 124] However the HRQOLISP-psychological encapsulated the entire spectrum of post-stroke emotional disorders (PSED), hence the higher percentage of stroke patients affected.[125]

Stroke is a major cause of disability as in Ibadan only 20% were reportedly back to work; 26% were independent but not back to work, while 54% were dependent [Table 8].[7] In Berlin only 5 patients were back to work while majority were pensioners. Hackett also reported greater than 50% dependence in stroke patients.[99]

4.3 INSTRUMENT'S PSYCHOMETRIC PARAMETERS AND HRQOL PROFILE

4.3.1 Administration and Importance Rating

The instrument [102 items in 7 domains] is stroke-specific, developed by patient involvement, and expected to be more valid, reliable, patient-centered, responsive and sensitive compared to generic measures.[7;15;53;67;70;76;80] However, the long completion time and large number of questions account for high respondent burden and sometimes missing responses.[53] The completion time is shorter than that of the SIP which has 138 items.[53] Since the mode of administration in both the control and study populations generally had no statistically significant effect on HRQOLsum or domain HRQOL score, the instrument is likely to retain its psychometric parameters regardless of the mode of administration.[53]

The instrument was generally acceptable to the respondents in both countries. They found it helpful, good, alright, uplifting, thought-provoking, and interesting despite being lengthy. In Ibadan, most domains were rated as very important or extremely important. In Ibadan, the spirit domain was rated most important by both stroke and control subjects. It was rated higher by the stroke group.[51] This is similar to the high ranking given to faith in God by Chicago and Polish stroke patients.[15; 100] In Berlin, the soul domain was rated higher by the stroke patients than by the control group in spite of the generally lower ranking of the spiritually-oriented domains. Furthermore, the internal consistency reliability for the instrument including the spiritual dimensional domains was 0.724 and fulfills the Nunnaly´s criterion.

The fact that the spirit domain was rated as very important by the patients is quite note-worthy, especially in this evolving era of patient-centered medicine. Hence medical treatment will be incomplete without sufficient attention, or in fact, paramount attention to this domain. The spirit-soul domain is the harmonizing and atoning [at-one-ment] principle between the psychological/intellectual body [emotion/reason] conflict/duality.[55; 112]

Beyond the outmoded reductionist view of hard scientific rationality, and beyond religion, is the winged reality and spiritual intelligence which is necessary for multi-dimensional and complete diagnosis and patient care. This is the artistic part of medicine, which even though metaphorical, can be acquired through patience, communication skills and psychodramatic learning from the full experience of the patient.[57; 112] In this paradigm, the doctor may complement healing by maximizing the patient-doctor interaction.[57; 112-114; 126]

Spiritual intelligence in this context is the intelligence, science and brilliance directed towards the establishment and improvement of the patient´s self-discovery, self-realization, self-actualization of a

purpose in life and achievement of transcendence in spite of or in consonance with his/her physical circumstances.

4.3.2 Reliability and Content Validity

Cronbach's alpha, a measure of internal consistency reliability, varied from 0.721 to 0.849 in Ibadan (Table 10A) and from 0.772 to 0.924 in Berlin (Table 10B). It therefore meets Nunnaly's criterion of 0.7.[65] This is similar to previous reports in stroke-specific measures.[7; 73; 82] Its internal consistency reliability profile is however better than that of the NEWSQOL, SAQOL-39 and SIS.[73; 82; 101; 105] This is most likely due to its distinctive conceptual model.[64; 127; 128]

The instrument showed no significant floor or ceiling effect. Absence of floor and ceiling effects improves validity. The measure would be able to assess the worst and the best health state possible and detect small improvements and deterioration.[52; 53]

The instrument has good content and face validity since it contains the stroke-specific items such as mobility, upper extremity function, work/productivity, mood , self-care, social roles, family roles, vision, language, thinking and personality. These stroke-specific items are mentioned in Section 1.8.1 of this thesis and discussed by Salter.[56] In fact, no additional item was suggested by the 203 stroke respondents.[53; 72] Hence, it is expected, like other stroke-specific measures, to be more valid and sensitive for stroke patients than generic measures such as the SF-36 which has poor validity in the social domain.[7; 65; 74] However, prospective studies are required to verify this.

4.3.3 Discriminant Validity Between Stroke and Control Groups

The instrument exhibited good discriminant validity between the stroke and control groups in all domains except in the soul domain (male only, female only Berlin), spirit domain (Berlin) and the spiritual interaction domain (Ibadan and Berlin). [Tables 11A and B, and Figures 1A and B]. The absence of significant difference between the stroke and study populations in these domains rather than implying poor discriminant validity, may actually imply that the spiritual dimension is relatively spared in stroke patients. This is similar to what was reported in a Canadian study of 339 stroke survivors in whom autonomy and purpose of life dimensions were spared and which illustrates the so-called phenomenon of disability paradox.[88] In summary, in both Ibadan and Berlin, the questionnaire exhibited its discriminant validity between stroke and normal respondents more robustly in the physical, psychological (emotional), ecosocial, intellectual domains and HRQOLsum.

4.3.4 HRQOL Profile

The mean values for the control populations in Nigeria and Germany were almost exactly equal in the physical domain, psychological domain and social interaction domains, and perhaps not significantly different in the intellectual domain. The arithmetic differences in these physical-dimensional domains' scores between the control and stroke populations in both countries were greater than the

differences between the controls in both countries. The instrument is not culture sensitive in domains where a real/ actual difference is not necessarily expected between Nigerians and Germans. (Tables 11A and B).

However, the arithmetic differences between the control population in the two countries in the spirit, soul and spiritual interaction domains are clearly greater than that between stroke and normal populations in both countries. Therefore the HRQOL-sum and domain scores in the spiritually-related domains are higher in Nigerian stroke patients. And this is real because religious status and spiritual beliefs were also clearly different between the two populations (Tables 11A and B). This difference found in HRQOL in the spiritual dimension between Ibadan and Berlin cannot be ascribed to socioeconomic class (SEC) differences as SEC had no impact whatsoever on the domains in this dimension.

