

**QUALITY OF LIFE ASSESSMENT IN PATIENTS UNDERGOING
UNINSTRUMENTED CENTRAL CORPECTOMY**

**Thesis submitted in part fulfilment of the M.Ch. Neurosurgery (Branch II) Examination of the
Dr. M.G.R. Medical University, Chennai, Tamil Nadu, to be held in February 2008**

CERTIFICATE

This is to certify that the thesis entitled “Quality of life assessment in patients undergoing uninstrumented central corpectomy” is a bona fide work of Dr. Sumit Thakar in part fulfilment of the M.Ch. Neurosurgery (Branch II) Examination of the Dr. M.G.R. Medical University, Chennai, Tamil Nadu, to be held in February 2008.

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1. INTRODUCTION

Quality-of-life assessment as part of a multimodal outcome-assessment is being increasingly measured in clinical and health services research. This is especially important in chronic degenerative conditions like cervical spondylotic myelopathy (CSM) which rarely is fatal, nor is completely cured, and hence has no clear endpoints for outcome assessment (22).

In diseases such as CSM, outcomes have been historically measured using myelopathy scales like those by Nurick, Harsh, Cooper and the JOA score. Although disease-specific scales like these are used to describe both, disease severity, and outcomes of treatment, they do not incorporate factors that may contribute to quality of life outcomes. It has been noted in a previous study that patients with CSM have deficiencies that extend beyond motor, sensory and bladder dysfunction, into the realms of emotional and mental health (15). These can only be assessed by using generic outcome-measurement QOL instruments like the SF-36 (Medical Outcomes Study Short Form-36) and the WHOQOL-BREF. Although both are generic QOL instruments, they measure different constructs (11). While the SF-36 measures objective health-related QOL, the WHOQOL-BREF measures subjective global QOL.

This study uses WHOQOL-BREF for the first time for patients with CSM along with the commonly used SF-36 generic instrument, to assess functional outcome across different Nurick grade patients.

2. OBJECTIVES

- 1) To assess the quality of life (QOL) preoperatively and at follow-up in patients with cervical spondylotic myelopathy (CSM) undergoing un-instrumented central corpectomy (CC).

- 2) To determine the relationships between Nurick grade, SF-36, WHOQOL-BREF and patient perceived outcome in these patients.

3. REVIEW OF LITERATURE

3.1 Cervical Spondylotic Myelopathy

Cervical spondylotic myelopathy (CSM) is a chronic degenerative condition of the cervical spine that results in narrowing of the spinal canal and disruption of spinal cord function (3). This disease was first characterised by Brain et al in 1952. Since then, researchers have gathered substantial experimental and clinical evidence on its etiology and pathophysiology. It is commonly accepted that a combination of compressive forces both, anatomical and dynamic, as well as vascular phenomena are responsible for this clinical syndrome (12). Its clinical manifestations and natural history are known to be variable and unpredictable, with some patients having a mild protracted course, and others progressive disability (21). Symptoms of CSM range from neck pain, walking difficulties, sphincter dysfunction, impotence and numb clumsy hands (23, 30, 31).

Treatment options for CSM include physical therapy, neck brace therapy, expectant management and surgical spinal cord decompression with or without fusion. Several surgical strategies have been used in the past fifty years or so for the treatment of CSM, with proponents for either the anterior or posterior surgical approach. Of concern is the proposition that surgical treatment does not alter the natural history of patients with CSM (12).

Because the impairments of patients with this protracted disease extend beyond motor, sensory and bladder dysfunctions, into the realms of emotional and mental health, a

robust evaluation of treatment outcome becomes difficult. Quality of life (QOL) parameters have become viable considerations in this direction.

3.2 Quality of Life – the concept

Diseases can cause premature death resulting in decreased “quantity of life”, but more often they cause structural and functional limitations that may seriously affect the quality of life. Death is easy to identify and record and therefore mortality has been a standard method for quantifying the impact of diseases.

Patient reported outcomes are measured in clinical and health services studies and are especially important for individuals with chronic conditions for whom the goal of health care is optimizing daily functioning and well-being, as well as extending longevity (11). The whole class of patient-reported outcomes is often referred to as Quality of Life (QOL), a term used interchangeably with health related quality of life (HRQL) and subjective well being (SWB). Concepts that are generally measured in these areas include somatic symptoms, physical capability, psychological issues, social activities and cognitive functioning, and also broad concepts of life satisfaction.

QOL has been difficult to measure and therefore its use in healthcare settings has been comparatively recent (35). QOL assessment does not replace the existing outcome variables like mortality and morbidity measurements but it can be an additional outcome variable, giving information about a patient’s life, which other variables do not.

QOL assessments have mostly been used in the past in the area of malignancies although their use has become common of late in several other chronic conditions like CSM.

Assessment of QOL provides measurement of functioning and well-being rather than of diseases and disorders, hence it is more comprehensive and compatible with the World Health Organization's (WHO) concept of health. It focuses attention on aspects of a patient's life beyond symptoms and signs. It encompasses "Those attributes valued by patients including their resultant comfort or sense of well-being; the extent to which they were able to maintain reasonable physical, emotional and intellectual function; and the degree to which they retain their ability to participate in valued activities within the family, in the workplace, and in the community" (29).

The WHO Quality of life assessment group has defined QOL as "Individuals' perception of their position in life in the context of the culture and the value system in which they live and in relation to their goals, expectations, standards and concerns" (1).

Despite the influence of WHO quality of life assessment group's definition of QOL, operationalisation of QOL still varies across different methods and studies.

3.3 Outcome-Assessment Methods for QOL

In diseases such as CSM where the primary effect is on patient morbidity, there is a growing appreciation for the importance of measuring health related QOL as a means of understanding the impact of disease symptoms and treatments on patients' lives. Health related Quality of Life (HRQL) can be assessed by health status instruments and preference-based techniques.

Primary dimensions of health-related quality of life (HRQL) include: physical functioning, psychological functioning, social functioning and role activities, and individuals' overall life satisfaction and perceptions of their health status (21). Additional HRQL dimensions include neuropsychological functioning, personal productivity, intimacy and sexual functioning, sleep disturbance, pain, study-specific symptoms, and spirituality.

Health status instruments are sub-divided into: generic health status techniques that encompass many aspects contributing to QOL, and disease-specific status techniques that focus on a particular disease or condition (17). Most commonly used generic health status instruments and what they focus on are listed for comparative purposes in Table 3-1 below (4).

Instrument	Domains/ Dimensions covered	Number of items
European Quality of Life Instrument (EQ-5D)	Mobility Self-care Usual activities Pain Anxiety / depression	5
Medical Outcome Study Short Form 36 (SF-36)	Physical health Mental health Social functioning Role limitations due to physical health Role limitations due to emotional health General health Vitality Bodily pain	36
Nottingham Health Profile (NHP)	Physical mobility Pain Emotional Reaction Energy level Sleep Social interaction	38
Quality of Life Index (QL-I)	Activity Daily living Health Support Outlook	6
WHO Disability assessment Schedule (WHODASII)	Understanding and communication Getting around Self care Getting along with people Participation in society	36
WHOQOL-BREF	Physical Health Psychological health Social relationships Environment	26

Table 3-1. Common generic health status instruments and their domains

The most common generic health status instrument amongst those listed above is SF-36

(17), while the cross-culturally adaptable concept and methodical strengths of WHOQOL-BREF suggest that the latter may also have a place among the leading generic QOL instruments (36).

Disease-specific health status measurements techniques include instruments like the Nurick scale, Cooper scale, Harsh scale, and the Japanese Orthopedic Association (JOA) scale. These are designed to be sensitive to the manifestations of a particular disease and provide a single value for QOL. However these are applicable only to specific diseases or conditions. The Nurick scale is based mostly on ambulatory function while the Harsh, Cooper and the JOA scales include additional items such as sensation, upper extremity function, and sphincter control. These scales classify patients into various disease categories and are used to describe both CSM disease severity and the outcomes of CSM treatment (17).

Preference based QOL measurement techniques also known as health value measures, elicit patients' valuations for their current health state expressed on a single zero to one scale. These instruments can be used for a variety of diseases. They integrate all domains contributing to QOL to the extent that the domains are important to each patient. However, these instruments are resource intensive (requiring patient interviews) and may be difficult for some patients to complete. Responses may also be influenced by patients' attitudes towards risk, time or money. Common instruments in this category include: like Visual Analogue Scale, Standard Gamble, Time trade-off, and Willingness to pay. While the Visual Analogue Scale asks patients to value their current health on a linear scale, the

Standard Gamble asks them to make a hypothetical choice between remaining in their current health state or accepting the result of a gamble with a variable probability of either death or perfect health as the outcome. Time Trade off was developed as an alternative utility measurement that may be easier to administer than the standard gamble. It requires patients to make a hypothetical choice between living out their current state of health or accepting a shorter life span in perfect health. Both Standard Gamble and Time Trade off are used to measure disease severity and treatment outcomes. Another method for measuring health states is the Willingness-to-pay technique that provides a monetary valuation of state of health by determining how much patients would be willing to pay to improve their health (17).

Preference based QOL measurements are becoming increasingly popular due to the advantages they offer in terms of incorporating individual attitudes towards functional status, pain, etc., and by way of their capability of being incorporated into cost effective analysis and decision making processes (27). Regardless of these advantages, however, these instruments have not been used widely for evaluation of QOL in spine disease, going by the marked dearth of literature related to this.

Different diseases have been found to have a differential effect on functioning of patients in domains of QOL. Consequently, the contribution of specific domains to QOL may differ between diseases (1).

Selection of appropriate approach and instrument for evaluating QOL should be based

on: clear definition of study endpoints, preferred use of standardized, valid and reliable scales, knowledge of strengths and weaknesses of various instruments, with due consideration to the characteristics of the study population (24). For outcome measures to be of any use, they must be responsive, valid, practical and reliable. Responsiveness refers to the ability to detect true changes in health beyond the expected random variability, while validity is gauged by the extent to which a questionnaire measures what it is intended to measure. Questionnaires should be as brief as possible to minimize response burden (22). Reliability simply refers to the stability and reproducibility of measures over time or across methods of gathering data.

3.4 Nurick Grades

Nurick grading system categorises patients with myelopathic grades as shown in Table 3-2.

Nurick grade	Description
0	Signs or symptoms of root involvement but without evidence of spinal cord disease.
1	Signs of spinal cord disease but no difficulty in walking.
2	Slight difficulty in walking which did not prevent full-time employment.
3	Difficulty walking which prevented full-time employment or the ability to do all housework, but which was not severe as to require someone else's help to walk.
4	Able to walk with someone else's help or with the aid of a frame
5	Chair-bound or bedridden.

Table 3-2 Nurick grades

These six grades (0 to 5) were initially developed by Nurick in 1972 in his study on the pathogenesis of cervical spondylotic myelopathy. The study patients were classified in

terms of the grade of disability based on degree on difficulty in walking recorded at the time of admission (31).

This disease-specific health status instrument has since been used very commonly in various studies. It provides ease of application, and a single value for QOL.

3.5 Medical Outcomes Study Short-Form (SF-36)

Ware et al state that general health can be measured using the various techniques briefly described above, the most widely used being the SF-36 instrument which is a shortened version of a battery of 149 status questions developed and tested on a population of over twenty two thousand patients (39). This exercise was a part of the Medical Outcomes study, which was an attempt to analyze how specific parts of the American health care system affect the outcomes of care.

The SF-36 was developed to assess functioning status and well-being in a US population of 2474 patients with a wide range of conditions. Eleven questions were selected in this version while retaining the validity and reliability of the parent questionnaire. Subsequently SF-36 has been validated in Chinese, Cuban, Spanish, Dutch, French, Greek, Italian, Japanese, and Swedish speaking populations. It has also been validated in patients with numerous diseases including benign prostatic hypertrophy, cancer, congestive heart failure, coronary artery disease, diabetes Type II, hypertension, low back pain, recent myocardial infarction, sciatica, and stroke (18).

A study by King et al has evaluated the construct validity and reliability of the SF-36 health status instrument in relationship with Nurick, Cooper, Harsh and modified JOA scales and demonstrated that SF-36 provides reliable and valid data in CSM patients also (18).

SF-36 yields a profile of functional health and well-being scores as well as psychometrically- based physical and mental health summary measures. It is comprised of eight separate multi-item scales (mentioned above) that contain 2 to 10 items each and a single item to assess health transition. A sub-scale score is calculated for each of the 8 dimensions. In recent years a scoring algorithm has been developed to calculate a Physical Component summary (PCS) and the Mental Component summary (MCS). The physical functioning, role limitations due to physical health, bodily pain and general health sub-scales are integrated to form the PCS; and the vitality, social functioning, role limitations due to emotional health, and mental health sub-scales are combined to form the MCS (see Figure 3-1). Summary measures such as these are useful in reducing the number of separate outcomes to be assessed during a particular study, which can complicate data analysis, while still preserving the ability of the instrument to examine two major aspects of daily life- physical and mental health dimensions (29).

