CHAPTER ONE

INTRODUCTION

1.1 Background and rationale for the study.

Pain is the common presenting symptom of most musculoskeletal conditions. It is complex and encompasses aetiology, as well as the psychological, social and economic status of the patient. Low back pain is a common problem in the developed world. The lifetime prevalence of low back pain has been estimated to affect sixty to eighty percent of the population in the developed world (Bardin, 2002).

Pain is a subjective sensation and is difficult to measure. It is however important to quantify pain as benefits are obtained by its quantification (Gridley and van den Dalder, 2001). Quantifying pain provides a measure of assessing the effectiveness of treatment and also helps when assessing the behaviour of the patient's pain. It provides a baseline from which to work and can be used to compare pain episodes. The quality and level of pain can be measured and recorded for future reference and for assessing the effectiveness of pain management strategies. A better understanding of a patient's perception of pain can be obtained leading to an understanding of the impact of pain on biopsychosocial aspects of the patient's life (Gridley and van den Dalder, 2001).

The validity and reliability of various measures of pain have been extensively researched in Europe, America and Asia (Bullinger, et al ,1998). In Africa on the other hand, very few studies have been done (Jelsma, et al, 2002). In Africa, most of the research into measurement of pain has been carried out thus far using the Anglo-American pain measures (Jelsma, et al, 2002) and (Olaogun, et al, 2003). No literature could be found supporting evidence of the existence of locally developed outcome measures. This lack of information in the South African scenario is of concern and has therefore prompted the researcher to test the historically used outcome measures to see if they are suited to, and understood by, our local population.

When developing a new outcome measure or translating an existing one the cross-cultural adaptation needs to take the literacy level and education level of the subjects into consideration. Care needs to be taken in the translation process in order to ensure that valuable information is not lost in the translation process and that the outcome measure that is developed, is valid and reliable (Trifilleti, et al, 2006) and (Kopec, 2000). A number of authors have stressed the importance of adhering to a standard procedure for cross-cultural adaptation of an outcome measure (Mannion, 2006). The appropriate language which is used in the scale should be one familiar to the patient. Common words from everyday language should be used and tailored to the individual's needs. Outcome measures should be written in a way in which the subjects talk and should be easy to understand (Kusec, et al, 2006). Local beliefs and customs affect interpretation of written material. Low literacy levels also affect the interpretation of the outcome measures. Lack of correct information, fear of what is strange or different often leads to misunderstanding. Pictures should be used in low literacy groups as this facilitates better understanding of the outcome measures. (Werner, 1987).

Scales commonly used in Western society are the Verbal Rating Pain Measure and the Visual Analogue scale. These scales are simple, reliable and easily reproducible methods for the assessment of pain (Carlsson, 1983).A scale which has in the past, been mostly used for children, is the Wong-Baker Faces Pain Scale. It is easy to understand and can be used for children, adults and for subjects with low educational levels (Wong-Baker, 1988).

1.2 Problem statement.

There is no reliable and valid measuring tool (outcome measure) for back pain amongst South Africans of different cultural backgrounds and different education levels. The outcome measures which are currently being used in South Africa are those from different cultures, Anglo-American in particular. No outcome measures have, up until

now been specifically designed for South African populations of differing cultural backgrounds.

1.3 Aim of study.

The aim of this study was to establish the validity and reliability of the Tswana translations of the three pain scales (Visual Analogue Scale, Verbal Rating Scale and the Wong-Baker Faces Pain Measure) in a group of people with varying literacy levels and to determine the most appropriate of the three scales to use in this population.

1.4 Objectives of study.

The objectives of this study were:

- to translate the Visual Analogue Scale (V.A.S), Verbal Rating Scale (V.R.S.) and the Wong-Baker Faces Pain Measure (W.B.F) into Tswana.
- to measure the subjects' pain thresholds (maximal and sub-maximal) in normal areas.
- to rate the above pressure readings on the pain scales and hence determine if there is a correlation between the Pressure Threshold Meter(P.T.M) and the Visual Analogue Scale.
- to assess the pain threshold using the Pressure Threshold Meter on the back (painful area)
- to rate the above pressures on the pain scales.
- to test the reliability of the three pain scales (Visual Analogue Scale, Verbal Rating Scale and the Wong-Baker Faces Pain Measure).
- to assess whether the subjects are able to put the verbal rating scale into the correct order ie. from nought (no pain) to ten (maximal pain).
- to determine whether there is a difference in the understanding of the scales in differing education levels.

- to determine whether there is a difference in the understanding of the scales in different age groups
- to determine whether an inverse relationship exists between maximum pain recorded by the Pressure Threshold Meter and the different scales. ie. whether a high (maximal) rating on the scales correlates with a low pressure threshold reading.
- to determine whether an inverse relationship exists between sub-maximal back pain recorded by the Pressure Threshold Meter and the different scales.ie. whether a lower (sub-maximal) rating on the scales correlates with a higher pressure tolerance reading.

1.5 Significance of study.

The study will establish the reliability and validity of the Tswana version of the Visual Analogue Scale, the Verbal Rating Pain Scale and the Wong-Baker Faces Pain Scale. No studies have been found in the literature on using these outcome measures in the assessment of back pain in South Africa. This study may demonstrate the usefulness of these scales in a South African population of varying literacy levels and ethnic differences.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction.

In this chapter concepts underlying the research aim are discussed in relation to the literature. This chapter covers the literature concerning various aspects of pain, the psychology of pain, cognitive behaviour in pain and back pain in particular. Currently used outcome measures and the use of pressure algometry are also investigated. Cross-cultural adaptation of the outcome measures and the importance of taking differing age groups and education levels into consideration are also explored. The translation process, the importance of communication and language are also considered in this review of current literature.