The physical, psychological and soul domains were the most affected in Ibadan, while the physical, social and psychological domains were the most affected in Berlin (Tables 12A and B). The spirit and spiritual interaction domains were generally better preserved. This tallies with involvement of activities of daily living, bathing, walking, meal preparation, cognitive and social disability with sparing of autonomy and purpose of life described by Clarke in Canada who used the Ryff measure of psychological wellbeing and the Mini Mental State Examination.[88] Anderson in Australia also described physical, mental and social disability using the SF-36, the Adelaide Activities Profile, the Barthel Index and the General Health Questionnaire 28.[65] This is further supported by studies in Indianapolis, Kansas City and Auckland in which various aspects of physical, cognitive and social dysfunction were described.[7;72;79;101] The same fact is buttressed by previous studies on HRQOL profile in stroke patients Berlin,[104] Hessen,[103] France,[129] Sweden,[119] Turkey,[130] Finland,[131] Ohio,[116] and elsewhere.[132-136]

In concordance with previous studies, HRQOL was generally high and comparable to normals, and unaffected in the spiritually-based domains.[15;49;90;91;94;99;119;137] This may be due to the fact that the majority of patients had only mild stroke. Other plausible explanations are the development of coping strategies [perception, expectations, social support] over time, response shift [changes in the QOL resulting from changes in internal standards, values and conceptualization] and the phenomenon of natural selection of the fittest as the survivor cohort.[15;49;90;91;94;99;138] People are able to enlarge themselves in relation to injury and grow new ways of being even when the body may not be able to grow another part.[49]

The sparing of quality of life in the spiritual-dimensional domains could also be related to the ‘onion theory of happiness’ concerning the preservation of general life satisfaction in stroke patients.[100] It is also good news because it can then provide support, healing and initiation of positive adjustments for the other aspects of life in order to maintain purposeful and meaningful life despite the stroke-induced

physical impairment. However this spiritual-resource base appears to be richer in Ibadan than in Berlin and in females than in males (Tables 11A and B, Fig 1C).

4.3.5 Construct Validity

In Ibadan, stroke levity discriminated domain scores except in spirit, social interaction and soul domains. In Berlin stroke levity and NIHSS discriminated HRQOL (domain and total scores) except in intellectual, spirit, soul and spiritual interaction domains [Table 13 B and 13C]. Hence the instrument has its best discriminant validity in both sites among various severities of stroke in the physical and psychological domains, and partly in the ecosocial interaction and intellectual domains. This good discriminant validity could be due to its stroke-specific nature and good content validity.

Furthermore, stroke levity (Ibadan and Berlin) and NIHSS (Berlin) correlated with physical domain, psychological domain, intellectual domain and social interaction domains which have similar constructs. This proves the construct validity of the HRQOLISP. Moreover, this pattern is similar to relationship between paralysis and functioning described in other studies.[15;72;123;132;139] The inter-domain correlation pattern and the relationship between stroke severity and the domains demonstrate convergent validity among the physically-based domains and spiritually-based domains; and discriminant validity between the two groups of domains (Tables 14A and B, Figures 2A,B and C, 3A and B). This, in consonance with the phenomenon of disability paradox, validates the duality model of man (spiritual and physical dimensions) utilized in this study.[138]

The correlation between the soul domain [including purpose of life] and intellectual domain is similar to that observed by Clarke.[88]

As shown in Figure 2A, some individuals with high stroke levity [mild stroke] had low physical functioning. This may be due to other illness[es] apart from stroke [e.g. hypertension and diabetes mellitus] which may coexist with stroke. Conversely, in Figure 3A, some individuals with low stroke levity [severe stroke] had good spiritual functioning. This is the phenomenon of disability paradox.[138] It is also illustrated by the sparing of the relative spiritual dimension.This paradox could be attributed to increased prioritization of existential, spiritual issues by the patients, as was demonstrated in this study.[138] This is the situation of a willing spirit in a weak body and a perishing outward man with the renewing inward man.[139] This again supports the dual nature of being and existence of man, the double helical nature of man [sense and 'antisense']. This study therefore presents the model ['doctrine of man'] required by the medical faculty to fulfill its theoretical task.[57]

4.4 DETERMINANTS OF HRQOL

4.4.1 Factors With Variable Impact on HRQOL

This is the first transnational study of determinants of HRQOL in stroke patients using a stroke-specific measure. Whereas in Ibadan, increasing age correlated with worse psychological domain [p =0.043, r = -0.215] and severe stroke, it did not emerge as an independent predictor of HRQOL in the regression analysis. In Berlin, age neither correlated with HRQOL (and NIHSS) nor predicted HRQOL. Even though age has been reported as a predictor of HRQOL using the SF-12 in a cohort of stroke and TIA patients in Berlin, reports of other studies have not consistently confirmed this.[15;79;88;99 ;100 ;104 ;116;120 ;130 ;131 ;137] At best, age cannot be conveniently and consistently said to be a strong predictor of HRQOL in stroke patients.

Even though in Ibadan gender had no significant effect on HRQOL, female stroke patients in Berlin had better HRQOL in the spirit and spiritual interaction domains than their male counterparts. However, gender was not reported as a predictor in the previous Berlin study which utilized an instrument without spiritual-dimensional domains.[104] While some studies did not report gender as predictive of HRQOL, some have reported male sex as a predictor of better global or physical HRQOL while others have reported female sex as a predictor of better global HRQOL.[99;103;130 ;137;141-143] Further studies using comparable instruments and methodologies are required to clarify the effect of gender on different domains of HRQOL. Similarly, the impact of socioeconomic class on HRQOL is variable.[133]

In Berlin even though aphasia correlated with physical and intellectual HRQOL, it neither correlated with nor predicted HRQOL-sum. In Ibadan, aphasia neither correlated with nor predicted HRQOL. Previous studies have also reported no correlation between aphasia and HRQOL.[15; 139] Rigorous studies using proxy-validated instruments are required to assess the impact of different grades of aphasia on specific domains of HRQOL that pertains to communication capability.[15; 49; 138]

There are conflicting reports about the impact of post-stroke duration on HRQOL. A study reported worsening in HRQOL over time, despite stable neurological function.[103] The effect of rehabilitation on HRQOL was studied by Hopman and Aprile.[144] Substantial gains during in-patient care were followed by significant declines after discharge.[86] In Ibadan, the correlation between duration of stroke and spiritual and intellectual domains may be due to response shift and coping strategies which are developed over time.[15; 49; 138] Prospective studies are required to confirm this finding.[145-147]

In both Ibadan and Berlin, the type of stroke, the side of the body affected, handedness and radiological extent of the stroke demonstrated no relationship to HRQOL. Previous studies have also reported no correlation between infarct volume and activities of daily living;[148] as well as HRQOL

and side of the lesion.[15;79;88 ;99 ;100 ;104;116 ;120;130;131;137] Similarly, no consistent relationship has been demonstrated between depression and stroke site. Robinson reported anterior left hemispheric lesion as a clear risk factor for post-stroke depression,[125] perhaps because of aphasia and dominant hand dysfunction (disability). Conversely, Hackett in a review article showed that most studies documented that stroke site had no effect on depression, while 1 out of 9 studies reported left hemispheric predisposition and 2 out of 5 documented right hemispheric predilection.[149] To the best of my knowledge, no study has conclusively reported stroke type as a predictor of HRQOL.[15;79;88;99;100 ;104;116 ;120;130;131;137]

In this study, neither diabetes mellitus nor atrial fibrillation predicted HRQOL. Previous studies have not uniformly reported them to be consistent predictors of HRQOL.[15;88;99 ;100;103;104;116;119;120;150]