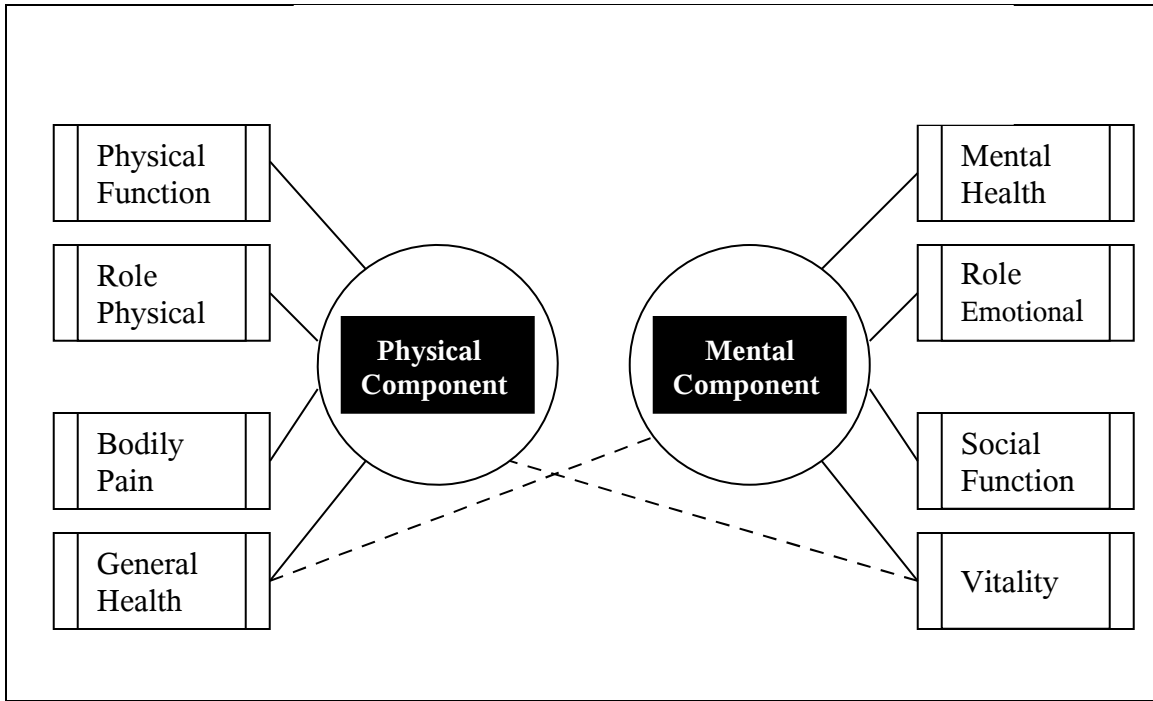


Fig. 3-1 SF-36 Scales Measure Physical and Mental Components of Health (38)

3.6 WHOQOL-BREF

In consonance with its definition of Quality of Life, the WHOQOL Group takes the view that it is important to know how satisfied, or otherwise, people are by important aspects of their life, and that this interpretation will be a very individual matter. The WHO Quality of life assessment - the WHOQOL 100- is a cross culturally valid assessment of well being. It was developed through collaborative studies in 15 sites throughout the world all working in their local languages. Agreed common protocols were used simultaneously by all centers in each stage of the development process (36). The original WHOQOL-100 was based on a 6 domain structure – physical, psychological, level of independence, social, environment and personal beliefs/ spirituality.

The WHOQOL-BREF is an abbreviated version of WHOQOL-100 and is suited for use in situations where time is a constraint and where respondent burden (of completing the questionnaire) must be minimal or where facet detail is unnecessary. WHOQOL-BREF has been developed on the basis of four domains - physical, psychological, social and environmental health. The WHOQOL-BREF contains one item from each of the 24 facets of quality of life included in the original version, plus two benchmark items from the original facet on overall QOL and general health- not included in scoring. Although longer than some other short-forms, the WHOQOL-BREF covers a very broad range of facets that were agreed by international consensus. A noteworthy feature is the inclusion of social and environment domains for assessment. It has wide ranging uses in clinical settings and clinical trials (36). The four domains and their related facets are shown below in Figure 3-2.

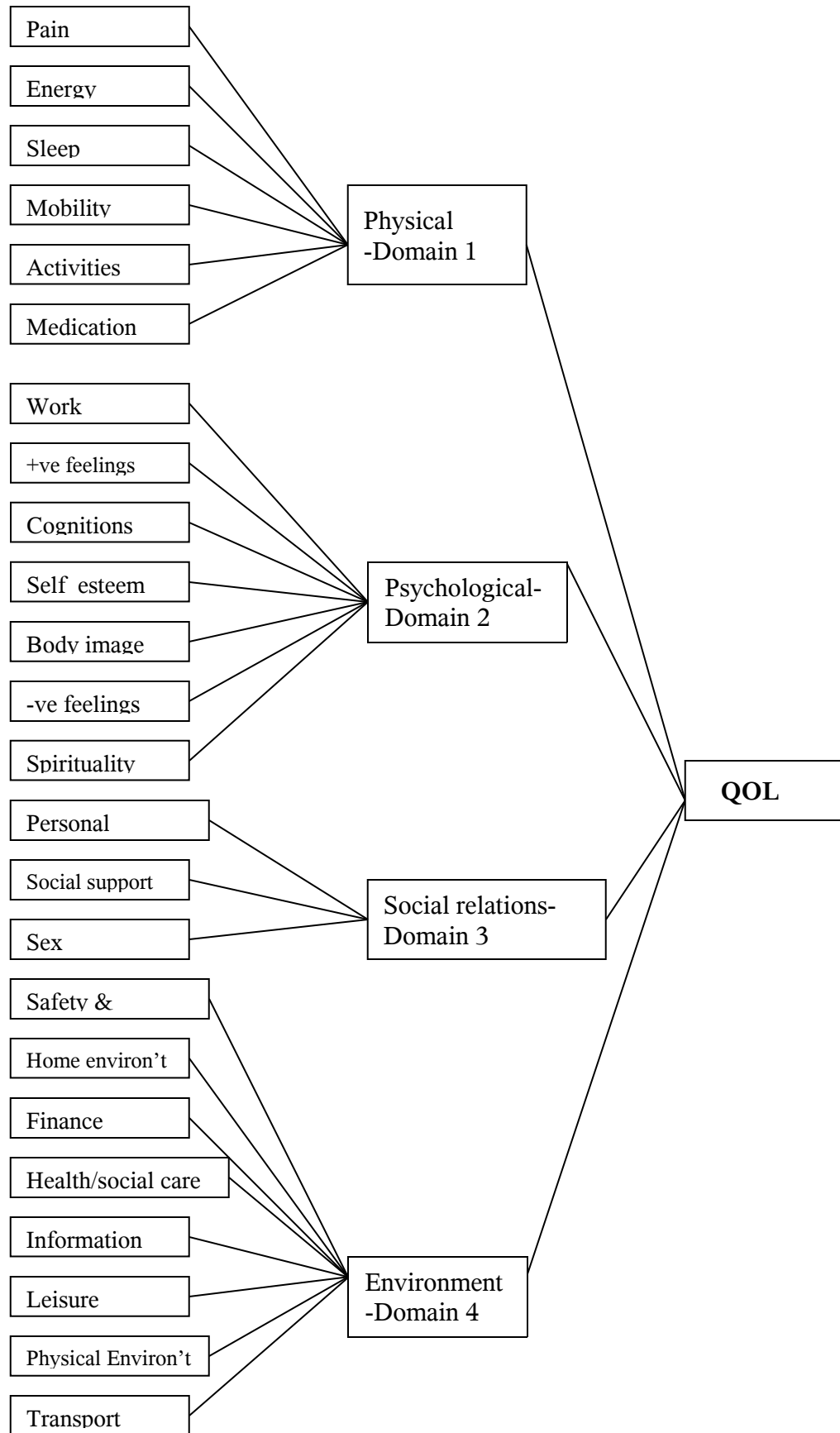


Fig. 3-2. WHOQOL-BREF: 4-domain confirmatory factor model.

The WHOQOL-BREF arises from 10 years of development research on QOL and health care. It is a person-centred, multilingual instrument for subjective assessment and is designed for generic use as a multi-dimensional profile, so enabling a wide range of diseases and conditions to be compared. It consists of QOL items that are concerned with the meaning of different aspects of life of the respondents and how satisfactory or problematic is their experience of them.

Evidence of test-retest reliability of WHOQOL-BREF has already been established by the WHOQOL Group (41). Furthermore, Skevington et al have found that analysis of internal consistency, item-total correlations, discriminant validity and construct validity of their study data indicate that WHOQOL-BREF has good to excellent psychometric properties of reliability and performs well in preliminary studies of validity (36).

The WHOQOL-BREF has several strengths. It is based on a cross-culturally sensitive concept and is available in most of the world's major languages; hence it is appropriate for use in multinational collaborative research.

Thus, WHOQOL-BREF is a sound and cross-culturally valid assessment of QOL as reflected its four domains and can be used in studies which incorporate QOL as one of several variables.

3.7 SF-36 and WHOQOL-BREF—A Comparison

Each instrument has its unique constructs and advantages. As indicated in literature, the SF-36 was originally developed as a generic instrument for health surveys. Subsequently it was widely used in studies of health-related Quality of Life. Therefore the items in SF-36 reflect more toward the scope of health status. The aim of WHOQOL-BREF, on the other hand, was to capture a broad ranging concept of QOL that even includes a domain on environment in its scope.

There are several ways to compare QOL instruments. Spilker's hierarchical QOL model consisting of a three-level pyramid that includes overall QOL, separate domains of QOL, and specific aspects of each domain (1) provides a useful methodology.

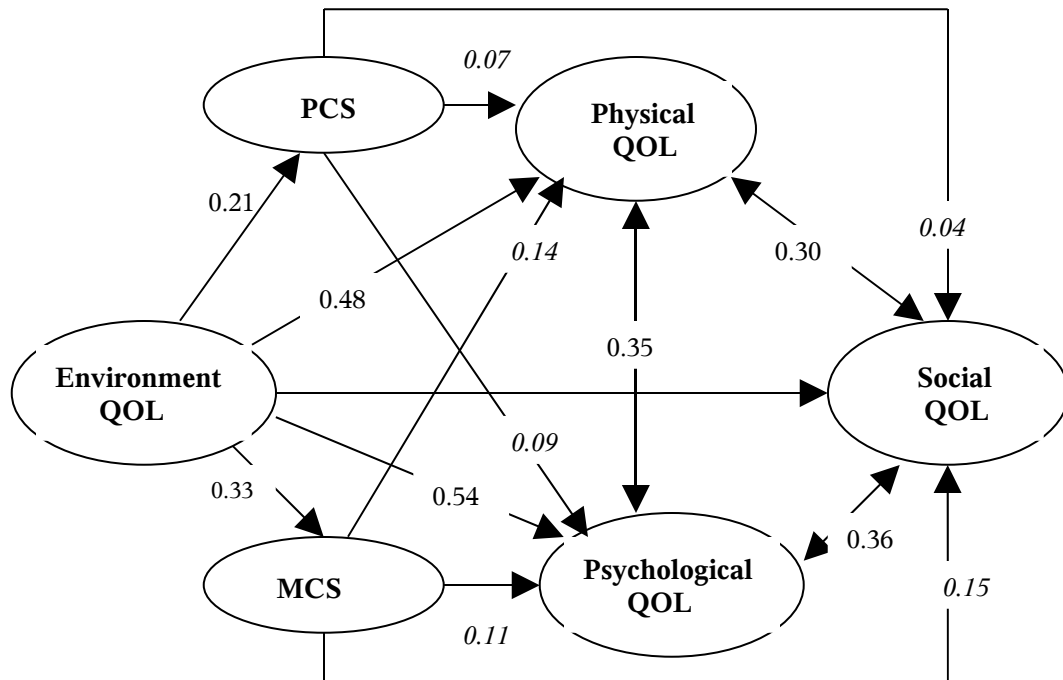
According to Spilker, the overall QOL is defined as “an individual's overall satisfaction with life, and one's general sense of personal well-being”; this covers the first level of Spilker's model. This can be interpreted as a global impression of overall QOL, measured by instruments like WHOQOL-BREF. The separate domains of QOL form the second level, with the most common domains being psychological, social and physical functioning. The third level of Spilker's model consists of the specific components of each domain of QOL (37). This model provides an analytical framework for comparing instruments because it allows researchers to examine QOL elements at the same level and across different levels.