2.2 Pain.

Pain is different from other sensations as it sounds a warning that something is wrong and preempts other signals. There is still much to learn about pain, but in general, it is convenient to talk about physiologic (acute) pain and pathological pain (inflammatory and neuropathic pain) (Ganong, 2003). Pain is the common presenting symptom of most musculoskeletal conditions. It is complex and encompasses aetiology, as well as the psychological, social and economic status of the patient (Zanoli, et al., 2001). Pain can be defined as an unpleasant and emotional experience associated with actual or potential tissue damage. Pain can also be described in terms of damage done to tissue (Readyard and Edwards, 1992). Pain is a subjective experience. A person's response to noxious stimuli may be affected by psychological factors such as conditioning experiences, state of mind and past experiences and also, sociological factors such as gender and culture (French, 1989). The mechanism of pain production in the spine can be either, nociceptive, neurogenic (peripheral evoked and or central evoked), cognitive and affective, motor mechanism or autonomic mechanism or a combination of some of them, or all of them.

2.3 Back pain.

Low back pain is a common problem in the developed world (Bardin, 2002). The lifetime prevalence of low back pain has been estimated to affect sixty to eighty percent of the population in the developed world (Bardin, 2002). Most episodes of low back pain are short-lived and approximately eighty to ninety percent of low back pain cases resolve on their own (without medical intervention) (Manchikanti, 2000). Risk factors for low back pain include physical factors, social demographics, habits and psychosocial factors. The percentage of the work force affected by low back pain varies from country to country and the resultant number of hours lost in the work place is great (Manchikanti, 2000). Eriksen, et al.,(2004) concluded that days taken off for sick leave due to back pain, were related not only to frequent mechanical exposure, but also to psychological and social work factors.

2.4 Assessment of pain.

Subjective and objective examination are an integral part of the manual therapist's treatment protocols. A subjective assessment (history) is carried out followed by the objective examination. Active listening to the patient's concerns about their pain, the recording of its localization, severity and consequences are all essential to good diagnosis and management of the patient (Moffet, et al., 2006).

Assessment of back pain is made easier by using scales to measure the severity (intensity) of the pain. By doing this the therapist has an idea as to whether the treatment employed is having an effect on the pain (worsening or improvement).Scales are a convenient ,easy and quick way of determining changes in the patient's symptoms (Moffet and McLean, 2006).

There is strong evidence to suggest that psychosocial factors are sometimes more important than biomechanical factors in influencing the development of back and probably neck pain too (Moffet and McLean, 2006).

2.5 The psychology of pain.

The perception of pain involves more than mere sensation. Pain has affective and evaluative components and these are often just as important as the production and transmission of the pain signal (Hansen and Streltzer, 2005). Pain perception is dependent on the context in which it occurs, the attention focused on it, the presence of anxiety or fear, the memory of pain, learned pain, the patient's expectations, beliefs and coping strategies. Pain also has psychological and emotional aspects to it. It can be a conditioned response or due to psychiatric disease.

Due to the influence of psychological factors on pain Hansen and Streltzer,(2005),suggest that brief screening of the patient be done at the initial evaluation. This will not only assist in the evaluation of the patient, but also in the correct treatment for the patient. Appropriate assessment tools need to take the patient's psychological status into consideration when analysing their outcomes. Understanding the impact of fear, expectations and attention to pain, will contribute greatly to the assessment and ultimately to the management of the patient suffering from pain, both acute and chronic. Psychosocial factors are important and must be considered for each patient, especially those with chronic pain, in order to achieve maximum effectiveness of assessment and treatment (Moffet and Mclean, 2006).For both back pain and neck pain there is evidence that cognitive-behavioural interventions can be successful (Moffet and McLean, 2006).

2.6 Cognitive-behaviour in pain.

The mind- body concept is one which emphasises the importance of the relationship between the mind and the body in the aetiology of pain. Cognitive-behavioural

components of the pain experience concentrate on the emotional, behavioural and social responses of patients. Responses to nociception are modulated by biopsychosocial factors, including individualized knowledge, beliefs and attitudes that may be mediated by variation in the pain transmission process (Dalton and Coyne, 2003). They suggest that educating the patient as to their condition, will increase the patient's understanding of, and beliefs about pain and its management. Assessment of pain also depends on functional health literacy.

Functional health literacy is defined as a person's ability to function in the health care setting using their skills in literacy and numeracy. Low functional health literacy may limit a patient's ability to comprehend, retain, recall and act on written health care measures (scales or questionnaires) of both literary and numerical content (Teutsch, 2003).

2.7 Cross-cultural adaptation.

The expression of pain differs between ethnic types depending on the way in which a culture encourages or discourages the expression of pain. Newman, et al., (2005), also found that the expression of pain depends on facial phenotype. They state that cross-racial validity of pain scales has been studied in certain ethnic minorities in the West and to a lesser extent in non-Western countries. Results from these studies are conflicting. Newman, et al., (2005), found that further research is necessary for proper cross-cultural validation of the scales they used, namely the Wong-Baker Faces pain measure and the Faces Pain Scale.

Race and sex differences also exist in the perception of pain (Sheffield, et al., 2001). Sheffield, et al., 2001 also found that African men tended to rate their pain as less painful than African women.This is due to the fact that in the African culture, men are expected to be more stoical.

Werner, (1988), is of the opinion that , local beliefs and customs affect interpretation of written material. Low literacy levels will also affect the interpretation of the various pain scales. Lack of correct information, fear of what is strange or different often leads to misunderstanding. He suggests that in order to make materials better understood by low literacy groups, pictures should be used.

Werner and Bower, (1987), feel that a person will sometimes tell you what they think you want to hear in the hope that you will treat them better or reward them if you are pleased with their answers. It is important that the subjects understand that by filling in the scales they need to be totally honest about their pain (Werner and Bower, 1987).