Whereas increased number of stroke predicted worse HRQOL in Berlin, this was not found to be the case in Ibadan. And previous studies have not found significant effect of number of stroke on HRQOL.[130]

4.4.2 Factors With Consistent Impact on HRQOL

Stroke levity, a reciprocal index of stroke severity, was a strong predictor of HRQOL in both Ibadan and Berlin. This is consistent with other studies which have consistently reported stroke severity and functional capacity as strong predictors of HRQOL.[15;100;104;116;120;132;134;151;153]

Negative emotions/feelings, and laughter frequency were predictors of HRQOL in both Ibadan and Berlin. The effect of depression per se, was not directly examined in this study. However, emotion and particularly depression has been reported as a predictor of HRQOL in stroke patients.[100;103;119 ;130;131;150] Social support correlated with HRQOL. It was however not investigated as an independent predictor in this study. The strongest predictors found by King et al. and Dorman et al. in separate studies were depression and social support.[15;72] Satisfactory personal and spiritual relationships were found to have a significant effect on HRQOL. This is consistent with the finding of King et al that faith in God and relationship with the spouse are highly valued (ranked) by stroke survivors.[15]

In summary, the consistent predictors of HRQOL are stroke levity, laughter frequency (and negative feelings frequency); and satisfactory relationships (including family and social support).

Thus, aside from stroke levity and disability, psychosocial factors such as emotional responses and social support determined HRQOL in stroke survivors. Conventionally, neuroscience of recovery from stroke as well as clinical acute care and neurorehabilitation, all focus on motor, cognitive and speech impairment and disability. Post stroke emotional disturbances (PSED) [125] might, however, be similarly relevant. Little is known about the epidemiology and effective treatment of PSED,[153] their neurobiological (lesion or disconnection) characteristics and psychoreactive determinants, and their

role in post-stroke functional cerebral reorganization (e.g., via motivational/demotivational factors) and social reintegration.[149; 154] Thus, the presented epidemiological data from Ibadan and Berlin suggest that both neuroscience and clinical management of stroke might benefit from a corresponding broader integrative conceptual framework for life after stroke.

4.5 CONCLUSIONS

1. The HRQOLISP has good face, content, construct, convergent and discriminant validity and internal consistency reliability in both countries. It has no significant floor or ceiling effect.
2. Stroke levity score is a valid time-saving reciprocal measure of stroke severity.
3. Stroke, even in mild cases, has a multidimensional effect on quality of life.
4. Stroke, in a manner proportional to its severity (or levity), affects mainly the physical, psychological, intellectual and social interaction domains, while relatively sparing the soul, spirit and spiritual interaction domains.
5. The HRQOL profile of stroke patients in Ibadan is better in the soul, spirit and spiritual interaction domains than in stroke patients in Berlin.
6. The HRQOL profile of female stroke patients in Berlin is better in the spirit and spiritual interaction domains than in their male counterparts.
7. The consistent predictors of HRQOL are stroke levity, laughter frequency (and negative feelings frequency), and satisfactory relationships (including family and social support).

4.6 RECOMMENDATIONS

1. The HRQOLISP should be subjected to further tests in larger studies to determine its sensitivity and responsiveness, and proxy validity. Item reduction is also desirable (after factor analysis) to reduce respondent burden while maintaining psychometric suitability. The instrument should be translated and back-translated to many languages for use in Nigeria and worldwide.
2. The instrument could be used to determine utility for stroke, DALYs, QALYs, for cost-utility, cost-benefit, and cost-effectiveness studies and health planning for stroke rehabilitation strategies.
3. Stroke levity score is recommended as a time-saving instrument for assessing stroke severity.
4. A holistic multidimensional approach is required in stroke rehabilitation.
5. The sparing of the spiritual dimension of HRQOL and its higher importance rating in stroke patients can be exploited to provide support, healing and initiation of positive adjustments for the other aspects of life in order to achieve and maintain purposeful and meaningful life despite the stroke-induced physical impairment.

6. Primary prevention and early and appropriate treatment of stroke to salvage the ischemic penumbra and mitigate its severity, family and social support and emotional therapy would improve quality of life in stroke patients.

5.1 SUMMARY

BACKGROUND: Stroke is a common cause of morbidity and mortality globally.[2] In developing countries like Nigeria, stroke is not only a major cause of mortality but also a major cause of disability and morbidity.[19;29;41;97] In published Caucasian studies, stroke principally affected physical and cognitive functioning and led to dependency in patients with the severe type.[7;71;78;100] No cross-cultural comparative study using a psychometrically robust stroke-specific measure in a developing country and in an industrialised country has been previously carried out by the same investigator to identify the profile and predictors of HRQOL in stroke patients. Such a study is necessary to provide us with information on how to improve the HRQOL of increasing numbers of stroke survivors and plan rehabilitative care in both settings.

It was hypothesized that man's life consists of physically-based and spiritually-based domains and that stroke would affect quality of life in multiple domains in a predictable fashion. The objectives of the study were to translate (into German), adapt and revalidate a new stroke-specific psycho-metrically robust HRQOL measure (the HRQOLISP) developed in Nigeria and to apply it to determine the profile and predictors of HRQOL in stable German stroke patients while comparing scores in different domains of quality of life in both countries.

METHODS: One hundred patients in Ibadan and 103 patients in Berlin who suffered from a stroke at least one month before the interviews, and could communicate reliably or had reliable proxies were recruited for the study. Those who had other co-morbid medical conditions apart from documented risk factors or complications of stroke were excluded. The Ibadan arm was carried out between 2002 and 2004 while the Berlin arm was carried out between 2005 and 2006.The questionnaire was also administered to control groups of one hundred (in Ibadan) and 50 (in Berlin) healthy adults with comparable age and sex. Stroke levity score and NIHSS were used as indices of stroke severity while the WHO stroke scale was used to classify stroke in Ibadan.

RESULTS: Most of the patients had mild stroke. Aphasia was present in 31% (Ibadan) and 38% (Berlin) while negative emotions were reported in 75% (Ibadan) and 68% (Berlin). The instrument [102 items in 7 domains] had Cronbach's alpha of greater than 0.70 in all domains in both stroke populations. It was able to discriminate between stroke and normal subjects especially in the physical, psychological, intellectual and social domains. It had good discriminant validity between different levities of stroke in the physically-based domains. The spirit domain was rated most important by stroke and normal subjects in Ibadan, and higher in Berlin stroke patients than the control group. Stroke levity, a newly-designed reciprocal index of stroke severity correlated well with NIHSS ($r = -0.80$, $p<0.0001$).

In comparison to the control groups, stroke had a multidimensional effect on HRQOL, most prominent in the physically-based domains (physical, psychological, intellectual, and social) with relative sparing of the spiritually-based domains. Stroke levity and NIHSS correlated with the physically-based domains but not with the spiritually-based domains. The HRQOL profile of stroke patients in Ibadan was better in the soul, spirit and spiritual interaction domains than in stroke patients in Berlin. The HRQOL profile of female stroke patients in Berlin was better in the spirit and spiritual interaction domains than in their male counterparts.