Another study conducted on HIV patients by Ping-Chuan Hsiung et al (10), indicated that

patients with fewer symptoms and with less intensity of symptoms had significantly higher scores on all four domains of WHOQOL-BREF, eight scales, PCS, and MCS (mental component summary) of the SF-36 scale. The correlations between the physical, psychological, and social domains of the WHOQOL-BREF and PF (physical functioning), MH (mental health), and SF (social functioning) of the SF-36 were 0.51, 0.75, and 0.54, respectively. There was also good correlation between PCS of the SF-36 and the physical domain of the WHOQOL-BREF ($r = 0.48$), and between MCS and all four domains of the WHOQOL-BREF ($r = 0.60-0.75$). They concluded that both SF-36 and WHOQOL-BREF are valid and reliable for assessing QOL, and that in general, there are good correlations between the corresponding scales of the two instruments.

A study conducted by Chan Huang et al (11), suggests that the SF-36's Physical Component summary (PCS) and the Mental Component summary (MCS) were weakly associated with WHOQOL-BREF (Figure 3-3). It suggests that SF-36 and WHOQOL-BREF measure different constructs: the SF-36 measures health-related QOL, while WHOQOL-BREF measures global QOL.

SF-36 is classified as the measure of an individual's internal capability of life, while WHOQOL is known as a measure of inner life satisfaction or subjective enjoyment of life (11).



(Figures reflect the regression coefficients as observed in a study by Huang et al.)

Fig. 3-3. Relationships observed between domains of SF-36 and WHOQOL-BREF (18).

3.8 CSM and Outcome Measurement Studies

Several authors have reported their studies of surgery in patients with CSM and reflected different results:

In a prospective study by Lunsford et al on 32 patients assessed 1-7 years postoperatively, 50% patients were reported to have improved, and 50% were the same or had continued to deteriorate (11).

In a 10-year study by Phillips on 102 cases, favorable outcome with sustained improvement was reported in 67% of the patients (32).

Ebersold had retrospectively followed up 84 patients for a mean of 7 years and reported improvement in 70% patients following surgical decompression (7).

In a prospective, non-randomized study during a 10-year period on 51 patients submitted to median corpectomy and fusion, Marcondes et al assessed functional outcomes in addition to anatomical and neurological results (26). Analysis of the retrospectively collected assessment of the level of satisfaction showed that 80.6% of the patients were very satisfied or satisfied with the outcome and would decide again for the surgery (87%) if the results were previously known.

In a prospective study by King et al, the results of surgery in 62 patients were assessed over a 6-month follow-up period using three types of outcome instruments (16). 28 patients underwent surgery. There were no base-line differences in demographics,

symptoms, myelopathy scores, health status or values (based on generic and preference-based outcome measures) between this group and the non-surgery-treated patients. At the six month follow-up interval, the surgical and non-surgical groups were essentially unchanged in terms of myelopathy scores, health status and values, and there was no benefit from surgery. Patients' postoperative perception of changes in their condition was not supported by the other outcome measures. In patients who reported improvement, only the SF-36 scores for mental health (MCS) had improved postoperatively.

In the only prospective randomized trial to date of surgery for CSM, Kadanka et al (13) classified randomized patients into a surgical group and a conservative regimen group. Their outcome measures included a modified JOA scale, timed 10 meter walk, self-assessment and blinded assessment of a videotape of activities of daily living. Three years after randomization, the surgical group had fared no better than the conservative treatment group.

3.9 SF-36 and CSM

King et al tested the validity (the extent to which a test measures what it is intended to measure) and reliability (the stability and reproducibility of measures of the same concept over time or across methods of collecting data) of the SF-36 in patients with CSM (18). The instrument was administered to a cohort of 88 patients on an outpatient basis. Such patients were found to exhibit decreased quality of life in all health domains, extending into the realms of emotional and mental health. The study suggested that the SF-36

measures a much broader range of health concepts than the disease-specific myelopathy scales which are focused predominantly on motor function. Analyses demonstrated that the SF-36 is a valid and reliable outcome instrument in patients with CSM.

Latimer et-al used the SF-36 to measure outcome in a cohort of 70 patients undergoing surgery for CSM (22). Health status was measured preoperatively and 3 months postoperatively. Twelve-month follow-up was available for 42 patients in the study group. The study patients were found to have lower preoperative scores than age-matched population controls. Improvement in the scores (postoperative versus preoperative) was not defined in terms of an absolute value, but in terms of statistical significance ($p < 0.05$). Comparing pre and postoperative SF-36 scores for the physical functioning domain, 64% of patients were found to have improved, 23% showed no change and 14% continued to deteriorate. These changes were similar to those in other domains and the other outcome measures. It was concluded that the SF-36 could be used in measuring outcome in the surgical treatment of CSM.

3.10 Patient perceived outcome and CSM

In a prospective study on 208 patients undergoing CC for CSM (33), the patients' perception of the outcome of surgery was studied considering the possibility that it might add another dimension to outcome assessment not reflected by other outcome measures. There were patients in both, the good Nurick grade group (preoperative grade 1-3) and in the poor Nurick grade group (preoperative grade 4 or 5), who reported improvement but

did not change their Nurick grade after surgery. The mean PPOS of such patients ranged from 30 to 90 (mean, 65; median, 70) in the good Nurick grade group and from 20 to 50 (mean, 39.4; median, 40) in the poor Nurick grade group.

A positive correlation was obtained between the patient perceived outcome score (PPOS) and the Nurick grade recovery rate (defined below). In most patients, PPOS paralleled change in Nurick grade, but in some, especially in the good grade patients, the PPOS seemed to indicate a better outcome from surgery than the Nurick grade. This suggested that the 2 scales evaluate slightly dissimilar functional domains in these patients.

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4. PATIENTS AND METHODS

During the period commencing July 2003 to April 2007, seventy patients with cervical spondylotic myelopathy presenting in Neurosurgery unit II were prospectively studied. All patients had unequivocal evidence of cervical cord compression due to spondylotic disease. After informed consent was obtained, a structured interview was used to collect information on demographic characteristics, co-morbid diseases and CSM symptoms. Details of a standardized neurological examination were noted.

All patients underwent uninstrumented central corpectomy, fusion with iliac or fibular bone graft and immobilization with a Philadelphia collar for six months postoperatively. The patients were followed up 12 months later, either by correspondence or on a repeat visit.

The patients' health status was assessed preoperatively and at one year follow-up using the Nurick grade, the SF-36 and WHOQOL-BREF questionnaires. At follow-up, the patients' self-perceived percentage improvement in health status was also obtained.

4.1 Classification by Nurick grades

Patients were divided into 2 groups according to their Nurick scores. Patients with Nurick grades from 1 to 3 were classified as "Good", while those with scores of 4 or 5 were classified as "Poor." The results of the two groups were analysed separately for all aspects of this study.

The change in Nurick grade was computed as a recovery rate percentage using the following formula:

Nurick grade recovery rate (NGRR) = $\frac{\text{preoperative Nurick grade} - \text{follow-up Nurick grade}}{\text{preoperative Nurick grade}} \times 100$. For example, a patient with a preoperative Nurick grade of 3 who improved to Nurick 2 after surgery would have an NGRR of 33%. This was used as an index of improvement in mobility and was used for analysis as a continuous variable.

4.2 Regional Language Translations

For the purpose of this study, the English versions of the SF-36 were translated into Hindi, Bengali and Tamil to facilitate responses from the respective lingual groups. These translated versions were back-translated into English and then compared with the original English version. Changes as necessary were made in the text.

The official versions of English, Hindi, and Tamil languages of WHOQOL-BREF were used for this study. The English version was translated into Bengali and this translated version was also back-translated into English and then compared with the original English version. Changes as necessary were made in the text.

4.3 Sample size

The formula used for determining a suitable sample size was:

$$n = 4 p q / d^2$$

Using:

p=65 from a previous study (22) in which 64% of the patients in the study group improved following surgery,

$$q = 100 - p = 100 - 65 = 35,$$

$$d = 15,$$

then **n=40**.

The total number of patients recruited in the study was **70**.

4.4 Normative Data

The SF-36 and WHOQOL-BREF scores of the study group were compared with normative data from an age-matched population from similar regional and cultural backgrounds.

4.5 Scoring the SF-36

Figure 4-1 shows the structure of SF-36 scoring system. It consists of 36 questions, 35 of which are compressed into eight multi-item scales. Question 2, self-evaluation of change in health during the past year (reported health), does not belong to any score, dimension, or the total SF36 score. The eight scales are:

- a) Physical functioning is a ten-question scale that captures abilities to deal with the physical requirement of life, such as attending to personal needs, walking, and flexibility;
- b) role-physical is a four-item scale that evaluates the extent to which physical capabilities limit activity;
- c) Bodily pain is a two-item scale that evaluates the perceived amount of pain experienced during the previous 4 weeks and the extent to which that pain interfered with normal work activities;
- d) General health is a five-item scale that evaluates general health in terms of personal perception;
- e) Vitality is a four-item scale that evaluates feelings of pep, energy, and fatigue;

It is to be noted that vitality and general health scales are overlapping components of both the physical health and mental health dimensions.

- f) Social functioning (SF) is a two-item scale that evaluates the extent and amount of time, if any, that physical health or emotional problems interfered with family, friends, and other social interactions during the previous 4 weeks;
- g) Role-emotional (RE) is a three-item scale that evaluates the extent, if any, to which emotional factors interfere with work or other activities; and
- h) Mental health is a five-item scale that evaluates feelings principally of anxiety and depression.

Hence, in the SF36 scoring system, the scales are assessed quantitatively, each on the basis of answers to two to ten multiple choice questions, and a score between 0 and 100 is then calculated on the basis of well-defined guidelines, with a higher score indicating a better state of health (28).

An Excel program was used for calculating the SF-36 scores (14).

“Improvement” in the SF-36 score was defined as improvement of 5 or more (out of 100) in the individual scale score or the total score.

ITEMS	SCALES	Dimensions
3. Vigorous activities	Scale 1: Physical Functioning (PF)	Dimension A: PHYSICAL HEALTH
4. Moderate activities		
5. Lift, carry groceries		
6. Climb several flights		
7. Climb one flight		
8. Bend, kneel		
9. Walk mile		
10. Walk several blocks		
11. Walk one block		
12. Bathe, dress		
13. Cut down time		
14. Accomplished less		
15. Limited in kind		
16. Had difficulty		
21. Pain-magnitude		
22. Pain-interfere	Scale 3: Bodily Pain (BP)	
1. General health rating		
36. Excellent	Scale 4: General Health (GH)	
34. As healthy as anyone		
33. Sick easier		
35. Health worse		
23. Pep/life		
27. Energy	Scale 5: Vitality (VT)	
29. Worn out		
31. Tired		
32. Social-extent	Scale 6: Social Functioning (SF)	
20. Social-time		
17. Cut down time	Scale 7: Role-Emotional (RE)	
18. Accomplished less		
19. Not careful		
24. Nervous	Scale 8: Mental Health (MH)	
25. Down in dumps		
26. Peaceful		
28. Blue/sad		
30. Happy		
2. Change in reported health		

Figure 4-1. The SF-36 quality of life (QOL) scoring system and its scales and dimensions.

4.6 Scoring the WHOQOL-BREF (40)

The WHOQOL-BREF produces a quality of life profile. It is possible to derive four domain scores. There are also two items that are examined separately: question 1 asks about an individual's overall perception of quality of life and question 2 asks about an individual's overall perception of their health. The four domain scores denote an individual's overall perception of their health. The four domain scores denote an individual's perception of quality of life in each particular domain. Domain scores are

scaled in a positive direction (i.e. higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100. A method for the manual calculation of individual scores is given in Figure 4-2. The method for converting raw scores to transformed scores when using this method is given in Appendix D

	Equations for computing domain scores	Raw score	Transformed scores*	
Domain 1	$(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18$ $\square + \square + \square + \square + \square + \square + \square$	=	4-20	0-100
Domain 2	$Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26)$ $\square + \square + \square + \square + \square + \square$	=		
Domain 3	$Q20 + Q21 + Q22$ $\square + \square + \square$	=		
Domain 4	$Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25$ $\square + \square + \square + \square + \square + \square + \square + \square$	=		

Figure 4-2. Method for the manual calculation of individual domain scores

An SPSS syntax file that automatically checks, recodes data and computes domain scores developed by Professor Mick Power, Department of Psychiatry, Royal Edinburgh Hospital, Morningside was used for calculations. “Improvement” in the WHOQOL-BREF score was defined as improvement of 5 or more (out of 100) in the individual domains and 20 or more (out of 400) in the total score.