If measures are to be used cross-culturally, the items must be translated well linguistically but must, more importantly be adapted culturally to maintain the content validity of the instrument (scales) at a conceptual level across different cultures (Beaton, et al., 2000). Cross-cultural adaptation therefore encompasses a process which looks at language and cultural adaptation of the scales which are to be used in a different setting. Recognition and understanding of the association between culture and health are important in patient care, as cultural issues impact on the presentation, assessment and management of patients (Chang, et al., 2006).

Communication is essential in the process of assessment and correct diagnosis of the patient. Successful communication and hence better assessment will lead to more accurate diagnosis and better treatment of the patient.

2.8 Communication.

Effective communication is essential for delivering quality care and for building better health –worker and patient relationships. Gaps in communication related to gender, culture and literacy can lead to an inferior standard in patient care (Teutsch, 2003).

Communication approaches need to be adapted to various settings. The patient's culture, gender, age and literacy levels need to be taken into consideration. Teutsch, (2003) suggests that sensitivity and adaptation of communication styles are needed for successful interaction of cultures. This needs to be borne in mind when adapting and using outcome measures. Without an appreciation of cultural implications of a disease and the need for cultural competence skills, communication and ultimately treatment of the patient will be affected. Education in cross-cultural efficacy helps facilitate better bidirectional communication. Culturally appropriate questions need to be formulated and asked when dealing with people from differing cultures.

Functional health literacy is defined as a person's ability to function in the health care setting using their skills in literacy and numeracy. Low functional health literacy may limit a patient's ability to comprehend, retain, recall and act on written health care measures (scales or questionnaires) of both literary and numerical content(Teutsch, 2003).

It has long been recognized that difficulties in the effective delivery of health care can arise from communication problems rather than from failing in the technical aspects of medical care. To be effective in the assessment, treatment and management of patients, the health-worker needs to gain a better understanding of the patient's perspective of his pain or illness and this is achieved by better communication.Outcome measures need to therefore be adapted to suit the group of individuals targeted.

2.9 Language and Literacy levels.

Effective communication has been shown to influence patient's adherence and hence will influence medical outcomes. This is particularly important for informed consent. The need to deliver culturally and linguistically appropriate measures is the patient's right and is a key factor in improving the quality of patient care (Kusec, et al., 2006). The appropriate language should be one familiar to the patient. Common words from every day language should be used and should be tailored to the individual's needs. The out

come measures should be written in a way in which the subjects talk and should be easy to understand (Kusec, et al., 2006).

Triffiletti, et al., (2006), supports this view point and states that there is a need for developing and implementing scales and instruments for all reading levels including those of low literacy levels. Health education materials have previously been written at levels far above what the general population can understand and they greatly exceed what people of a low literacy level can understand. Recent work suggests tailoring of cultural variables such as spirituality, time orientation and racial pride when developing a new outcome measure. All these variables can enhance the effectiveness of health communication (Triffiletti, et al., 2006).

In the Zimbabwean context Jelsma, et al., (1997), found that although the V.R.S. and V.A.S. were most widely used, a pictorial scale was found to be easier to use for subjects who have limited education. The specific aims of their study included determining if the education level of the subjects influenced the level of correlation of the scales used (McGill Verbal Descriptive Scale, the V.A.S. and the 11 point Box scale). They concluded that both numerical and verbal pain rating scales could be used in the better educated Zimbabwean population. Alternate methods of pain measurement were recommended for Zimbabweans of limited education. A pictorial pain scale was found to be easier to use for these subjects.

Kusec, et al. ,(2006), suggest that, exploring a way of improving communication is essential. They suggest that the patient's conversational style be adopted in the development of written materials (outcome measures). In their study Nuhr, et al. ,(2004), state that clinical intervention research in back pain would be greatly facilitated if a small number of relevant, patient centered measurement tools became internationally used. Some tools are more particularly suited to cross-cultural adaptation.

Mannion, et al., (2006) propose that the availability and consistent use of established outcome measures in different languages facilitates the collection of reliable data and

enables the pooling of data from different studies for use in meta-analysis. This allows a valid comparison of outcome measures between nations and different cultures. The adaptation of the instrument in question has to undergo cross-cultural adaptation for the chosen target language before it is used in a study.

2.10 The translation process.

Ostlund, et al., (2006) advise that the following procedure be adhered to when translating and culturally adapting pain scales. Two teams independently translate the scale (instrument) and two other teams produce the back- translations. The pre-test interviews done by them allowed the subject's verbal responses to be analysed and used for a second revision. They established that the initial translations varied in words, expressions and grammar, shown in a lack of equivalence to the original instrument after back-translation. In order to establish semantic equivalence, the teams had to change some grammar and some words needed to be replaced in order for experiential and conceptual equivalence.

Padua, et al., (2002) state that over the past ten years, patient-oriented evaluations using questionnaires and measurement tools have become an important aspect of clinical spinal outcome studies. Any outcome measure must be translated and culturally adapted in order to be used in different language groups. They then advise that the translated version be evaluated for reliability and validity, which are fundamental attributes of any measurement tool.

A poor translation may lead to an outcome measure that is not equivalent to the originalone. Adaptation of outcome measures for use for a new setting is time consuming and costly. However, adaptation of outcome measures for different ethnic and cultural groups would be of great benefit for those subjects who are not English speaking (first language). These subjects would otherwise have been excluded from studies. By

adapting outcome measures to suit the local population, selection bias can be avoided and a better understanding of the outcome measures can hopefully be achieved.

2.11 Assessment tools.

The Verbal Rating Pain measure(V.R.S), the Visual Analogue Scale(V.A.S) and the Wong- Baker Faces Pain Scale(W.B.F) have been used frequently in the subjective (patient's perception) measurement of pain.