The consistent predictors of HRQOL were stroke levity, laughter frequency (and negative feelings frequency), and satisfactory relationships (including family and social support).

CONCLUSIONS: The HRQOLISP has good face, content, construct and discriminant validity and internal consistency reliability in both countries. Stroke levity score is a valid and time-saving reciprocal measure of stroke severity. Stroke, even in mild cases, has a multidimensional effect on quality of life which is most pronounced in the physical dimension. The consistent predictors of HRQOL were stroke levity, laughter frequency (and negative feelings frequency), and satisfactory relationships (including family and social support).

The sparing of the spiritual dimension of HRQOL and its higher importance rating in stroke patients may be exploited to provide support, healing and initiation of positive adjustments for the other aspects of life in order to achieve and maintain purposeful and meaningful life despite the stroke-induced physical impairment.

5.2 ZUSAMMENFASSUNG

"Ibadan-Berlin interkulturelle Vergleichstudie von Lebensqualität bei Schlaganfallpatienten unter Nutzung eines neuen krankheitsspezifischen Messinstrumentes (HRQOLISP)"

HINTERGRUND: Der Schlaganfall ist weltweit einer der häufigsten Ursachen von Morbidität und Mortalität.[2] Auch in Entwicklungsländern wie Nigeria ist ein Schlaganfall nicht nur eine Hauptursache von Mortalität, sondern auch von Behinderung und Morbidität.[19;29;41;97] Nach veröffentlichten Studien an Kaukasiern beeinträchtigt ein Schlaganfall hauptsächlich körperliche und kognitive Funktionen und führt bei Patienten mit schweren Insulten zu einer Abhängigkeit von anderen.[7;71;78;100] Eine direkte interkulturelle Vergleichstudie mit paralleler Datenerhebung in einem Entwicklungsland und in einem industrialisierten Land unter Einsatz eines psychometrisch robusten Schlaganfall-spezifischen Fragebogens mit dem Ziel, das Profil und die bestimmenden Faktoren von gesundheitsbezogene Lebensqualität festzustellen, ist bislang noch nicht durchgeführt worden. Solch eine Studie wäre notwendig, um uns darüber zu informieren, wie man die Rehabilitation entsprechend

der kulturellen Besonderheiten spezifisch planen kann und so die gesundheitsbezogene Lebensqualität von Schlaganfallüberlebenden möglichst optimal fördern kann.

Die vorliegende Studie basiert auf der Annahme, dass das menschliche Leben eine körperliche und eine spirituelle Dimension hat und dass ein Schlaganfall die Lebensqualität in mehreren Bereichen beeinträchtigen in einer vorhersagbaren Art und Weise beinträchtigen kann. Die Zielsetzungen der vorliegenden Studie waren

(a) die Übersetzung (ins Deutsche) eines neuen psychometrisch robusten schlaganfallspezifischen gesundheitsbezogenen (HRQOL) Lebensqualitätsfragenbogen, (HRQOLISP), der in Nigeria entwickelt wurde,

(b) die Adaptation und Validierung der deutschen Version und

(c) die Anwendung des Fragebogens bei einem deutschsprachigen Studienkollektiv, um das Profil und die bestimmenden Faktoren für gesundheitsbezogene Lebensqualität bei deutschen Schlaganfall-patienten festzustellen, und

(d) die Ergebnisse in den unterschiedlichen Bereichen der Lebensqualität in beiden Ländern zu vergleichen.

METHODEN: 100 Patienten in Ibadan und 103 Patienten in Berlin, die mindestens einen Monat vor Studieneinschluss einen Schlaganfall erlitten hatten und kommunizieren konnten oder auskunftsbereite Angehörige mit einer engen persönlichen Beziehung hatten, wurden in die Studie eingeschlossen. Patienten, die andere schwere Erkrankungen (Komorbidität) mit Ausnahme von dokumentierten Risikofaktoren oder Komplikationen des Schlaganfalls hatten, wurden ausgeschlossen. Der Íbadan Teil der Studie wurde zwischen 2002 und 2004 durchgeführt. Der Berlin Teil wurde zwischen 2005 und 2006 durchgeführt. Der Fragebogen wurde auch von Kontrollpersonen (100 in Ibadan, 50 in Berlin) ausgefüllt. Dabei handelte es sich um gesunde Probanden mit vergleichbarem Alter und Geschlecht. Ein „Schlaganfall-Erholungs-Score“ und der NIHSS wurden als Indizes für die Schwere eines Schlaganfalls erhoben, die WHO Skala wurde verwendet, um Schlaganfälle in Ibadan zu klassifizieren.

ERGEBNISSE: Die meisten Patienten hatten einen leichten Schlaganfall. Eine Aphasie wurde in 31% (Ibadan) bzw. 38% (Berlin) der Patienten beobachtet, negative Gefühle wurden in 75% (Ibadan) bzw. 68 % (Berlin) berichtet. Das Instrument [102 Einzelfragen] und seine 7 Teilbereiche zeigten eine ausreichende interne Konsistenz (Cronbachs > 0,70 in allen Bereichen bei beiden Schlaganfall-gruppen). Es konnte zwischen Schlaganfallpatienten und normalen Probanden besonders im körperlichen, psychologischen, intellektuellen und sozialen Bereich unterscheiden. Es hatte eine gute diskriminierende Validität für unterschiedliche Schweregrade des Schlaganfalls in den körperlichen

Lebensqualitätsbereichen. Der seelische / spirituelle Bereich war für Schlaganfallpatienten und normale Probanden in Ibadan besonders wichtig und von höher Wichtigkeit bei Berliner Schlaganfallpatienten im Vergleich zur gesunden Berliner Kontrollgruppe. Der „Schlaganfall-Erholungs-Score“ („stroke levity score“), ein neu-entworfener reziproker Index der Schlaganfallsschwere, korrelierte gut mit dem NIHSS ($r = -0.80$, $p<0.0001$).

Im Vergleich zur gesunden Kontrollgruppe hatte ein Schlaganfall-Ereignis einen mehrdimensionalen Effekt auf den HRQOL, am stärksten in den direkt körperlich begründbaren Bereichen (neurologisch, psychologisch, intellektuell und sozial) bei einer relativen Unversehrtheit der seelisch-spirituellen Bereiche. Der „Schlaganfall-Erholungs-Score“ („stroke levity score“) und der NIHSS korrelierten mit den körperlichen Bereichen, aber nicht mit den seelisch-spirituellen Bereichen. Das HRQOL Profil der Schlaganfallpatienten in Ibadan war in den Bereichen „Seele“, „Geist“ und „spirituelle Interaktion“ besser als bei Schlaganfallpatienten in Berlin. Das HRQOL Profil der weiblichen Schlaganfallpatienten in Berlin war besser in den Bereichen „Geist“ und „spirituelle Interaktion“ als bei den männlichen Schlaganfallpatienten in Berlin.