4.7 Patient perceived outcome score (PPOS)

Patients were asked to report their perception of the outcome of surgery as a percentage (0-100) relative to their preoperative status. Patients who felt that there was no change in their health status reported a score of 0, and those who became asymptomatic after surgery reported a score of 100.

4.8 Statistical Methods

The **Pearson's correlation** is used to find a correlation between at least two continuous variables. The value for a Pearson's can fall between 0.00 (no correlation) and 1.00 (perfect correlation). Generally, correlations between 0.40 and 0.60 are considered moderate, while those above 0.60 are considered high. In our analysis, this tool was used for establishing correlations between the different outcome measures and that between the various subscales and domains of the QOL instruments.

The **Mann-Whitney U** is one of the best-known non-parametric significance tests and is used for assessing whether two independent samples of ordinal or continuous observations come from the same distribution. The null hypothesis is that the two samples are drawn from a single population, and therefore that their probability distributions are equal. In this study, this tool was used for checking correlations between symptoms/signs and QOL scores.

Wilcoxon Signed-Rank Test is a nonparametric procedure used with two related variables to test the hypothesis that the two variables have the same distribution. It makes no assumptions about the shapes of the distributions of the two variables. This test takes into account information about the magnitude of differences within pairs and gives more weight to pairs that show large differences than to pairs that show small differences. In our analysis, this test was used to check whether the change in

QOL scores at follow-up in the two Nurick groups was significant.

Kappa can be used as a measure of agreement between model predictions and reality (Congalton1991) or to determine if the values contained in an error matrix represent a result significantly better than random (Jensen 1996). Cohen's kappa measures the agreement between the evaluations of two raters when both are rating the same object. A value of 1 indicates perfect agreement. A value of 0 indicates that agreement is no better than chance. Kappa is only available for tables in which both variables use the same category values and both variables have the same number of categories. This procedure is a useful way to evaluate the performance of classification schemes in which there is one variable with two categories by which subjects are classified.

This qualitative statistical technique has been used in this study to measure degree of agreement between improvement in Nurick grade and improvement in the QOL instrument scores.

5. RESULTS

5.1 Demographics and clinical features:

5.1.1 Age distribution

The mean age of the seventy patients in this study was 51.9 years +/- 9.9 (range, 32 – 71).

Analysis of the data indicated that there was no correlation between age and QOL scores (SF-36 and WHOQOL-BREF) in either group (good or poor Nurick grades).

Pearson's correlation with preoperative SF-36 scores was -0.104 (p=0.391) and with preoperative WHOQOL-BREF was -0.238 (p=0.047).

5.1.2 Comorbidities

Number of patients showing various comorbidities is shown below in Table 5-1:

Comorbidities	No. of patients	Percentage of cohort
Hypertension	17	24.3
Diabetes	12	17.1
Ischemic heart disease	2	2.9
Asthma	1	2.9
Others (lumbar canal stenosis, hypothyroidism)	3	4.3

Table 5-1 Distribution of comorbidities

23 (32.8%) patients had 1 or more comorbidities. There was no correlation between

comorbidities and QOL scores (SF-36 and WHOQOL-BREF) in either group.

5.1.3 Symptoms And Signs

The number of patients with various symptoms and signs at presentation is shown below in Table 5-2:

Symptoms	Number of patients	Percentage of cohort
Numb hands/arms	67	95.7
Numb legs/feet	64	91.4
Clumsy hands	56	80
Neck pain	31	44.3
Difficulty in climbing	49	70
Difficulty in eating	38	54.3
Walking aid	22	31.4

Signs	Number of patients	Percentage of cohort
Hyperreflexia	68	97.1
Hand intrinsic muscle atrophy	56	80
Hand intrinsic muscle weakness	48	68
Hoffmann sign	56	80
Ankle clonus	24	34
Babinski sign	61	87

Table 5-2 Patients' symptoms and signs.

We used the Mann-Wilcoxon (MWW) non-parametric test for independent samples (symptoms or signs and QOL scores) and found that there was significant correlation

only between:

- a) Numb legs /feet and total SF-36 scores (p=0.045)
- b) Difficulty in climbing and total SF-36 scores (p=0.013)
- c) Difficulty in eating and total SF-36 scores (p=0.006)
- d) Use of walking aid and total SF-36 scores (p=0.045)
- e) Hoffmann's sign and total SF-36 scores (p=0.001)

5.2 Preoperative scores

5.2.1 SF-36

Figures 5-3 to 5-13 below show the distribution and mean Preoperative scores of the eight components of SF-36, as well as for the Physical Component summary (PCS), the Mental Component summary (MCS) and the Total SF-36 scores.

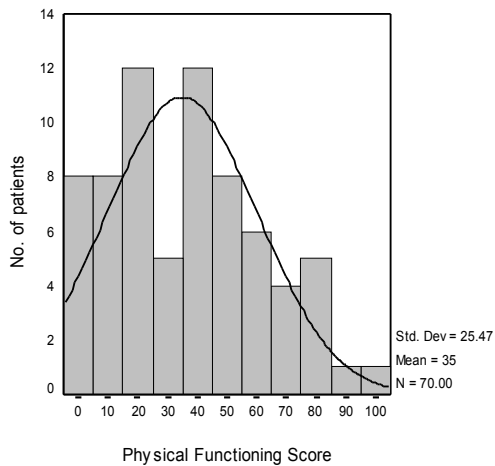


Fig. 5-3

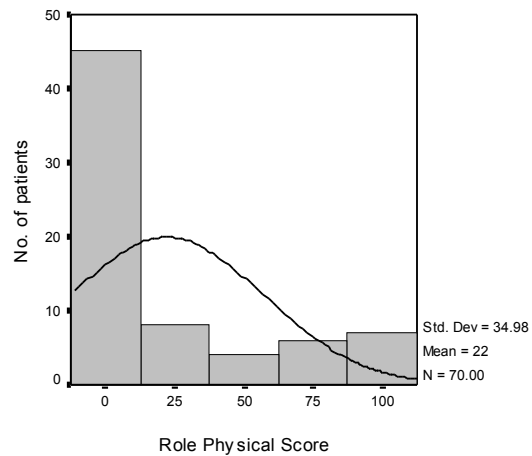
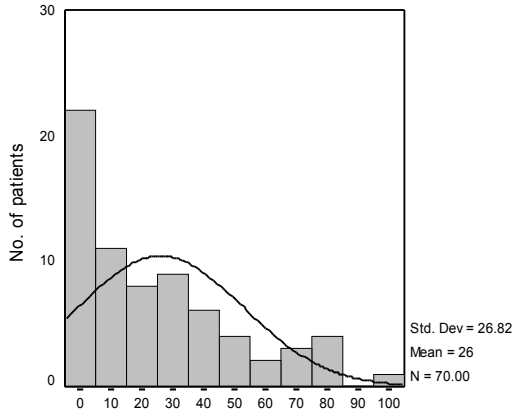
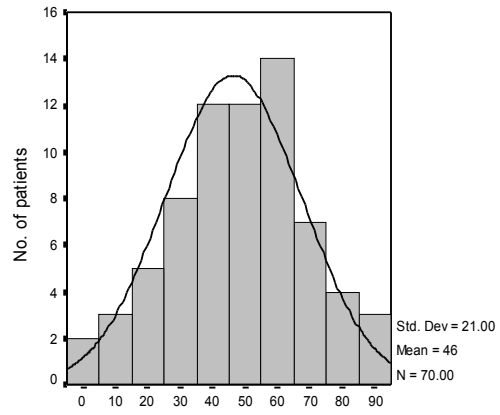


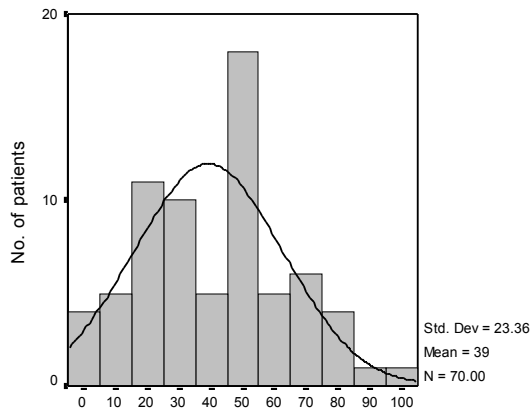
Fig. 5-4



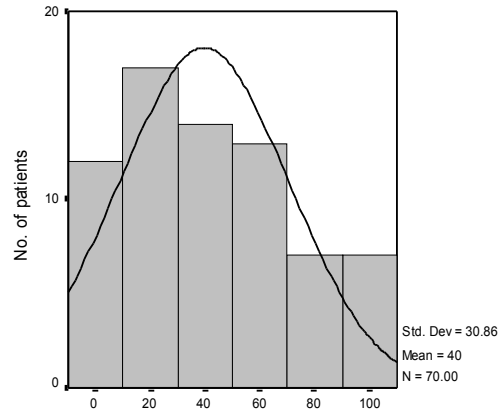
Bodily Pain Score
Fig. 5-5



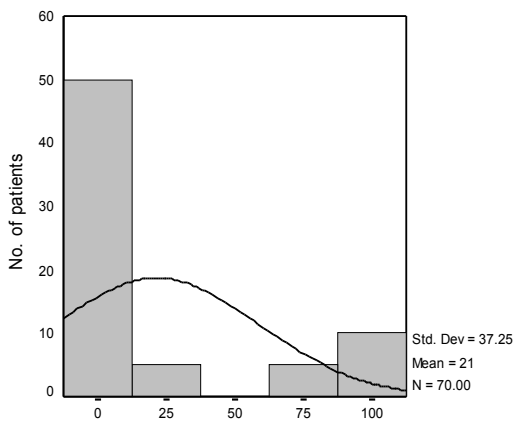
General Health Score
Fig. 5-6



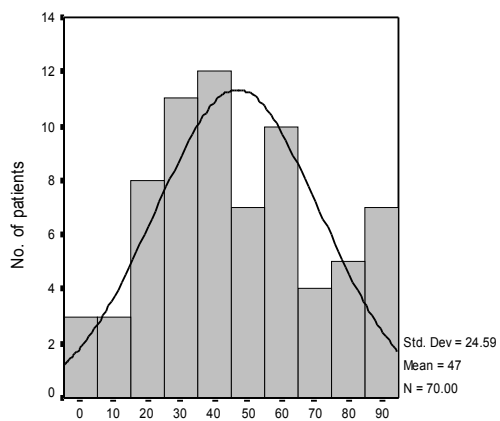
Vitality Score
Fig. 5-7



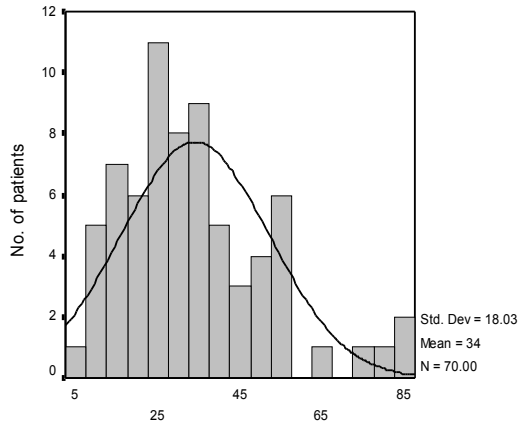
Social Functioning Score
Fig. 5-8



Role Emotional Score
Fig. 5-9

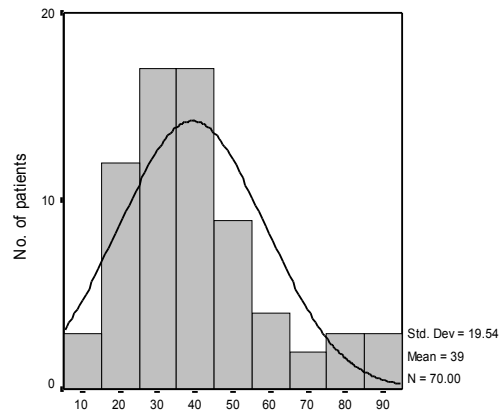


Mental Health Score
Fig. 5-10



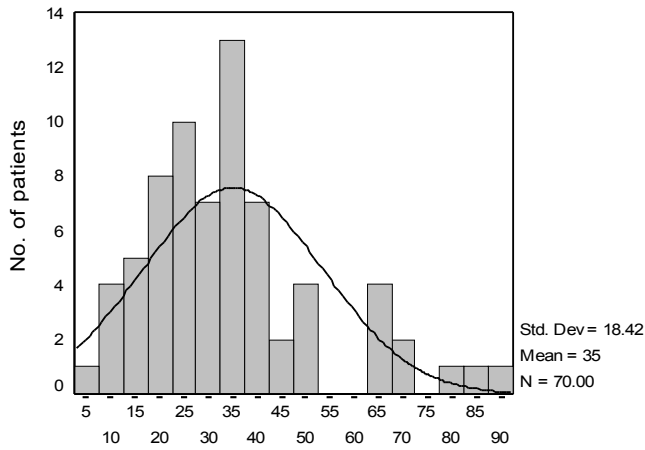
Physical Component Summary

Fig. 5-11



Mental Component Summary

Fig. 5-12



SF-36 Total score

Fig. 5-13

5.2.2 WHOQOL-BREF

Figures 5-14 to 5-18 below show the distribution and mean preoperative scores of the four domains of WHOQOL-BREF, as well as for the total score.