The Verbal Rating Pain measure and the Visual Analogue Scale are both simple, reliable and easily reproducible methods for the assessment of pain (Carlsson, 1983). The Wong-Baker Faces Pain Scale is easy to understand and is used widely and very commonly for children (Wong and Baker, 1988). It is also used, albeit less commonly for adults and for subjects with low educational levels (Kim and Buschmann, 2006).

Different pain scales have, in the past been used interchangeably. In their study Freeman, et al, (2001) looked at the interchangeability of two pain scales, namely the Visual Analogue Scale and the Wong- Baker Faces pain rating scale in a population of hospitalized, elderly patients with ulcer pain. Their aim was to better understand the statistical properties of the two pain scales to see if they can be used appropriately in clinical practice. They concluded that there was high reliability between the Visual Analogue Scale and the Wong -Baker pain scale for assessment of pain in populations with diminished verbal and abstract thinking abilities.

Kim and Buschmann, (2006), supported the appropriateness of using the Wong- Baker Faces scale (W.B.F.) in older adults as well as in children, to measure pain intensity. Their study also provided cross-cultural evidence to evaluate the usefulness of the W.B.F. pain scale. Terai, et al., (1998), state that the V.A.S. is a simple and sensitive means of pain assessment. The faces pain scale is also, they say, a simple, self-reporting method for children. In their study they used the faces pain scale to assess the pain in

postoperative adult patients in an I.C.U. (intensive care unit) in Osaka, Japan. They concluded that the faces pain scale was a reliable and valid means of measuring pain in adults.

The Visual Analogue Scale (V.A.S.) is a simple and frequently used method of measurement of variations of intensity of pain (Carlsson, 1983). The absolute V.A.S. is preferable to the comparative V.A.S. because the comparative V.A.S. is influenced by the effects of expectancy and deficient memory of pain. The V.A.S. was also found to be better at detecting small changes of pain over time (Clark, et al., 2003).

When comparing pain scales in patients Clark, et al.,(2003), found that patients preferred the Verbal Rating Pain scale (V.R.S.) to the V.A.S. The reason given for this preference was that the patients found the V.R.S. easier to use and were more comfortable using words to express their pain, than numbers. They concluded that although both scales are valid measures of pain intensity, the choice of scale used should depend on the clinical setting, the clinician's goal and the patient's level of education.

Ogon, et al., (1996) suggest that a horizontal V.A.S be used instead of a vertical one in the measurement of chronic back pain. They found the horizontal V.A.S. to be of a higher sensitivity. Ogon, et al., (1996), also state that a short written explanation of how the scales work is sufficient and oral explanations are not essential. For the purpose of our study we however chose to use both explanations for the benefit of the illiterate subjects and for those of lower education levels.

2.12 Reliability and Validity.

Ferraz, et al. ,(1991), believe that the assessment of a measure of chronic pain should be reliable, valid and sensitive to change. They evaluated the reliability of three pain scales, the V.A.S. 1 (nought and ten only), the V.A.S . 2 (nought through to ten), and the verbal rating scale (V.R.S.) in subjects with rheumatoid arthritis. Subjects participating in their

study were literate and illiterate. Their findings show that the V.A.S. 2 (numerical rating scale) had the higher reliability in both groups of subjects.

A study done by Olaogun, et al., (2003), in Nigeria to determine the reliability and validity of the V.A.S. and modified V.R.S. of pain assessment found that there was a good correlation between the V.A.S. and V.R.S. and that the McGill Pain Questionnaire (M.P.Q.) was not easily understood in a low literacy setting. The test-retest reliability of the scales will indicate whether the same results are obtained on repeated administration of the given instrument (the scales). This test-retest reliability indicates the extent to which results are obtained when no change is expected (Mannion, 2006).

2.13 Age-related differences.

Gagliese and Katz, (2003), analysed age-related patterns in three pain scales. They used the V.A.S, P.P.I. (present pain intensity) and the McGill pain questionnaire to determine pain following radical prostatectomy in younger (56 years) and older (67 years) men. Age differences in pain were found to be dependent on the type of scale used. All three scales had comparable sensitivity within an age group. The V.A.S. however, was found to be not sufficiently sensitive to detect age differences. They therefore recommend that in order to determine age differences in pain intensity, verbal descriptions of pain qualities are more reliable than non-verbal measures of intensity.

2.14 Pressure algometry.

Pressure algometry is an objective way of measuring pain and has become established as a clinical and research tool for the investigation and treatment of pain (Johnson and Watson,1997). Pressure tolerance can be measured by the maximum stimulus tolerated by the subject and pressure threshold is defined as the minimum force or stimulus that induces discomfort or pain. Both measures have been shown to be very useful in evaluating patients with chronic pain (Fischer, 1987).

Pressure threshold is the minimum pressure or force which induces pain. The pressure threshold meter (P.T.M.) has been shown to be useful in clinical practice for the quantification of deep muscle tenderness or pain (Fischer, 1987). Mersky and Spear, (1964), in their study showed that the pressure at which a subject first describes awareness of pain (threshold) correlates well between observers, occasions and sites. Their study concluded that pressure pain has a degree of reliability which makes possible its quantitive use for the investigation of a subject's perception of pain in spite of the fact that the pain threshold report depends a great deal upon factors such as attitude, sex and cultural role.

Fischer, (1987), found that there was a difference in pressure threshold between males and females. Females demonstrated lower pressure thresholds than males and the difference between the sexes were significant in all muscle groups tested. Differences were also encountered in the pressure thresholds of individual muscles. In general he found that muscles situated in the lower parts of the body are less sensitive and are characterized by a higher pressure threshold.

2.15 Conclusion.

Pain is subjective and is difficult to measure or quantify. The Pressure Threshold Meter(P.T.M) has been shown to be an effective means of measuring pain objectively. The V.A.S., the V.R.S. and the W.B.F. pain measure have all been used successfully to quantify pain subjectively. Anglo-American scales and questionnaires have been used extensively throughout the Western World. Few studies have researched whether these scales are suitable for the African continent.