Die in beiden Kulturen bestimmenden Faktoren des HRQOL waren die Schlaganfallschwere, die Häufigkeit von Lachen (und die Frequenz negativer Gefühle) sowie zufriedenstellende persönliche Beziehungen (einschließlich Familie und Sozialunterstützung).

SCHLUSSFOLGERUNGEN: Das HRQOLISP hat in beiden Ländern (und damit für beide Sprachversionen) eine hohe interne Konsistenz und eine gute inhaltliche („face“ und „content validity“), Konstrukt- und diskriminante Validität. Der „Schlaganfall-Erholungs-Score“ („stroke levity score“) ist ein valides und zeitsparendes reziprokes Maß für die Schlaganfallschwere. Ein Schlaganfall, selbst in den leichten Fällen, hat einen mehrdimensionalen Effekt auf die Lebensqualität, der in der körperlichen Dimension am ausgeprägtesten ist. Die transkulturell übereinstimmend bestimmenden Faktoren von HRQOL bei Schlaganfallpatienten waren die Schwere des Schlaganfalles (Schlaganfall-Milde-Score [„stroke levity score“]), die Frequenz negativer Gefühle (bzw. eines Lachens) sowie zufriedenstellende persönliche Beziehungen (einschließlich Familie und Sozialunterstützung). Die relative Aussparung der seelisch-spirituellen Bereiche der HRQOL und deren höheren subjektive Wichtigkeit bei Schlaganfallpatienten könnte eventuell genutzt werden, um diese Patienten bei ihrer Krankheitsverarbeitung zu unterstützen und eine positive Adaptation an die anderen Aspekte des Lebens im Sinne eines zweckmäßigen und sinnvollen Lebens – auch beim Vorliegen einer durch den Schlaganfall verursachten körperlichen Beeinträchtigung - zu erzielen und beizubehalten.

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APPENDIX I : THE HEALTH_RELATED QUALITY OF LIFE IN STROKE PATIENTS (HRQOLISP) QUESTIONNAIRE

Today's date.

BIODATA **I.D. NUMBER** ☐☐☐

Please respond to the following questions by filling in the space provided or circling the correct response. **The answers you give shall be regarded as anonymous and kept in strict confidence.**

What is your gender? **1** Male **2** Female

What is your date of birth [if known]
[or approximate age]?
Day Month Year

Age

What is the highest formal education you have received? **1** None **2** Primary **3** Secondary **4** Tertiary **5** Other [Specify] ----

What is your occupation?

What is your handedness? **1**.Right **2**. Left

What is your average income in naira every month? **1**. 0-10,000 **2.** 10,001 -25,000 **3**. 25,001- 50,000 **4.** 50,001- 100,000 **5**. 100, 001-150,000 **6**.> 150, 000

What is your marital status? **1** Single **2** Separated **3** Married **4** Divorced **5** Living as married **6** Widowed **7**. Remarried

Number of husbands/wives ---------

How many children do you have? **1.** 0 **2.** 1 or2 **3.** 3or4 **4.** 5 or 6 **6**. 7 and above

What is your tribe/race? **1**. Yoruba **2.** Hausa **3**. Igbo **4.** Others [specify]

What is your religion/denomination? **1**. Christianity [specify denomination if any] ---
2. Islam [specify denomination if any] ---
3. Traditional [specify denomination if any] ---
4. none
5. others [please specify]

STROKE TYPE, DURATION, FREQUENCY

Are you on admission now? YES NO

When did you [first] develop stroke? ----------

How many times have you had stroke? ----------

Did you have any of the following: [To be filled by the investigator/interviewer]

Loss of consciousness?	YES	NO
Headache ?	YES	NO
Vomiting	YES	NO
T.I.A.?	YES	NO
Gradual onset of symptoms?	YES	NO
Activity at onset?	YES	NO
Bloody C.S.F.?	YES	NO
High Blood Pressure?	Nil/mild BP < 160/100	moderate/severe >or=160/100mmHg

Which side of the body is affected? ----------

Risk factors identified for stroke[including smoking/alcohol]? ----------

C.T. scan / M.R.I. report: stroke type, extent and site ----------

Co-morbid factors identified :----------

PLEASE REPORT THE NEXT SECTION AS INTACT OR IMPAIRED

Orientation[in time, place, **person]**----------**Memory**[3-item registration and recall, past life events]----------**Calculation** [serial subtraction of 3 from 20]----------

Judgement----------**Abstraction** [interpretation of proverb]----------

INSTRUCTIONS

This assessment asks about how you perceive your current state of health, quality of life, or other areas of your life. **Please answer all the questions honestly**. If you are unsure about what response to give to a question, please choose the nearest most appropriate response. **Please keep in mind your standards, hopes, pleasures and concerns. Think about your life in the last two weeks. You should circle the number that best fits your response.**

1.1.1.1. : PHYSICAL DOMAIN [i-iii] to be filled by the investigator

i	Best motor power in the dexterous hand/ upper limb	0 nil	1 flicker	2 gravity eliminated	3 against gravity	4 against resistance	5 normal
iia.	Best motor power in the affected upper limb	0	1	2	3	4	5
iib	Best motor power in the affected lower limb	0	1	2	3	4	5
iii.	Speech defect [aphasia]	nil 0	present 1’				
iv.	Mobility	bed bound 1	chair bound 2	walks with helpers 3	walks with aids[frame/ tripod] 4	walks unaided 5	

		Not at all 1	**A little 2**	**A moderate amount 3**	**Very much 4**	**Extremely 5**
v	To what extent do you have difficulties gripping objects, turning door-knob, using cutlery, writing, opening jar/can, carrying heavy objects?	0	1’	2’	3’	4’
vi	To what extent do you have difficulties controlling your bladder/bowels?	0	1’	2’	3’	4’
vii	To what extent do you have difficulties sitting/standing without losing your balance?	0	1’	2’	3’	4’
viii	To what extent do you have difficulties seeing objects off to one side/ reaching for objects because of poor eyesight?	0	1’	2’	3’	4’
ix	To what extent do you think physical pain/discomfort /abnormal sensation/absent sensation prevent you from doing what you need to?	0	1’	2’	3’	4’
x	How much do you need any medical treatment [drugs or aids] and/or hospital attendance to function in your daily life?	0	1’	2’	3’	4’
xi	To what extent has your sex life been adversely affected?	0	1’	2’	3’	4’

		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
xii	How satisfied are you with your ability to perform your daily living activities [feeding, bathing, toileting, dressing, grooming, e.t.c.]?	1	2	3	4	5
xiii	How satisfied are you with your capacity for work?	1	2	3	4	5
xiv	How satisfied are you with your sex life?	1	2	3	4	5
xv	**How important to you are the aspects of your life covered in questions iv-xiv in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