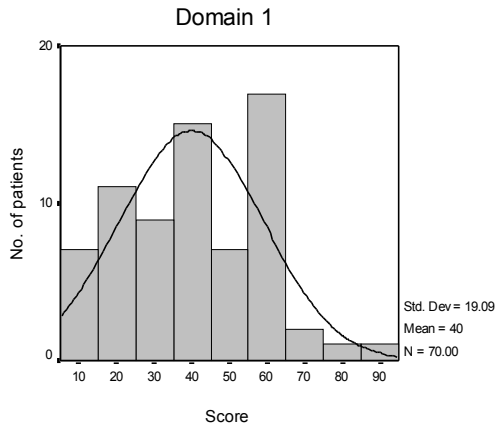


Fig. 5-14

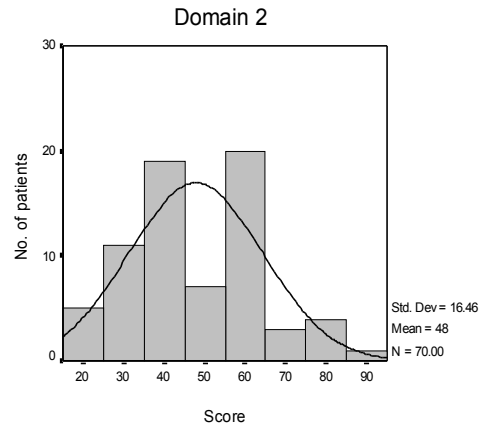


Fig. 5-15

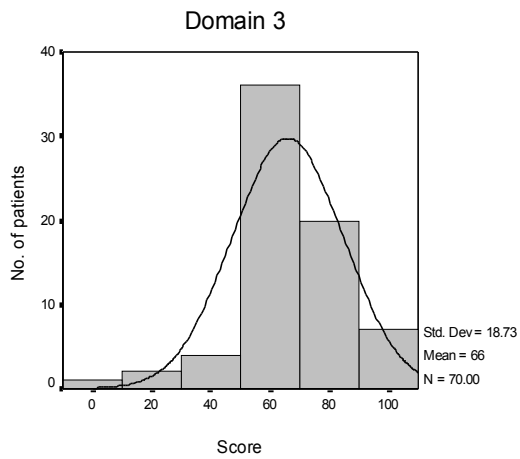


Fig. 5-16

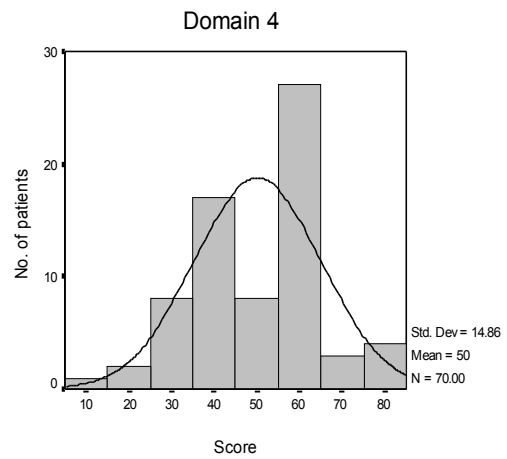


Fig. 5-17

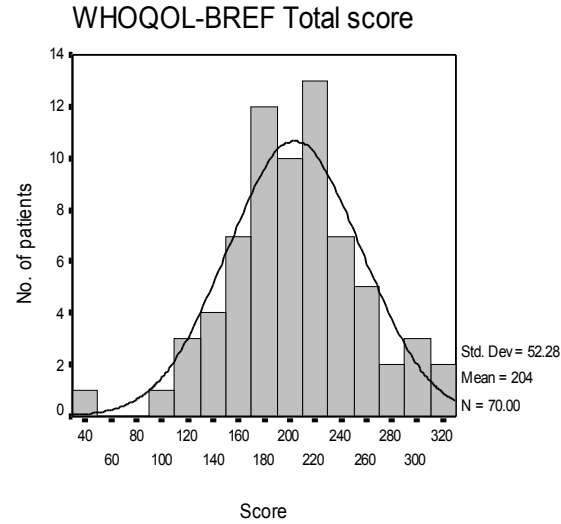


Fig. 5-18

5.2.3 Nurick grade

Out of the 70 patients included in this study, 47 (67%) were classified as “Good” Nurick grade (1- 3); and the remaining 23 patients were classified as “Poor” Nurick grade (4 or 5).

The mean Nurick grade for the whole group of 70 patients was 3.10, while that for the good group was 2.60 and that for poor group was 4.22.

The distribution and mean of Nurick grade for the whole group is represented in the histogram in Fig. 5-19.

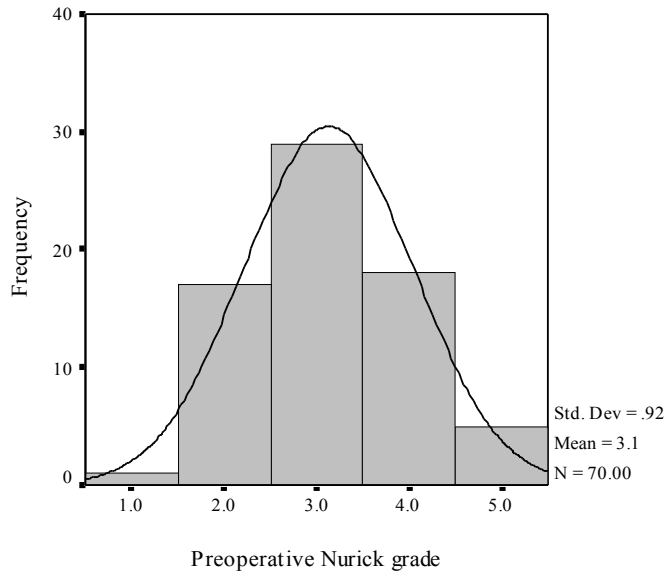


Fig. 5-19

5.3 Comparison of preoperative scores of study group with normative scores

SF-36:

Analysis by T-test of significance showed that the mean total SF-36 score for the normative population was 67.92 +/- 19.05 as compared to 35.01 +/- 18.43 for the study group, and this difference was significant ($p < 0.001$).

WHOQOL-BREF:

Analysis by T-test of significance showed that the mean total WHOQOL-BREF

score for the normative population was 262.64 +/- 44.33 as compared to 203.81 +/- 52.28 for the study group, and this difference was significant (p<0.001).

5.4 Comparison of preoperative scores with follow-up scores

5.4.1 SF-36

Analysis was done using the Wilcoxon Signed Ranks Test

Whole cohort:

For all scales, there was a significant improvement in the follow-up scores (p<0.05)

The error bar charts shown in Figures 5-20 to 5-30 below reflect improvement (preoperative to follow-up) of the mean scores of the eight components of SF-36, as well as for the Physical Component summary (PCS), the Mental Component summary (MCS) and the Total SF-36 scores for the whole cohort.

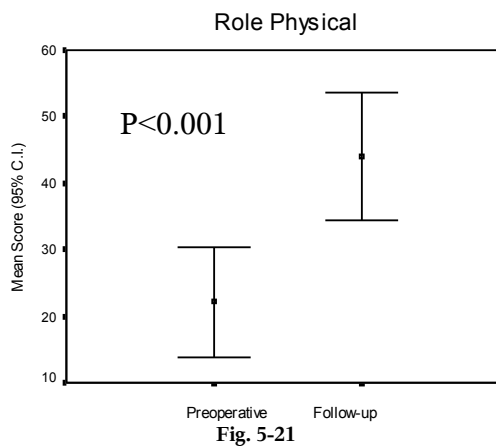
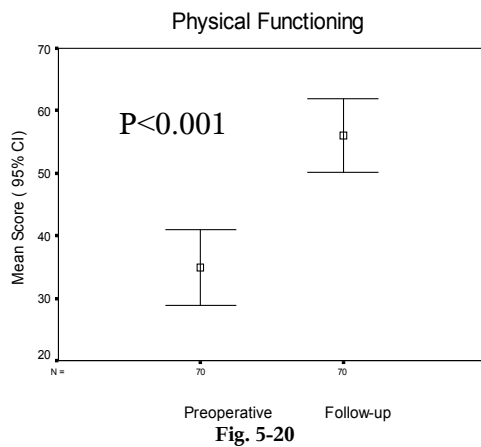