From a review of the literature it becomes apparent that when one develops a new outcome measure or modifies an outcome measure for a new setting, the culture of the target group, its literacy level, language, age, gender and education level, need to be

taken into consideration. Correct translation and cross-cultural adaptation is required to ensure that the outcome measure developed is both valid and reliable. Communication is also important in ensuring that the outcome measures are understood and therefore used correctly. Appropriate assessment tools (outcome measures) also need to take the patient's psychological status into consideration when analysing their outcomes. Understanding the impact of fear, expectations and attention to pain, will contribute greatly to the assessment and management of the patient suffering from pain.

Adaptation of outcome measures for use in a new setting is time consuming and costly. This adaptation is however, of great benefit for subjects who are not English speaking (first language) and who would otherwise, because of this fact, be excluded from studies.

CHAPTER THREE

METHOD

3.1 Introduction.

This chapter describes the method behind the research study. Study design, sample selection, inclusion and exclusion criteria as well as the translation process are all described. The entire research process is described as well.

3.2 Study setting.

The subjects were tested at Wilmed Park, Anncron Hospital, Duff Scott Hospital, Wesvaal Hospital, Sunningdale Hospital and the Klerksdorp Hospital over a period of approximately two weeks at each hospital.The retesting of thirty seven subjects took place at the Wilmed Hospital, Duff Scott Hospital and the Sunningdale Hospital. Subjects who were tested in the morning of one day were tested on the following day also in the morning. Those who were tested in the afternoon of one day were retested on the afternoon of the next day. Hereby the reliability of the translated versions of the four pain scales could then be statistically established.

3.3 Pilot Study.

The pilot study (ten subjects) was carried out over two days at the Wilmed Hospital (the morning of each day).

3.4 Ethics.

Permission was obtained from management of all five hospitals (see appendix A). Subjects were invited to participate in the study. They were free to decline should they choose to do so and were not disadvantaged in any way by doing so.

Subjects who met the inclusion criteria were asked to sign informed consent prior to participation in the study. (see appendix A). The subjects were informed as to the entire process ie. the taking of the pressure threshold measurements and answering the questionnaires as well as the interview in which they were asked about their present back pain. Confidentiality and anonymity were guaranteed.

Questionnaires were numbered according to the number of subjects taking part in the study. The numbers correlated with the subject's details which were recorded and kept confidential in a separate file. The subject's details also included whether they belonged to the group of kitchen workers, cleaners, laundry workers or out patient department patients. The research commenced once ethical clearance had been granted by the ethics committee of the University of the Witwatersrand. (Clearance Certificate protocol number M060719).

3.4 Study Design.

This was a cross–sectional study to validate and test the reliability of pain scales

3.5 Study setting.

The study was conducted at the Wilmed Park Private Hospital, the Sunningdale Hospital, Duff Scott Hospital, Wesvaal Hospital and the Klerksdorp Hospital, all situated in the North-West Province.

3.5.1 The inclusion criteria.

- females and males.
- cleaners, kitchen or laundry workers in all hospitals as well as patients attending the out patient department of the various hospitals.
- education level grade twelve and lower.

- mechanical back pain. The presence of mechanical back pain was determined by an Orthopaedic Manipulative examination of the subjects and was also determined from information taken from the subjects' medical files.Subjects with lumbar,thoracic and cervical spine pain were selected.
- Tswana speaking (first language) and those fluent in Tswana.

3.5.2 The exclusion criteria.

- younger than 18 years.
- individuals not fluent in Tswana.
- previous surgical intervention for back pain.
- serious illness (cancer, H.I.V.).
- patients suffering from any neurological or psychiatric conditions.
- Subjects on analgesics or heavy sedatives.

3.5.3 Sample size.

Eighty to one hundred subjects gave sufficient power to test the validity and the reliability of the pain scales (there are ten items per scale). (Jensen and Turner1994).

3.6 Measurement devices.

Pain tolerance of the subjects was measured using a pressure threshold meter (P.T.M.) (distributed by Pain Diagnostics and Thermography Inc, 233 East Shore Road Great Neck, New York 11023 U.S.A.). The P.T.M. consists of a gauge calibrated from1kg/cm^2 to 10kg/ cm^2 .The rubber disc at the end of the gauge measures 1cm^2 in surface. The middle deltoid muscle was measured for normal reference for muscle. (Fischer, 1987). The shin was measured as well, to provide a normal reference for bone, as suggested in the study by Fischer and Chang, (1986). Normal muscle tolerance was found to be higher than that of bone. The pain scales used were the V.A.S. one (nought and ten only), the V.A.S. two (nought through to ten), the W.B.F pain measure and the V.R.S.

The V.R.S used came in two forms. The first form was that written on cue cards which the subjects arranged in order and the second form was the questionnaire version of the V.R.S.

3.7 Procedure.

3.7.1 Translation of scales

The translation process took place in five stages. The stages of cross-cultural adaptation recommended by Beaton, et al, (2000) are:

Stage one – Two translations into the target language (Tswana).

Stage two – Resolving any discrepancies of translator's reports. A common translation was produced from translator 1 and 2.

Stage three –Back translation. Two English (first language) translations who were naïve to the outcome measurement worked from translator 1 and 2's version. They then created two back translations ie. B.T.1 and B.T.2.

Stage four –Expert committee review. All reports were reviewed by the two forward translators, the two back translators, a physiotherapist and a nursing sister. Consensus was reached on all discrepancies. A pre-final version was then produced.

Stage five –Pre-testing ie. testing of the pre-final version of the scales. A sample of ten subjects was tested. They completed the scales and this showed that they had an understanding of the scales and an understanding of what was required of them. They were also asked what they thought of the scales (layout, wording, ambiguities, ease of understanding).