1.1.1.2	**EMOTION/PSYCHOLOGICAL DOMAIN**	**Not at all/ Never 1**	**A little/ Seldom 2**	**Moderately/ Quite often 3**	**Mostly/ Very often 4**	**Completely/Always 5**
i	How often do you have negative feelings such as blue mood, anger, despair, anxiety, depression, fear?	0	1’	2’	3’	4’
ii	Do you have enough energy for everyday life?	1	2	3	4	5
iii	To what extent are you able to accept your bodily appearance?	1	2	3	4	5
iv	To what extent do you enjoy your work?	1	2	3	4	5
v	How often do you laugh?	1	2	3	4	5
vi	To what extent do you enjoy recreation/pastimes/leisure/rest /relaxation?	1	2	3	4	5
vii	How safe do you feel in your daily life?	1	2	3	4	5
viii	To what extent have you ever felt death to be better than your present condition?	0	1’	2’	3’	4’

ix	To what extent have you ever felt like ending your life?	0	1’	2’	3’	4’
		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
x	How satisfied are you with your sleep [duration and quality]?	1	2	3	4	5
xi	How satisfied are you with your feelings?	1	2	3	4	5
xii	**How important to you are the aspects of your life covered in questions i-xi in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

1.1.2	**INTELLECTUAL/COGNITIVE DOMAIN**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much/ Mostly 4**	**Extremely /Completely 5**
i	How well are you able to concentrate?	1	2	3	4	5
ii	To what extent is your memory impaired?	0	1’	2’	3’	4’
iii	To what extent are you able to learn new things?	1	2	3	4	5
iv	To what extent do you understand your disease process?	1	2	3	4	5
v	To what extent are you able to think out/plan logical solutions to [your] problems and take decisions?	1	2	3	4	5
vi	To what extent are you able to relax your mind?	1	2	3	4	5
vii	How available to you is the information that you need for your day-to-day life?	1	2	3	4	5
viii	To what extent are you able to communicate?	1	2	3	4	5
		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
ix	How satisfied are you with your memory and ability to concentrate?	1	2	3	4	5

x	How satisfied are you with your ability to communicate?	1	2	3	4	5
xi	How satisfied are you with your ability to think and learn?	1	2	3	4	5
xii	**How important to you are the aspects of your life covered in questions i-xi in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

1.2.1	**SOUL DOMAIN**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very Much 4**	**Extremely 5**
i	How much do you value yourself?	1	2	3	4	5
ii	How much confidence do you have in yourself?	1	2	3	4	5
iii	How much confidence do you have in your God?	1	2	3	4	5
iv	How creative are you?	1	2	3	4	5
v	To what extent are you independent and individualistic in reasoning and taking decisions?	1	2	3	4	5
vi	To what extent do you believe you have a purpose for living?	1	2	3	4	5
vii	To what extent are you interested in fulfilling your purpose for living?	1	2	3	4	5
viii	To what extent do you accept/ believe in destiny/predestination?	1	2	3	4	5
ix	To what extent do you believe in freewill?	1	2	3	4	5
x	To what extent do you think your present condition has prevented you from fulfilling your purpose of life?	0	1’	2’	3’	4’
xi	To what extent do you think your present condition has assisted you in fulfilling your purpose of life?	1	2	3	4	5
xii	To what extent have your dreams/visions/ESP [if any]portrayed your present condition bad?	0	1’	2’	3’	4’
xiii	To what extent are you intuitive/ inspired/ ingenuous?	1	2	3	4	5

xiv	To what extent do you rely on God to solve your problems?	1	2	3	4	5
xv	To what extent do you rely on yourself to solve your problems?	1	2	3	4	5
xvi	To what extent do you believe the devil is responsible for your present situation?	0	1’	2’	3’	4’
xvii	To what extent are you or other people responsible for your situation more than God?	0	1’	2’	3’	4’
xviii	To what extent do you believe in afterlife?	1	2	3	4	5
xix	To what extent do you believe in God?	1	2	3	4	5
xx	To what extent do you practice your religion/faith?	1	2	3	4	5
xxi	To what extent do you accept your present state?	1	2	3	4	5
xxii	How strong is your will to live?	1	2	3	4	5
		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
xxiii	To what extent are you satisfied with your faith in God?	1	2	3	4	5
xxiv	How satisfied are you with yourself?	1	2	3	4	5
xxv	How satisfied are you with your abilities?	1	2	3	4	5
xxvi	**How important to you are the aspects of your life covered in questions i-xxv in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

1.2.2	**SPIRIT DOMAIN**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**
I	To what extent do you understand God?	1	2	3	4	5
Ii	To what extent are you guided / motivated by God in your [daily] life?	1	2	3	4	5
Iii	To what extent do you understand your religion/faith?	1	2	3	4	5

Vi	To what extent do you think God is responsible for your present state?	1	2	3	4	5
V	To what extent do you perceive your life to be meaningful?	1	2	3	4	5
		Very Dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
Vi	To what extent are you satisfied with divine guidance in your life?	1	2	3	4	5
Vii	**How important to you are the aspects of your life covered in questions i-vi in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

2.1	**ECOSOCIAL DOMAIN**					
i	Activities of daily living[feeding, bathing, toileting, etc]	Fully dependent **1**	Requires substantial help **2**	Requires minimal help **3**	Requires no help but not back to work **4**	Back to work **5**
		Not at all 1	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely/ Completely 5**
ii	How easy is it for you to communicate with people?	1	2	3	4	5
iii	How much support do you get from your relations?	1	2	3	4	5
iv	How much respect do you expect from others?	1	2	3	4	5
v	How much respect do you get from others?	1	2	3	4	5
vi	How much support do you get from your friends?	1	2	3	4	5
vii	To what extent are you compelled by others to do what you do not consider suitable for you?	0	1’	2’	3’	4’
viii	How well are you able to meet your financial needs?	1	2	3	4	5
ix	How surplus is your financial resources?	1	2	3	4	5
x	To what extent do you have access to optimal health services?	1	2	3	4	5
xi	To what extent do you have access to social support?	1	2	3	4	5
xii	How well are you able to manage your home and perform your domestic roles?	1	2	3	4	5

xiii	To what extent are you performing your occupational duties?	1	2	3	4	5
xiv	How healthy is your physical environment?	1	2	3	4	5
xv	To what extent do you have access to transport facilities?	1	2	3	4	5
xvi	To what extent do you have opportunities to learn and acquire new skills?	1	2	3	4	5
		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied? 3**	**Satisfied 4**	**Very satisfied 5**
xvii	How satisfied are you with your personal relationships?	1	2	3	4	5
xviii	How satisfied are you with the support you get from your friends?	1	2	3	4	5
xix	How satisfied are you with the conditions of your living place?	1	2	3	4	5
xx	How satisfied are you with your access to health services?	1	2	3	4	5
xxi	How satisfied are you with your treatment?	1	2	3	4	5
xxii	How satisfied are you with your access to transportation?	1	2	3	4	5
xxiii	**How important to you are the aspects of your life covered in questions i – xxii in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

2.2	**SPIRITUAL INTERACTION DOMAIN**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**An extreme amount/ Completely 5**
i	To what extent do you consider yourself close to God or your object of worship?	1	2	3	4	5
ii	To what extent do you meditate and/or study religious books?	1	2	3	4	5
iii	To what extent do you discuss aspects of your faith/religion with people of the same religious interest/faith in order to strengthen your individual resolve?	1	2	3	4	5

		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
iv	How satisfied are you with your relationship with God or your object of worship?	1	2	3	4	5
v	How satisfied are you with your effort to develop your faith/religion?	1	2	3	4	5

vi	**How important to you are the aspects of your life covered in questions i-v above?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

Did someone help you to fill out this form [excluding 1111 i-iii]? **1** interviewer **2** proxy

How long did it take you to fill this form out?