Fig. 5-22

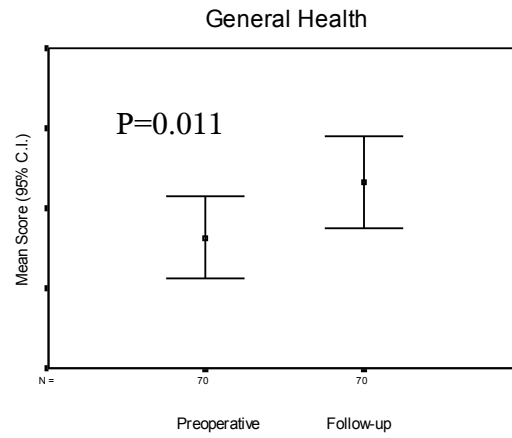


Fig. 5-23

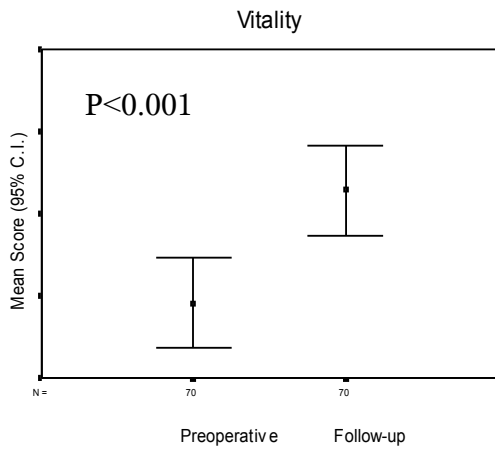


Fig. 5-24

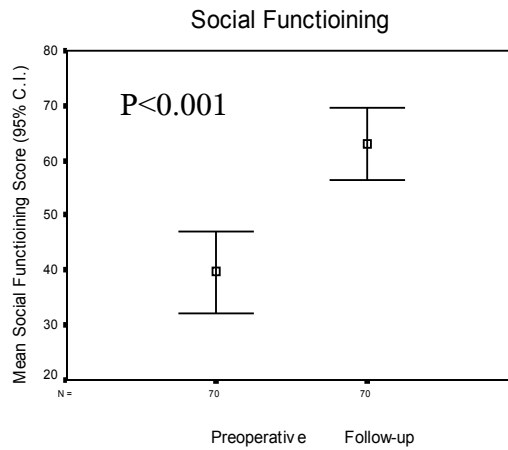


Fig. 5-25

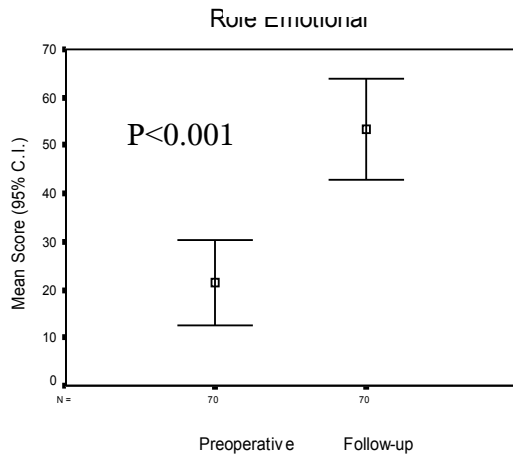


Fig. 5-26

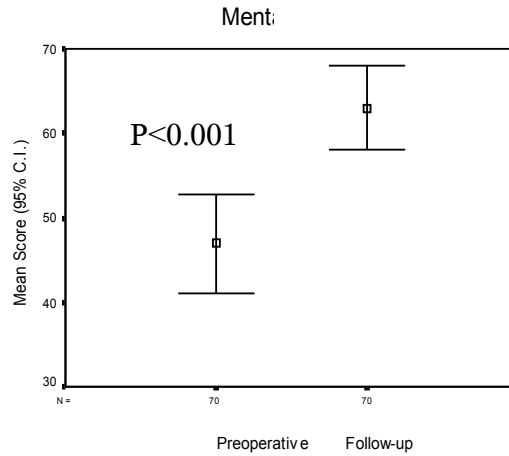


Fig. 5-27

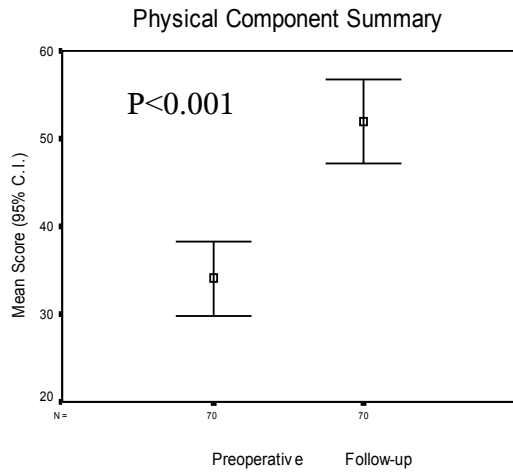


Fig. 5-28

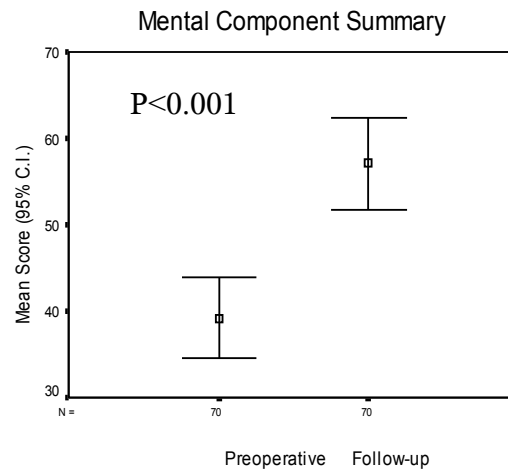


Fig. 5-29

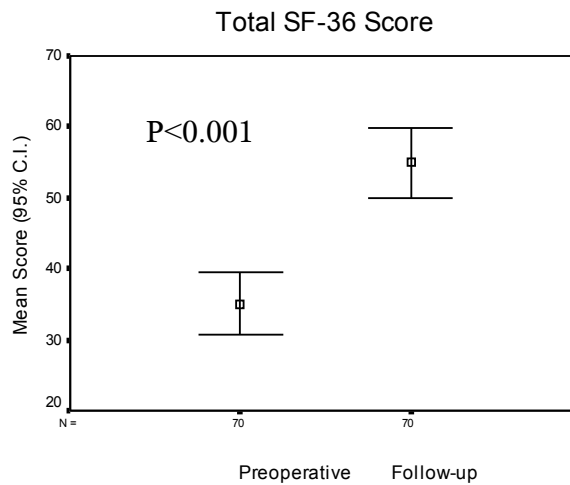


Fig. 5-30

For the good Nurick group:

For all scales, there was a significant improvement in the follow-up scores ($p < 0.05$)

For the poor Nurick group:

Except for **Role Physical** and **general health**, for all other scales, there was a significant improvement in the follow-up scores ($p < 0.05$)

5.4.2 WHOQOL-BREF

Analysis was done using the Wilcoxon Signed Ranks Test

Whole cohort

For all domains except domain 3 (social relations), there was a significant improvement in the follow-up scores ($p < 0.05$)

The simple error bar charts shown in Figures 5-31 to 5-35 below reflect the improvement (preoperative to follow-up) of the mean scores of the four domains of WHOQOL-BREF, as well as for the total score for the whole cohort.

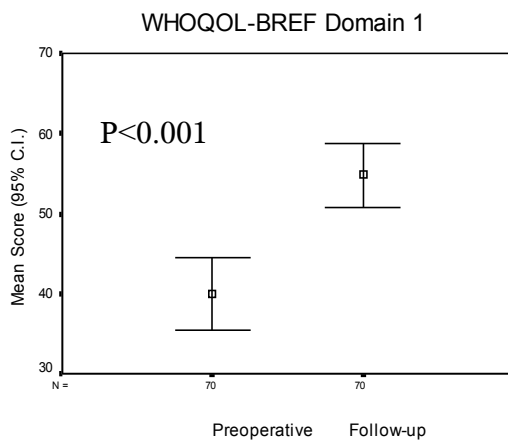


Fig. 5-31

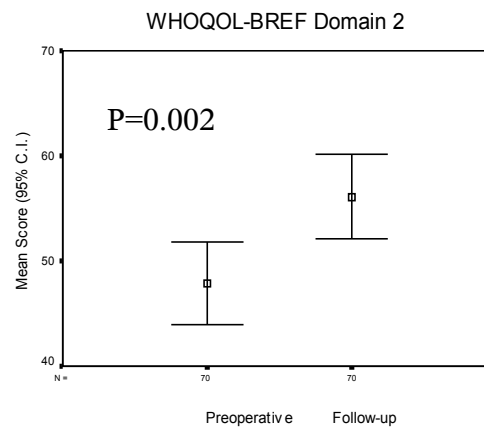


Fig. 5-32

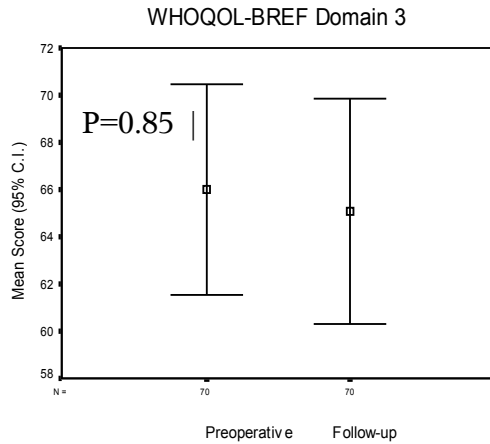


Fig. 5-33

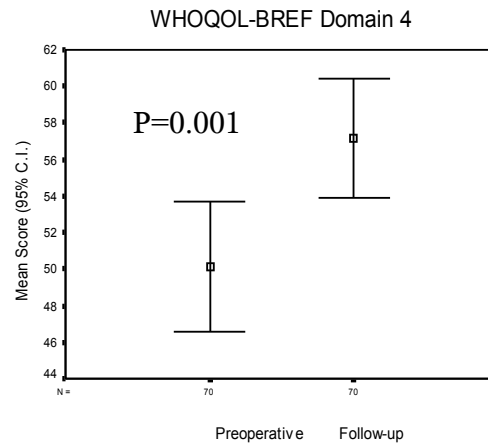
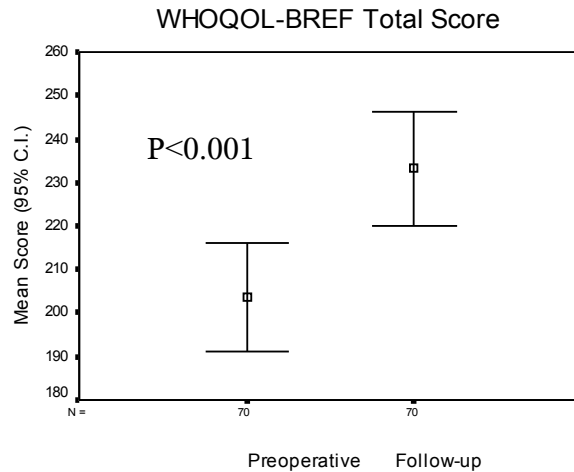


Fig. 5-34



For the good Nurick group: Fig. 5-35

For all domains except domain 3 (social relations), there was a significant improvement in the follow-up scores ($p<0.05$).

For the poor Nurick group:

Except for domain 3 (social relations) and 4 (environment), for the other two domains (physical and psychological), there was a significant improvement in the follow-up scores ($p<0.05$).

5.4.3 Nurick grade recovery rate (NGRR)

While the NGRR for the whole group was 43%, that for the good group was 44% and that for the poor group was 42%.

The error bar charts in Figures 5-36 to 5-38 show the Nurick improvement (preoperative to follow-up) in absolute terms, for the poor and the good groups and for the whole group ($p < 0.001$).

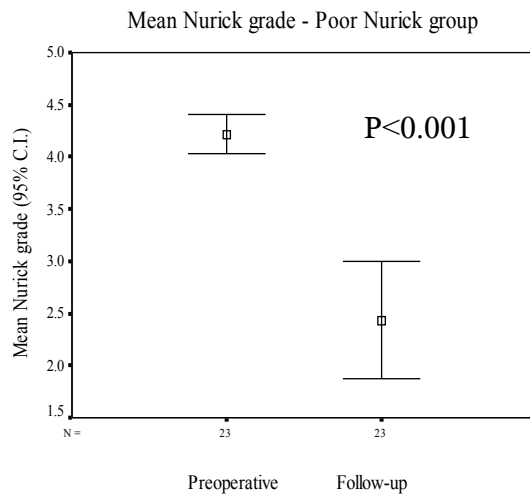


Fig. 5-36

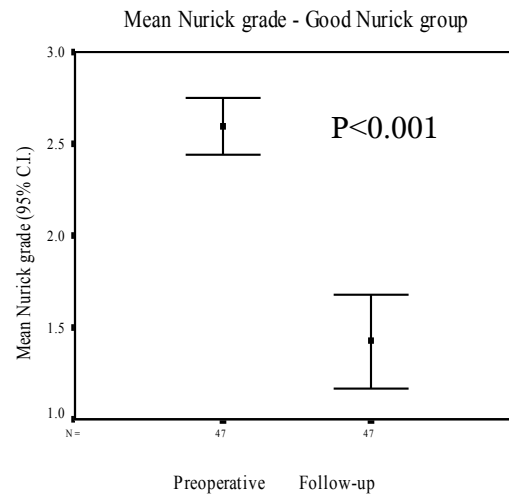


Fig. 5-37

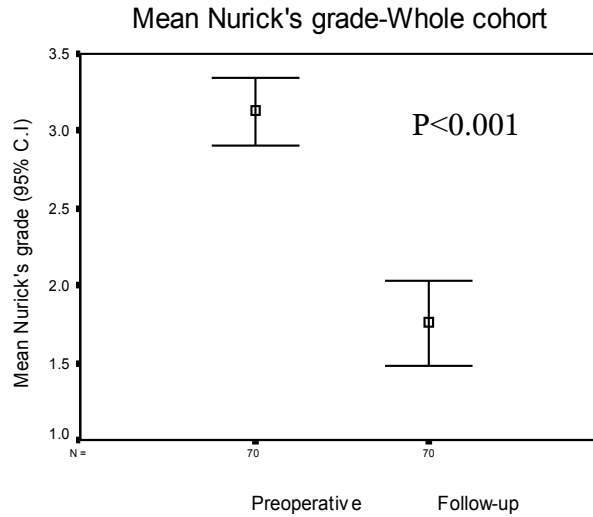


Fig. 5-38

5.5 Patient perceived outcome score (PPOS)

The PPOS was positive in 68 (97.1%) of the patients. The PPOS group ranged from 0 to 100 (mean, 60.11; median, 60) in the good Nurick and from 20 to 90 (mean, 67.17; median, 70) in the poor Nurick group.

5.6 Correlation between outcome measures - Qualitative analysis

Kappa analysis was done to assess degree of agreement: between improvement in different outcome measures.

5.6.1 Nurick grade and SF-36

Degree of agreement between improvement (1 or more) in **Nurick grade** and improvement (5 or more) in **SF-36 total scores** was found to be not significant:

Whole cohort : Kappa = 0.255

For good Nurick grade: Kappa = 0.287

For poor Nurick grade: Kappa = 0.104

Similarly, the degree of agreement between improvement (1 or more) in Nurick grade and improvement (5 or more) in individual SF-36 scales as well the Component Summary scales (PCS and MCS) were all found to be not significant.

5.6.2 Nurick grade and WHOQOL-BREF

Degree of agreement between improvement (1 or more) in **Nurick grade** and improvement (20 or more) in **WHOQOL-BREF total scores** was found to be not significant:

Whole cohort : Kappa = -0.029

For good Nurick grade: Kappa = 0.007

For poor Nurick grade: Kappa = -0.155

Similarly, the degree of agreement between improvement (1 or more) in Nurick grade and improvement (5 or more) in individual domains of the WHOQOL-BREF were all found to be not significant.

The degree of agreement between patient perceived outcome score and improvement (5 or more) in individual scales of SF-36 as well as the 4 domains of the WHOQOL-BREF were all found to be not significant.