3.7.2 Detail of Pain scale completion.

Step 1 The subject was taught how to use the V.A.S. (marked only with a 0 and a 10) correctly (current pain) and once this was achieved, step 2 was undertaken.

Step 2 The pain threshold was measured using the Pain Threshold Meter over pain free areas ie. right and left deltoid and right and left shin. Maximal pain which the subject could tolerate was elicited (pressure tolerance). The pressure reading was recorded in kg/cm^2. Subject then rated pain on V.A.S. one.

Step 3 The subject was then asked to order the Verbal Rating Pain scale. This was done using cue cards. Each cue card had one sentence written on it. They were numbered on the back, where the subject was not able to see the number. This made it easier for the researcher to interpret the order in which the subject put the cards. The subject was asked to put the cue cards in order ie. from no pain to worst pain. (excruciating pain).

Step 4 The pain threshold was once more measured over the normal areas. This time only sub- maximal pain was elicited (pressure threshold).

Step 5 The V.A.S. one (marked only with a 0 and a 10) was then filled in again.

Step 6 The verbal rating pain scale was again put into order using the cue cards (as with step 3).This was done to see if the subjects fared better at their second attempt. Reliability could then be determined.

Step 7 Upon completion of the above steps the subject was requested to fill in all the pain scales(V.A.S.1,V.A.S. 2,V.R.S and the W.B.F pain scale). This was done in the following way:

- The subjects were then asked to complete a list of five questions relating to his/her back pain (see Appendix B for the list of questions).The presence of mechanical back pain was determined by an Orthopaedic Manipulative examination of the subjects and was also determined from information taken from the subjects' medical files.

Subjects then filled in the three pain scales. The interview was tape recorded in order for it to be transcribed. The transcription enabled the researcher to compare the way in which the subjects described their pain to the ratings of pain they made on the three pain scales.

Upon completion of the interview the pressure threshold of the painful area (back) was tested. The pressure testing was done at a rate of one kilogram per centimetre squared per second.

The cervical spine was marked area one, the thoracic spine area two and the lumbar spine marked area three to enable easy translation of the results. The pressure tolerance (maximum pain) was then measured using the same P.T.M. (Pressure Threshold Meter) as used on the non painful areas (arms and legs). Subjects then filled in the three pain scales as before. (V.A.S. one, V.A.S. two, the V.R.S. and lastly the W.B.F. pain scale).

The pressure threshold (sub-maximal pain) was then measured over the painful area. After this the subject then followed the same procedure as with the measurement of maximal pain ie all the pain scales were then filled in.

- After this was done, the subjects were thanked for their participation and those who were required for the retest were asked to return the following day (twenty four hours later).Approximately a third of the sample(37) was retested the following day.

3.7.3 Testing of scales

Upon completion of page one only then was page two given to the subjects and this was done with all subsequent pages until all pages were successfully completed. Information on the pages is as below.

- Page one is the subject information sheet.
- Page two is the demographics of the subject.
- Page three has the V.A.S version one on it, marked only with a 0 **and** 10 and is used to aquaint the subjects with the scale.
- Page four has the recorded P.T.M. threshold readings and the five questions.
- Page five and six has the V.A.S. version one on it marked only with a 0 **and** 10 and with the Tswana translation next to both numbers. These two pages were for the measurement of maximal pain on the (non-painful areas) arms and legs respectively.
- Page seven is for the ordering of the V.R.S cue cards (for the first time).
- Page eight and nine is for the V.A.S.version one marked only with a 0 **and** 10 , for measurement of sub-maximal pain on the arms and legs (non-painful areas).
- Page ten is once more for the ordering of the V.R.S cue cards(for the second time)
- Page eleven is for the V.A.S. version one, marked only with a 0 **and** 10 and with the Tswana translation next to both numbers, for measurement of maximal back pain.
- Page twelve is for the V.A.S version two marked from 0 **to** 10 with the Tswana translation at both ends of the scale, for measurement of maximal back pain.
- Page thirteen is for the written form of the Verbal Rating Pain Scale marked 0 to 10 with the Tswana translation opposite each digit. (For maximum back pain).
- Page fourteen is for the Wong-Baker Faces pain scale consisting of six faces marked 0, 2, 4, 6, 8, 10 and the Tswana translation under each face.(For maximum back pain.)
- Page fifteen is for the V.A.S. version one, marked only with a 0 **and** 10 and with the Tswana translation next to both numbers for measurement of sub-maximum back pain.
- Page sixteen is for the V.A.S version two marked from 0 **to** 10 with the Tswana translation at both ends of the scale for measurement of sub-maximum back pain.
- Page seventeen is for the V.R.S written form for measurement of sub-maximum back pain.

- Page eightteen is for the Wong-Baker Faces pain scale consisting of six faces marked 0, 2, 4, 6, 8, 10 and the Tswana translation under each face, for measurement of sub-maximum back pain.

When maximal and sub-maximal pain were measured on the deltoid and the shin (non-painful area), only the V.A.S. one, was filled in. This was done prior to testing the back pain in order to get an idea of the subject's pain threshold, to compare the results of the arms and legs to those of the back and to give the subject time to get used to the correct use of the V.A.S. pain scale. All scales are in Appendix B.

3.7.3.1 Pilot Study.

A pilot study was conducted prior to commencing the major study. The pilot study tested ten subjects. This took two days to do as the subjects were only allowed to be absent from work for a half an hour in the morning. Each subject took approximately a half an hour to complete the entire test. The time spent on explaining the entire procedure took about five minutes, the filling in of the consent forms took three minutes on average. Total testing time for pressure threshold and pressure tolerance took about ten minutes. The V.R.S. cue card ordering took a total of six minutes and the actual filling in of the scales was quick taking less than five minutes. The results from the pressure threshold readings were compared with those from the three pain scales and were compared with the answers given in the interview. Correlation was determined between the P.T.M. recorded and the rating on the pain scales. The presence of an inverse relationship was determined.