Do you have any comments about this assessment?

Could you please state any other important aspect[s] of your life that has not been assessed.----

APPENDIX II : THE QUESTIONNAIRE , CONTROL VERSION

Today's date.

BIODATA **I.D. NUMBER**

Please respond to the following questions by filling in the space provided or circling the correct response. **The answers you give shall be regarded as anonymous and kept in strict confidence.**

What is your gender? **1** Male **2** Female

What is your date of birth [if known] ___ _____ ____

[or approximate age]? Day Month Year

Age _____[years]

What is the highest formal education .

you have received? **1** None **2** Primary **3** Secondary

4 Tertiary **5** Other [Specify] ----

What is your occupation? _____

What is your handedness? **1**.Right **2**. Left

What is your average income in naira

every month? **1**. 0-10,000 **2.** 10,001 -25,000 **3**. 25,001- 50,000

4. 50,001- 100,000 **5**. 100, 001-150,000 **6**.> 150, 000

What is your marital status? **1** Single **2** Separated

3 Married **4** Divorced

5 Living as married **6** Widowed **7**.Remarried

Number of husbands/wives ---------

How many children do you have? **1.** 0 **2.** 1 or2 **3.** 3or4 **4.** 5 or 6 **5**. 7 and above

What is your tribe/race? **1**. Yoruba **2.** Hausa **3**. Igbo **4.** Others [specify]

What is your religion/denomination? **1**. Christianity [specify denomination if any] ---

2. Islam [specify denomination if any] ---

3. Traditional [specify denomination if any] ---

4. none

5. others [please specify]

INSTRUCTIONS This assessment asks about how you perceive your current state of health, quality of life, or other areas of your life. **Please answer all the questions honestly**. If you are unsure about what response to give to a question, please choose the nearest most appropriate response.

Please keep in mind your standards, hopes, pleasures and concerns. Think about your life in the last two weeks. You should circle the number that best fits your response.

1.1.1.1. : PHYSICAL DOMAIN

i						
ii[a]						
ii.[b]						
iii.						
iv.						
		Not at all 1	**A little 2**	**A moderate amount 3**	**Very much 4**	**Extremely 5**
I	To what extent do you have difficulties gripping objects, turning door-knob, using cutlery, writing, opening jar/can, carrying heavy objects?	0	1’	2’	3’	4’
vi	To what extent do you have difficulties controlling your bladder/bowels?	0	1’	2’	3’	4’
vii	To what extent do you have difficulties sitting/standing without losing your balance?	0	1’	2’	3’	4’
viii	To what extent do you have difficulties seeing objects off to one side/ reaching for objects because of poor eyesight?	0	1’	2’	3’	4’
ix	To what extent do you think physical pain/discomfort /abnormal sensation/absent sensation prevent you from doing what you need to?	0	1’	2’	3’	4’
x	How much do you need any medical treatment [drugs or aids] and/or hospital attendance to function in your daily life?	0	1’	2’	3’	4’
xi	To what extent has your sex life been adversely affected?	0	1’	2’	3’	4’
		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**

xii	How satisfied are you with your ability to perform your daily living activities [feeding, bathing, toileting, dressing, doing buttons/zippers, grooming, shaving, doing pedicure/manicure e.t.c.]?	1	2	3	4	5
xiii	How satisfied are you with your capacity for work and household chores?	1	2	3	4	5
xiv	How satisfied are you with your sex life?	1	2	3	4	5
Xv	**How important to you are the aspects of your life covered in questions v-xiv in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

1.1.1.2	**EMOTION/PSYCHOLOGICAL DOMAIN**	**Not at all/ Never 1**	**A little/ Seldom 2**	**Moderately /Quite often 3**	**Mostly/ Very often 4**	**Completely/ Always 5**
i	How often do you have negative feelings such as blue mood, anger, despair, anxiety, depression, disinterest, fear?	0	1’	2’	3’	4’
ii	Do you have enough energy for everyday life?	1	2	3	4	5
Iii	To what extent are you able to accept your bodily appearance?	1	2	3	4	5
iv	To what extent do you enjoy your work?	1	2	3	4	5
v	How often do you laugh?	1	2	3	4	5
Vi	To what extent do you enjoy recreation/pastimes/leisure/rest/relaxation?	1	2	3	4	5
vii	How safe do you feel in your daily life?	1	2	3	4	5
Viii	To what extent have you ever felt death to be better than your present condition?	0	1’	2’	3’	4’

Ix	To what extent have you ever felt like ending your life?	0	1’	2’	3’	4’
		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
x	How satisfied are you with your sleep [quality and duration]	1	2	3	4	5
Xi	How satisfied are you with your feelings?	1	2	3	4	5
Xii	**How important to you are the aspects of your life covered in questions i-viii in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

1.1.2	**INTELLECTUAL/ COGNITIVE-DOMAIN**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much/ Mostly 4**	**Extremely /Completely 5**
I	How well are you able to concentrate/do simple calculations?	1	2	3	4	5
Ii	To what extent is your memory impaired?	0	1’	2’	3’	4’
Iii	To what extent are you able to learn new things?	1	2	3	4	5
Iv						
V	To what extent are you able to think out/plan logical solutions to [your] problems and take decisions?	1	2	3	4	5
Vi	To what extent are you able to relax your mind?	1	2	3	4	5
Vii	How available to you is the information that you need for your day-to-day life?	1	2	3	4	5
Viii	To what extent are you able to communicate?	1	2	3	4	5

		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
Ix	How satisfied are you with your memory and ability to concentrate?	1	2	3	4	5
X	How satisfied are you with your ability to communicate?	1	2	3	4	5
Xi	How satisfied are you with your ability to think and learn?	1	2	3	4	5
Xii	**How important to you are the aspects of your life covered in questions i-x in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