5.7 Correlation between outcome measures - Quantitative analysis:

5.7.1 Correlation amongst Patient perceived outcome score, Nurick grade recovery

rate, SF-36 and WHOQOL-BREF

The scatter-plot matrix showing the correlation between various instruments is shown below

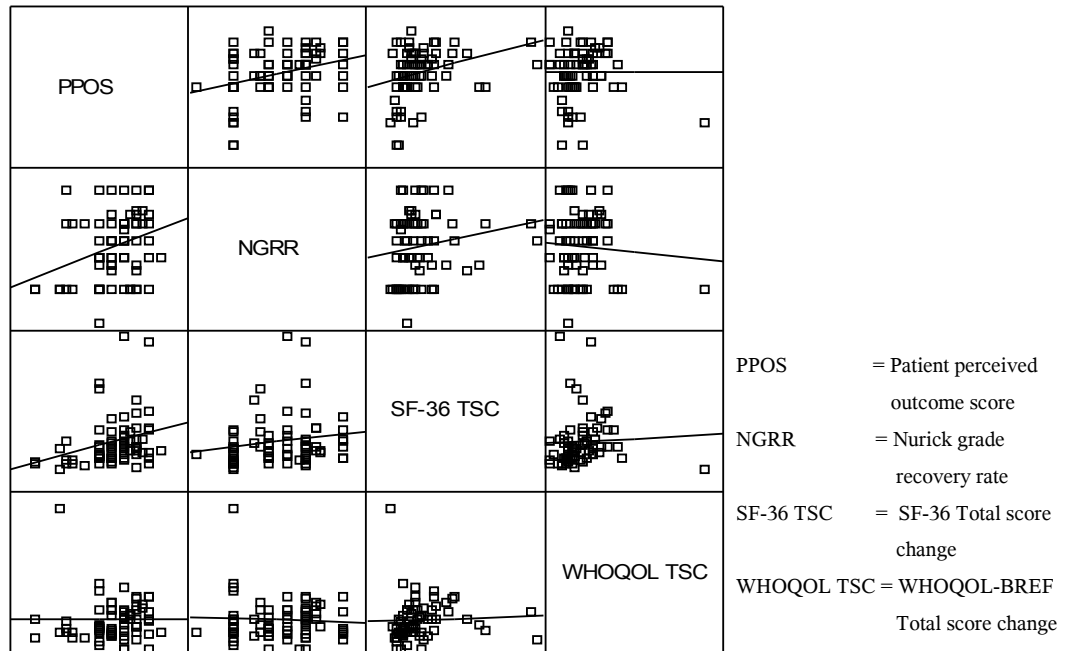


Fig. 5-39 Scatter-plot matrix for correlation between instruments rate, SF-36 Total score change and WHOQOL-BREF Total score change cohort are shown in Table 5-3 below.

Correlations-Whole cohort (N=70)

		PPOS	NGRR	SF-36 TSC	WHOQOL-BREF TSC
PPOS	Pearson Correlation	1	0.320 **	0.296 *	-0.001
	Sig. (2-tailed)	-	0.007	0.013	0.992
NGRR	Pearson Correlation	0.320 **	1	0.174	-0.068
	Sig. (2-tailed)	0.007	-	0.150	0.576
SF-36 TSC	Pearson Correlation	0.296 *	0.174	1	0.054
	Sig. (2-tailed)	0.013	0.150	-	0.656
WHOQOL-	Pearson	-0.001	-0.068	0.054	1

BREF TSC	Correlation				
	Sig. (2-tailed)	0.992	0.576	0.656	-

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

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

Table 5-3 Correlations amongst instruments – whole cohort

From the above table, it becomes apparent that there were positive correlations between PPOS and NGRR ($r=0.320$, $p=0.007$), and between PPOS and SF-36 total score change ($r=0.296$, $p=0.013$). The correlations between the other outcome measures were not statistically significant.

Pearson's correlates between patient perceived outcome score, Nurick grade recovery rate, SF-36 Total score change and WHOQOL-BREF Total score change for the two Nurick groups are shown in Tables 5-4 and 5-5 below.

Correlations-Good Nurick group (N=47)

		PPOS	NGRR	SF-36 TSC	WHOQOL-BREF TSC
PPOS	Pearson Correlation	1	0.260	0.354*	0.276
	Sig. (2-tailed)	-	0.078	0.015	0.061
NGRR	Pearson Correlation	0.260	1	0.320*	0.144
	Sig. (2-tailed)	0.078	-	.029	.335
SF-36 TSC	Pearson Correlation	0.354*	0.320*	1	0.342*

	Sig. (2-tailed)	0.015	0.029	-	0.019
WHOQOL-BREF TSC	Pearson Correlation	0.276	0.144	0.342*	1
	Sig. (2-tailed)	0.061	0.335	0.019	-

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

Table 5-4 Correlations amongst instruments – good Nurick group

Correlations -Poor Nurick group (N=23)

		PPOS	NGRR	SF-36 TSC	WHOQOL-BREF TSC
PPOS	Pearson Correlation	1	0.580 *	0.113	-0.535 *
	Sig. (2-tailed)	0.	0.004	0.607	0.008
NGRR	Pearson Correlation	0.580 *	1	-0.061	-0.312
	Sig. (2-tailed)	0.004	0.	0.783	0.147
SF-36 TSC	Pearson Correlation	0.113	-0.061	1	-0.254
	Sig. (2-tailed)	0.607	0.783	.	0.242
WHOQOL-BREF TSC	Pearson Correlation	-0.535 *	-0.312	-0.254	1
	Sig. (2-tailed)	0.008	0.147	0.242	.

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

Table 5-5 Correlations amongst instruments – poor Nurick group

For the good Nurick group (Table 5-4), positive correlations were obtained between PPOS and SF-36 total score change ($r=0.354$, $p=0.015$) and between NGRR and SF-36 total score change ($r=0.320$, $p=0.029$).

For the poor Nurick group (Table 5-5), a positive correlation was obtained between PPOS and NGRR ($r=0.580$, $p=0.004$). A negative correlation was obtained between PPOS and WHOQOL-BREF total score change ($r=-0.535$, $p=0.008$).

5.7.2 Correlation between SF-36 and WHOQOL-BREF

Reliability for the SF-36 subscales and WHOQOL-BREF domains is high for the study samples ($\alpha =0.9032$ and 0.7447 respectively). Pearson’s correlation coefficients between SF-36 scales and WHOQOL-BREF domains are shown in Table 5-6.

SF-36

	PF	RP	BP	GH	VT	SF	RE	MH	Dom 2	Dom 2	Dom 3	Dom 4
PF	1											
RP	0.254 ^a 0.034 ^b	1										
BP	0.546 0.000	0.297 0.012	1									
GH	0.133 0.272	0.126 0.299	0.307 0.010	1								

VT	0.422 0.000	0.438 0.000	0.532 0.000	0.344 0.004	1							
SF	0.434 0.000	0.273 0.022	0.428 0.000	0.290 0.015	0.683 0.000	1						
RE	0.100 0.410	0.604 0.000	0.262 0.028	0.111 0.362	0.454 0.000	0.292 0.014	1					
MH	0.266 0.026	0.256 0.033	0.396 0.001	0.261 0.029	0.662 0.000	0.389 0.001	0.534 0.000	1				
WHOQOL-BREF												
Dom 1	0.577 0.000	0.229 0.056	0.535 0.000	0.268 0.025	0.398 0.001	0.415 0.000	0.131 0.278	0.170 0.159	1			
Dom 2	0.392 0.001	0.150 0.217	0.315 0.008	0.236 0.050	0.324 0.006	0.220 0.067	0.040 0.744	0.347 0.003	0.457 0.000	1		
Dom 3	0.233 0.053	0.151 0.211	0.205 0.088	0.370 0.002	0.215 0.074	0.313 0.008	-0.005 0.969	0.121 0.319	0.372 0.002	0.477 0.000	1	
Dom 4	0.064 0.598	-0.114 0.346	0.028 0.816	0.287 0.016	0.036 0.766	-0.003 0.982	-0.151 0.211	0.116 0.339	0.230 0.056	0.560 0.000	0.495 0.000	1

a = Pearson's correlate (r)

b = Significance (p)

Table 5-6 Correlation coefficients between SF-36 and WHOQOL-BREF scales and domains

PF (physical functioning), BP (bodily pain) and SF (social functioning) were moderately correlated ($r > 0.40$) with domain 1 (Physical domain) of WHOQOL-BREF.

The other subscales of SF-36 correlated weakly ($r < 0.4$) with any of the domains of the WHOQOL-BREF.

Analysing intra-class correlations, the domains of the WHOQOL-BREF were moderately correlated ($r: 0.4-0.6$) with each other, as were some of the scales of the SF-36.

6. DISCUSSION

The entire study population with CSM was found to have a significantly decreased quality of life (measured by SF-36 and WHOQOL-BREF instruments) as compared with age-matched normative population from similar cultural and regional backgrounds. The scores were expectedly worse for the poor Nurick grade patients. It is to be noted that even the good grade patients had a significantly worse QOL compared with normative scores.

6.1 Change in Nurick grade

The mean preoperative Nurick grade of the whole cohort was 3.10. A large proportion of the patients had a significant ambulatory dysfunction (74.2 % were Nurick grade 3 or higher). This degree of functional impairment was similar to that noted in other published series. (2, 7). The mean Nurick grade improved significantly from 2.6 to 1.43 ($p < 0.001$) in the good Nurick group and from 4.22 to 2.43 ($p < 0.001$) in the poor Nurick group.

33 of the 70 patients became “normal” or “cured” (defined as follow-up Nurick grade 0 or 1). Out of these, 26 were from the good group and 7 were from the poor group. 30.4%

of patients in the poor group obtained a “cure”. This finding was similar to that of a previous study (34) where 24% of the poor grade patients had obtained a cure after surgery.

Nurick grade recovery rate (defined as preoperative minus follow-up grade divided by the preoperative grade x 100), was used as an index of improvement in mobility and was used for analysis as a continuous variable. This was almost similar for both the groups (44% for the good Nurick group and 42% for the poor Nurick group).

These results indicate that there was no significant difference in the degree of improvement in the myelopathy scale scores between the two Nurick groups.

6.2 Change in QOL scores in the good and poor grade groups

Most of the published series on outcome analysis in patients with CSM have reported results in patient with better Nurick grades (grade 1-3). The reported functional outcome in patients with worse Nurick grades has been varied. In the first report (34) published exclusively on outcome in patients with poor Nurick grade after decompressive surgery, it was observed that more than three-fourth such patients improved in their functional status. The observed change in the SF-36 and WHOQOL-BREF scores in the two Nurick groups is discussed below.

a) Change in SF-36 Scores

In our study, it was found that there was a significant change in scores at follow-up in all

scales for the whole cohort, and for the good Nurick grade group. In the poor Nurick grade group, the “role physical” and “general health” scale scores did not improve significantly.

The “role physical” subscale objectively (yes/no answers) covers difficulties in accomplishing routine physical activities. The poor Nurick grade patients, inspite of improving substantially as assessed by other measures, probably did not feel adequately healthier to demonstrate improvement in this very objective subscale.

“General health” includes questions derived from items assessing the patient’s self-perceived general health rating as compared to normal people. Though the poor grade patients did not improve significantly in this rating, this should not be construed as lack of self-perceived improvement. The poor grade patients in fact reported a higher mean self-reported improvement value at 67.17 % (S.D. 15.65) as compared to 60.11 % (S.D. 23.75) reported by the good grade patients.

Interestingly, as found in a previous study conducted by King et al (15), difficulties of the study patients were found to extend beyond physical debility to diminished emotional functioning and mental health, and these improved after surgery.

In another study by King et al (16), only the MCS had improved postoperatively in the patients who reported improvement. In this study, both the MCS and PCS improved significantly. The PCS for the whole cohort improved from 34 to 52 and the MCS improved from 39 to 57. Improvement in both these component summary measures was

significant across all Nurick grades.

The facets within the mental health summary scores include those related to anxiety, depression, social functioning, freedom, opportunities for acquiring new information and skills, and participation in leisure activities. Of these, depression and anxiety have been shown to be strongly associated with decreased mobility (19). Improvement in these areas of functioning probably result from changes seen commonly in CSM patients following surgery i.e. improvement in overall mobility.

b) Change in WHOQOL-BREF Scores

There was significant follow-up improvement in the physical and psychological scores for both the groups. These domains are derived from mobility and mental status related items respectively, and higher scores in these could be explained as above for similar changes in the corresponding SF-36 subscale scores.

It was observed that social relationship was not altered significantly following surgery irrespective of the severity of CSM. This could be partly attributed to the socio-cultural prejudices prevailing in the regions where majority of the study patients hailed from viz., from the eastern part of the country.

The poor grade patients did not demonstrate significant improvement in the environment domain also. The environment domain includes highly subjective and self-perceived measures of safety, home environment, leisure, access to health care, transport and the

physical environment –all important factors that contribute to the global health status of an individual. The relatively poor environment conditions prevailing in the eastern part of the country could have had an additional impact on the disease-related burden in the poor grade patients, making the conditions more unbearable than for the good group patients.