Minor alterations were made to the V.R.S. and the W.B.F. scales in that the numbers next to the written sentences were left out as were the numbers under the faces. This was done as it was observed by the researcher that the subjects were choosing the suitable sentence or face by number and did not look at the faces nor read the sentences. They were going solely according to number.

3.7.3.2 The main study.

The testing of one hundred subjects as well as the retesting of thirty seven subjects took approximately two months to complete.

The main study was conducted in the same way as the pilot study. The subjects were recruited by the person in charge of the cleaning services at the Wilmed and Wesvaal Hospitals. The subjects tested at the out patient department of the Klerksdorp Hospital were recruited by the physiotherapists working there.
The subjects at the Duff Scott Hospital were recruited by the hospital superintendent and those at the Sunningdale Hospital were recruited by the matron of that hospital. The subjects were contacted two days prior to the test day and were advised not to take any analgesics the day of the test and the day prior to the test.

Consent was given by the subjects. Then the subject was made comfortable and the procedure was explained to the subject. A research assistant who is Tswana speaking (first language) read the scales to the subjects. This was done in order to assist in the case of there being any problems with the understanding of the entire process and for the benefit of illiterate subjects. The patient consent form was also read in Tswana and in English. The research assistant read the scales to some of the elderly subjects who had poor vision and she assisted with subjects who were unable to sign due to injury of their dominant arm or hand. A thumb print was taken in the case of illiterate subjects.

The subject sat on a chair at a desk for the entire testing process. The pressure testing of the arms and legs was carried out with the patient seated, arms resting on the arm rests and feet comfortably supported on the floor. The pressure testing of the back was done with the patient lying prone on an examination couch in the same room. The subject's privacy was ensured by drawing the curtain around the examination couch prior to exposing the affected area on the back.

The subjects who were illiterate were assisted by the research assistant who translated and helped explain all the ensuing steps.

Then the following procedure was followed with each subject

Step 1 The subject was taught how to use the V.A.S. (marked only with a 0 and a 10) correctly (current pain) and once this was achieved, step 2 was undertaken.

Step 2 The pain threshold was measured using the Pain Threshold Meter over pain free areas ie. right and left deltoid and right and left shin. Maximal pain which the subject could tolerate was elicited (pressure tolerance). The pressure reading was recorded in kg/cm^2. Subject then rated pain on V.A.S. one.

Step 3 The subject was then asked to order the Verbal Rating Pain scale. This was done using cue cards. Each cue card had one sentence written on it. They were numbered on the back, where the subject was not able to see the number. This made it easier for the researcher to interpret the order in which the subject put the cards. The subject was asked to put the cue cards in order ie. from no pain to worst pain. (excruciating pain).

Step 4 The pain threshold was once more measured over the normal areas. This time only sub- maximal pain was elicited (pressure threshold).

Step 5 The V.A.S. one (marked only with a 0 and a 10) was then filled in again.

Step 6 The verbal rating pain scale was again put into order using the cue cards (as with step 3).

Step 7 Upon completion of the above steps the subject was requested to fill in all the pain scales. This was done in the following way:

The subjects were then asked to complete a list of five questions relating to his/her back pain (see Appendix B for the list of questions) in order to check subjects' rating of pain. Subjects then filled in the three pain scales. The interview was tape recorded in order for it to be transcribed. The transcription enabled the researcher to compare the way in

which the subjects described their pain in the interview, to the ratings of pain they made on the three pain scales.

Upon completion of the interview the pressure threshold of the painful area (back) was tested. The pressure testing was done at a rate of one kilogram per centimetre squared per second.

The cervical spine was marked area one, the thoracic spine area two and the lumbar spine marked area three to enable easy translation of the results. The pressure tolerance (maximum pain) was then measured using the same P.T.M. (Pressure Threshold Meter) as used on the non painful areas (arms and legs). Subjects then filled in the three pain scales as before. (V.A.S. one, V.A.S. two, the V.R.S. and lastly the W.B.F. pain scale).

The pressure threshold (sub-maximal pain) was then measured over the painful area. After this the subject then followed the same procedure as with the measurement of maximal pain i.e. all the pain scales were then filled in. After this was done the subjects were thanked for their participation and those who were required for the retest were asked to return the following day (twenty four hours later).The whole of the above procedure was carried out the following day. This was done to ensure that their pain had not changed as it could possibly do if the time span between test and retest was too long. The twenty four hour period was therefore selected to ensure that that the subject's pain did not change and thereby helped to ensure that the rating of their pain be the same as that or as close to that of the previous day's rating.

3.8 Data Analysis.

- descriptive statistics were used to summarise the data.
- tables were used to present the data.
- demographic data were presented as means and standard deviation.
- statistical significance is considered when the p value was <and= to 0.05. Marginally significant values are regarded when the p value was <0.05 and <

and = to 0.1. A p value > 0.1 was regarded as being not significant.

- construct validity was measured using the Pearson's product moment correlation coefficient which was used to determine the correlation between the V.A.S., V.R.S. and Wong-Baker Faces Pain Measures Scores and the P.T.M.
- test-retest reliability was measured using the Pearson's correlation coefficient, the p value and the rho. (Spearman's rank order coefficient).

3.9 Conclusion.

The research was conducted in the North-West province after permission was obtained from the relevant authorities. The study design was a cross–sectional study to validate and test the reliability of pain scales. Subjects who met the inclusion and exclusion criteria were selected. A pilot study which included ten subjects was carried out prior to the main research study of a hundred subjects. The retesting process included thirty seven subjects. Cross-cultural adaptation of the scales and translation of the scales was done prior to the entire testing process.