1.2.1	**SOUL DOMAIN**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very Much 4**	**Extremely 5**
I	How much do you value yourself?	1	2	3	4	5
Ii	How much confidence do you have in yourself?	1	2	3	4	5
Iii	How much confidence do you have in your God?	1	2	3	4	5
Iv	How creative are you?	1	2	3	4	5
V	To what extent are you independent and individualistic in reasoning and taking decisions?	1	2	3	4	5
Vi	To what extent do you believe you have a purpose for living?	1	2	3	4	5
Vii	To what extent are you interested in fulfilling your purpose for living?	1	2	3	4	5
Viii	To what extent do you accept/ believe in destiny/predestination?	1	2	3	4	5
Ix	To what extent do you believe in freewill?	1	2	3	4	5
X	To what extent do you think your present condition has prevented you from fulfilling your purpose of life?	0	1’	2’	3’	4’

Xi	To what extent do you think your present condition has assisted you in fulfilling your purpose of life?	1	2	3	4	5
Xii	To what extent have your dreams/visions/ESP [if any]portrayed your present condition bad?	1	2	3	4	5
Xiii	To what extent are you intuitive/ inspired/ ingenuous?	1	2	3	4	5
Xiv	To what extent do you rely on God to solve your problems?	1	2	3	4	5
Xv	To what extent do you rely on yourself to solve your problems?	1	2	3	4	5
Xvi	To what extent do you believe the devil is responsible for your present situation?	0	1’	2’	3’	4’
Xvii	To what extent are you or other people responsible for your situation more than God?	0	1’	2’	3’	4’
Xviii	To what extent do you believe in afterlife?	1	2	3	4	5
Xix	To what extent do you believe in God?	1	2	3	4	5
Xx	To what extent do you practice your religion/faith?	1	2	3	4	5
Xxi	To what extent do you accept your present state?	1	2	3	4	5
Xxii	How strong is your will to live?	1	2	3	4	5
		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
Xxiii	To what extent are you satisfied with your faith in God?	1	2	3	4	5
Xxiv	How satisfied are you with yourself?	1	2	3	4	5
Xxv	How satisfied are you with your abilities?	1	2	3	4	5
Xxvi	**How important to you are the aspects of your life covered in questions i-xxv in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

1.2.2	**SPIRIT DOMAIN**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**
I	To what extent do you understand God?	1	2	3	4	5
Ii	To what extent are you guided / motivated by God in your [daily] life?	1	2	3	4	5
Iii	To what extent do you understand your religion/faith?	1	2	3	4	5
Vi	To what extent do you think God is responsible for your present state?	1	2	3	4	5
V	To what extent do you perceive your life to be meaningful?	1	2	3	4	5
		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
Vi	To what extent are you satisfied with divine guidance in your life?	1	2	3	4	5
Vii	**How important to you are the aspects of your life covered in questions i-ix in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

2.1	**ECOSOCIAL DOMAIN**					
i	Activities of daily living[feeding, bathing, toileting, etc]	Fully dependent **1**	Requires substantial help **2**	Requires minimal help **3**	Requires no help but not able to work **4**	Able to work **5**
		Not at all 1	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely/ Completely 5**
Ii	How easy is it for you to communicate with people?	1	2	3	4	5
Iii	How much support do you get from your relations?	1	2	3	4	5
Iv	How much respect do you expect from others?	1	2	3	4	5
V	How much respect do you get from others?	1	2	3	4	5
Vi	How much support do you get from your friends?	1	2	3	4	5

Vii	To what extent are you compelled by others to do what you do not consider suitable for you?	0	1’	2’	3’	4’
Viii	How well are you able to meet your financial needs?	1	2	3	4	5
Ix	How surplus is your financial resources?	1	2	3	4	5
X	To what extent do you have access to optimal health services?	1	2	3	4	5
Xi	To what extent do you have access to social support?	1	2	3	4	5
Xii	How well are you able to manage your home and perform your domestic roles?	1	2	3	4	5
Xiii	To what extent are you performing your occupational duties?	1	2	3	4	5
Xiv	How healthy is your physical environment?	1	2	3	4	5
Xv	To what extent do you have access to transport facilities?	1	2	3	4	5
Xvi	To what extent do you have opportunities to learn and acquire new skills?	1	2	3	4	5
		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
Xvii	How satisfied are you with your personal relationships?	1	2	3	4	5
Xviii	How satisfied are you with the support you get from your friends?	1	2	3	4	5
Xix	How satisfied are you with the conditions of your living place?	1	2	3	4	5
Xx	How satisfied are you with your access to health services?	1	2	3	4	5
Xxi						
Xxii	How satisfied are you with your access to transportation?	1	2	3	4	5
Xxiii	**How important to you are the aspects of your life covered in questions i – xxi in this section?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

2.2	**SPIRITUAL INTERACTION DOMAIN**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**An extreme amount/Completely 5**
i	To what extent do you consider yourself close to God or your object of worship?	1	2	3	4	5
ii	To what extent do you meditate and/or study religious books?	1	2	3	4	5
iii	To what extent do you discuss aspects of your faith/religion with people of the same religious interest/faith in order to strengthen your individual resolve?	1	2	3	4	5

		Very dissatisfied 1	**Dissatisfied 2**	**Neither satisfied nor dissatisfied 3**	**Satisfied 4**	**Very satisfied 5**
iv	How satisfied are you with your relationship with God or your object of worship?	1	2	3	4	5
v	How satisfied are you with your effort to develop your faith/religion?	1	2	3	4	5

vi	**How important to you are the aspects of your life covered in questions i-v above?**	**Not at all 1**	**A little 2**	**Moderately 3**	**Very much 4**	**Extremely 5**

Did someone help you to fill out this form **1** interviewer **2** proxy **3**nobody

How long did it take you to fill this form out?

Do you have any comments about this assessment?

Could you please state any other important aspect[s] of your life that has not been assessed.----

APPENDIX III: OCCUPATIONAL STRATIFICATION

This is a method of occupational classification developed by the Department of Preventive and Social Medicine, and the Institute of Child Health , University of Ibadan for use by Nigerians.

SOCIAL CLASS	PROFESSION/OCCUPATION
I	Academic professionals, doctor, lawyer, engineer, senior administrative/military officer, large scale contractors.
II	Nonacademic professionals, nurses, secondary school teacher, secretary, owner of medium scale business.
IIIa	Non-manual skilled worker, clerk, typist, telephonist, police officer
IIIb	Manual skilled workers, drivers, carpenters, goldsmiths
IV	Semiskilled workers and small-scale traders
V	Unskilled workers: farmers, petty traders, peddlers

Erklärung

„Ich, Mayowa Ojo OWOLABI, erkläre, dass ich die vorgelegte Dissertationsschrift mit dem Thema: IBADAN-BERLIN BICULTURAL COMPARATIVE STUDY OF QUALITY OF LIFE IN STROKE PATIENTS USING A NEW INSTRUMENT selbst verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel benutzt, ohne die (unzulässige) Hilfe Dritter verfasst und auch in Teilen keine Kopien anderer Arbeiten dargestellt habe."

31st August 2008

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