6.3 Correlation between outcome measures

6.3.1 Qualitative analysis

It would be natural to expect a fairly high degree of agreement between improvement in the myelopathy scale and the mobility-related items of the two QOL instruments, as also reported in a previous study (18). However, in this study, it was found that there was no congruence between the Nurick grade and the preoperative PCS score of the SF-36 or domain 1 (physical domain) score of the WHOQOL-BREF. This reflects that these two outcome measures are mutually exclusive and hence the need for using them to supplement each other.

6.3.2 Quantitative analysis

For the whole cohort (Table 5-3) and for the poor Nurick group (Table 5-5), there was a positive correlation between NGRR and PPOS. Such a correlation between the objective NGRR and the subjective PPOS, obtained in another study as well (33), reflects the high priority that patients with CSM tend to place on mobility in preference to other factors while considering improvement in their health status.

Analysing correlations between the QOL instruments and other outcome measures, the SF-36 total score change was positively correlated with PPOS and NGRR in the good group (Table 5-4). The WHOQOL-BREF had no significant positive correlation with the other outcome measures in either of the Nurick groups. This indicates that while the generic SF-36 scale and the PPOS and NGRR may have measured similar health dimensions at least in some patients, the WHOQOL-BREF seems to have functioned as a mutually exclusive outcome measure.

6.4 Correlation between SF-36 and WHOQOL-BREF

Cronbach's alpha was used to measure internal consistency of the two QOL instruments. The alpha values for the overall QOL measurement by the SF-36 and WHOQOL-BREF were 0.90 and 0.74 respectively ($\alpha > 0.7$ is an acceptable co-efficient). Convergent and discriminant validity of the subscales of the two instruments was measured using multitrait analysis (Table 5-6).

In the study sample, of all the subscales that measure similar concepts in the SF-36 and WHOQOL-BREF, only PF (physical functioning), BP (bodily pain) and SF (social functioning) were moderately correlated ($r > 0.40$) with domain 1 (Physical domain) of WHOQOL-BREF. This finding corroborates the observations made in earlier studies (11).

The other subscales of SF-36 correlated weakly ($r < 0.4$) with any of the domains of the WHOQOL-BREF. The domains of the WHOQOL-BREF were moderately correlated with each other ($r: 0.4-0.6$).

For SF-36, the inter-subscale correlation was moderate for:

- BP (bodily pain) with PF (physical functioning);
- VT (vitality) with PF (physical functioning), RP (role physical) and BP (bodily pain);
- SF (social functioning) with PF (physical functioning), BP (bodily pain) and VT (vitality);
- RE (role emotional) with RP (role physical) and VT (vitality);
- MH (mental health) with VT (vitality) and RE (role emotional).

The above observations can be explained by the fact that the two instruments were designed with different objectives and have been established to measure different constructs (11, 10). While the objective of WHOQOL-BREF was to measure a broad ranging concept of QOL, that of the SF-36 was to measure health-related QOL focused on health related functioning and perceptions. Further more, WHOQOL-BREF measures subjective QOL aspects while the SF-36 measures objective capabilities and functioning.

7. CONCLUSIONS

1. Patients with CSM, including those with good Nurick grades (1-3), experience a decreased quality of life compared to normative population.
2. There was a significant improvement in scores of all the SF-36 scales at follow-

up for the good Nurick grade group. For the poor Nurick grade group, except for the scores of the “role physical” and “general health” scales, there was a significant improvement in scores of all the other scales.

3. There was significant improvement in the physical and psychological WHOQOL-BREF domain scores at follow-up for patients in both the Nurick groups. The scores of the social relationship domain in both the groups, and that of the environment domain in the poor grade group did not improve significantly.
4. Amongst the different outcome measures used, there was an association between Nurick grade recovery rate (NGRR) and patient perceived outcome score (PPOS) in the poor Nurick group. Change in the SF-36 scores was positively correlated with NGRR and PPOS in the good Nurick group. This underscores the importance of a multimodal outcome assessment in patients with CSM.
5. Since there was moderate correlation only between physical functioning, bodily pain and social functioning subscales of the SF-36 with domain 1 (Physical domain) of WHOQOL-BREF, it is recommended that both the instruments be used in conjunction to obtain a comprehensive assessment of quality of life for patients with cervical spondylotic myelopathy.

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Appendix A

Scoring the SF-36 Questionnaire (39)

All questions are scored on a scale from 0 to 100, with 100 representing the highest level of functioning possible. Shown below is the scoring system of the RAND 36-Item Health Survey 1.0 (distributed by RAND), which has the same items and similar scoring algorithm as that of the SF-36. Aggregate scores are compiled as a percentage of the total points possible (STEP I chart). The scores from those questions that address each specific area of functional health status (STEP II chart) are then averaged together.

STEP 1: SCORING QUESTIONS:

Question Number	Original Response	Recorded Value
1, 2, 20, 22, 34, 36	1	100
	2	75
	3	50
	4	25
	5	0
3, 4, 5, 6, 7, 8, 9, 10, 11, 12	1	0
	2	50
	3	100
13, 14, 15, 16, 17, 18, 19	1	0
	2	100
21, 23, 26, 27, 30	1	100
	2	80
	3	60
	4	40
	5	20
	6	0
24, 25, 28, 29, 31	1	0
	2	20
	3	40
	4	60
	5	80
	6	100
32, 33, 35	1	0
	2	25
	3	50
	4	75
	5	100

STEP 2: AVERAGING ITEMS TO FORM 8 SCALES:

Scale	Number Of Items	After Recording as per Table 1, Average the following Items
Physical Functioning	10	3, 4, 5, 6, 7, 8, 9, 10, 11, 12
Role limitations due to physical health	4	13, 14, 15, 16
Role limitations due to emotional problems	3	17, 18, 19
Energy/ fatigue	4	23, 27, 29, 31
Emotional well being	5	24, 25, 26, 28, 30
Social functioning	2	20, 32
Pain	2	21,22
General health	5	1,33,34,35,36

APPENDIX B

Scoring the WHOQOL-BREF (38)

A method for the manual calculation of individual scores is given in Fig.4-2. The method for converting raw scores to transformed scores when using this method is given in Table D-1 below. The first transformation method converts scores to range between 4-20. The second transformation method converts domain scores to a 0-100 scale.

Where more than 20% of data is missing from a assessment, the assessment is discarded. Where an item is missing, the mean of other items in the domain is substituted. Where more than two items are missing from the domain, the domain score is not calculated (with the exception of domain 3, where the domain should only be calculated if less than 1 item is missing).

Table D-1. Method for converting raw scores to transformed scores

DOMAIN 1			DOMAIN 2			DOMAIN 3			DOMAIN 4		
Raw Score	Transformed scores		Raw score	Transformed scores		Raw score	Transformed scores		Raw score	Transformed scores	
	4-20	0-100		4-20	0-100		4-20	0-100		4-20	0-100
7	4	0	6	4	0	3	4	0	8	4	0
8	5	6	7	5	6	4	5	6	9	5	6
9	5	6	8	5	6	5	7	19	10	5	6
10	6	13	9	6	13	6	8	25	11	6	13
11	6	13	10	7	19	7	9	31	12	6	13
12	7	19	11	7	19	8	11	44	13	7	19
13	7	19	12	8	25	9	12	50	14	7	19
14	8	25	13	9	31	10	13	56	15	8	25
15	9	31	14	9	31	11	15	69	16	8	25
16	9	31	15	10	38	12	16	75	17	9	31
17	10	38	16	11	44	13	17	81	18	9	31
18	10	38	17	11	44	14	19	94	19	10	38
19	11	44	18	12	50	15	20	100	20	10	38
20	11	44	19	13	56				21	11	44
21	12	50	20	13	56				22	11	44
22	13	56	21	14	63				23	12	50
23	13	56	22	15	69				24	12	50
24	14	63	23	15	69				25	13	56
25	14	63	24	16	75				26	13	56
26	15	69	25	17	81				27	14	63
27	15	69	26	17	81				28	14	63
28	16	75	27	18	88				29	15	69
29	17	81	28	19	94				30	15	69
30	17	81	29	19	94				31	16	75
31	18	88	30	20	100				32	16	75
32	18	88							33	17	81
33	19	94							34	17	81
34	19	94							35	18	88
35	20	100							36	18	88
									37	19	94
									38	19	94
									39	20	100
									40	20	100

SF36 Health Survey. INSTRUCTIONS: This set of questions asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking the answer as indicated. If you are unsure about to answer a question please give the best answer you can.

1.	In general, would you say your health is: (Please tick one box.)				
	Excellent	Very Good	Good	Fair	Poor
2.	<p><u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>? (Please tick one box.)</p> <p>Much better than one year ago</p> <p>Somewhat better now than one year ago</p> <p>About the same as one year ago</p> <p>Somewhat worse now than one year ago</p> <p>Much worse now than one year ago</p>				
3.	The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much? (Please circle one number on each line.)				
	<u>Activities</u>	Yes, Limited A Lot	Yes, Limited A Little	Not Limited a All	
3(i)	Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3	
3(ii)	Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3	
3(iii)	Lifting or carrying groceries	1	2	3	
3(iv)	Climbing several flights of stairs	1	2	3	
3(v)	Climbing one flight of stairs	1	2	3	
3(vi)	Bending, kneeling, or stooping	1	2	3	
3(vii)	Waling more than a mile	1	2	3	

3(viii)	Walking several blocks	1	2	3
3(ix)	Walking one block	1	2	3
3(x)	Bathing or dressing yourself	1	2	3

4.	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities as a result of your <u>physical health</u> ? (Please circle one number on each line.)			
		YES	NO	
4(i)	Cut down on the amount of time you spent on work or other activities	1	2	
4(ii)	Accomplished less than you would like	1	2	
4(iii)	Were limited in the kind of work or other activities	1	2	
4(iv)	Had difficulty performing the work or other activities (for example, it took extra effort)	1	2	
5.	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities as a result of <u>any emotional problems</u> (such as feeling depressed or anxious)?			
	(Please circle one number on each line.)	Yes	No	
5(i)	Cut down on the amount of time you spent on work or other activities	1	2	
5(ii)	Accomplished less than you would like	1	2	
5(iii)	Didn't do work or other activities as carefully as usual	1	2	
6.	During the <u>past 4 weeks</u> , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups? (Please tick one box.)			
	Not at all Slightly Moderately Quite a bit Extremely			
7.	How much <u>physical</u> pain have you had during the <u>past 4 weeks</u> ? (Please tick one box.)			
	None Very mild Mild Moderate Severe Very Severe			
8.	During the <u>past 4 weeks</u> , how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)? (Please tick one box.)			
	Not at all A little bit Moderately Quite a bit Extremely			

9.	These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u> . Please give the one answer that is closest to the way you have been feeling for each item.						
	(Please circle one number on each line.)	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
9(i)	Did you feel full of life?	1	2	3	4	5	6
9(ii)	Have you been a very nervous person?	1	2	3	4	5	6
9(iii)	Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
9(iv)	Have you felt calm and peaceful?	1	2	3	4	5	6
9(v)	Did you have a lot of energy?	1	2	3	4	5	6
9(vi)	Have you felt downhearted and blue?	1	2	3	4	5	6
9(vii)	Did you feel worn out?	1	2	3	4	5	6
9(viii)	Have you been a happy person?	1	2	3	4	5	6
9(ix)	Did you feel tired?	1	2	3	4	5	6
10.	<p>During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives etc.) (Please tick one box.)</p> <p>All of the time Most of the time Some of the time</p> <p>A little of the time None of the time</p>						
11.	How TRUE or FALSE is <u>each</u> of the following statements for you?						
	(Please circle one number on each line.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False	

11(i)	I seem to get sick a little easier than other people	1	2	3	4	5
11(ii)	I am as healthy as anybody I know	1	2	3	4	5
11(iii)	I expect my health to get worse	1	2	3	4	5
11(iv)	My health is excellent	1	2	3	4	5

APPENDIX D

QUESTIONNAIRE FOR WHOQOL-BREF (38)

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

		Very poor	Poor	Neither poor nor good	Good	Very good
1(G1)	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2 (G4)	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4(F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5(F4.1)	How much do you enjoy life?	1	2	3	4	5
6(F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7(F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life?	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12 (F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

Poor Neither poor
 Nor good

		Very poor		poor nor good	Good	Very good
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how good or satisfied you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to **how often** you have felt or experienced certain things in the last two weeks.

		Never	Seldom	Quite often	Very often	Always
26 (F8.1)	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	2	3	4	5

Did someone help you to fill out this form?.....

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

Do you have any comments about the assessment?

.....

THANK YOU FOR YOUR HELP