In the next chapter the findings of the collected data will be described.

CHAPTER FOUR

RESULTS

4.1 Introduction.

In this chapter the results of the study are presented .The research objectives mentioned in the first chapter are met and interpreted. The statistical analyses of the results are presented in table and graph (scatter plot) form.

4.2 Presentation of the results.

The statistical analyses of the results are presented in table and graph(scatter plot) form.

4.3 Interpretation of the results.

The validity of the pain scales was determined by the, face validity, criterion validity and construct validity. Dawson and Trapp, (2004) and Sim and Wright, (2002).

1. The scales already have face validity and the translation procedure ensured clarity of the scales and hence, face validity was enhanced.

2. Criterion validity measured the extent to which the scales correlated or agreed with a "gold standard". In this study the scales were compared with the pressure threshold measurements of the subjects to establish agreement or correlation. (Pearson's product moment correlation coefficient was used for this purpose, as was the p value). Dawson and Trapp, (2004) and Sim and Wright, (2002).

3. Construct validity showed whether a scale shows consistent associations with theoretical models or "constructs". In this study the construct validity showed that, for example, the subjects with low educational levels should find the scales easy to interpret and use. Construct validity was measured using the Spearman rank correlation coefficient. (rho). Dawson and Trapp, (2004) and Sim and Wright, (2002).

Table 4.1 This table lists the age, sex, education levels, different groups of subjects as well as the different areas on the back which were painful in the pilot group of subjects.

Demographic data of subjects. Pilot group. n = 10.

Parameter	Units	Categories	Value
Age	Mean (standard deviation)	n/a	38.4 (±5.42)
Sex	%	Male Female	0 100
≤ g			
Group	%	Cleaner Kitchen Laundry O.P.D	50 40 10 0
Area of Back	%	Cervical Thoracic Lumbar	0 0 100

The above table shows that all the subjects suffered from lumbar spine pain and that the majority of the subjects were cleaners, had a high school education and were female.

Table 4.2 This table lists the age, sex, education levels, different groups of subjects as well as the different areas on the back which were painful in the main group of subjects.

Demographic data of subjects. Main group. n = 100

Parameter	Units	Categories	Value
Age	Mean (standard deviation)	n/a	43.9 (±11.18)
Sex	%	Male Female	14 86
Education level	%	≤grade8 ≥grade9	47 53
Group	%	Cleaner Kitchen Laundry O.P.D	39 15 9 37
Area of Back	%	Cervical Thoracic Lumbar	0 31 69

The above table shows that most of the subjects suffered from lumbar spine pain followed by thoracic spine pain. Once more the majority of the subjects were cleaners, had a high school education and were female.

Table 4.3 This table lists the age, sex, education levels, different groups of subjects as well as the different areas on the back which were painful in the test- retest group of subjects.

Demographic data of subjects. Retest group. n = 37.

Parameter	Units	Categories	Value
Age	Mean (standard deviation)	n/a	40.4 (±8.64)
Sex	%	Male Female	8 92
Parameter	%	≤grade8 ≥grade9	30 70
Group	%	Cleaner Kitchen Laundry O.P.D	54 38 8 0
Area of Back	%	Cervical Thoracic Lumbar	0 32 68

The above table shows that most of the subjects suffered from lumbar spine pain followed by thoracic spine pain .Once more the majority of the subjects were cleaners, had a high school education and were female.

The following tables 4.4 – 4.13 display the correlation between the pressure threshold meter readings and the scale measurements. Although several significant p values ($p \leq 0.05$) were found, none of the correlations illustrated a strong relationship, as there were none in excess of 0.5 indicating a moderate correlation or greater than 0.7 indicating a good correlation. The statistical significance only indicates that the observed values were not due to chance (Poltney and Watkins 2000).

Table 4.4 shows Pearson's correlation coefficient between the maximum and sub-maximum readings on the P.T.M. and the corresponding patient evaluation on the V.A.S. 1 for the deltoid and shin (unaffected areas). Total n = 100.

Table 4.4 The correlation between the V.A.S. 1 and the pressure threshold meter readings. Maximum and sub-maximum pressure thresholds for unaffected areas. n=100.

	Maximum pressure threshold.		Sub-maximum pressure threshold .	
Area	Pearson's correlation coefficient(r)	p-value	Pearson's correlation coefficient(r)	p-value
Right deltoid	0.11	0.29	-0.03	0.78
Left deltoid	0.21	0.03	0.01	0.92
Right shin	-0.01	0.93	-0.02	0.87
Left shin	-0.12	0.22	-0.04	0.66

The table shows that the maximum P.T.M readings and V.A.S 1 do not have good correlation despite the low p- value for the left deltoid measurements(r = 0.21; p= 0.03). No good correlations are seen in any of the sub-maximum readings.

Table 4.5shows the correlation between the V.A.S. 1, the V.A.S. 2, the V.R.S. and the W.B.F. pain measure and the maximum and sub-maximum pressure threshold meter readings on the back (painful area). Total n = 100.

Table 4.5 Correlation between maximum and sub-maximum P.T.M. readings of the back with the three scales. n= 100.

	Maximum pressure threshold.		Sub-maximum pressure threshold.	
Scale	Pearson's correlation coefficient	p-value	Pearson's Correlation coefficient	p-value
V.A.S. 1	-0.12	0.18	-0.23	0.02
V.A.S. 2	-0.09	0.36	-0.18	0.07
V.R.S.	-0.16	0.10	-0.09	0.40
W.B.F	-0.24	0.02	-0.17	0.08

This table shows a significant p- value (p = 0.02) for the Wong- Baker Faces pain scale and the maximum P.T.M readings taken on the back. However, the correlation coefficient (r) of -0.24 is in fact very low. This table also shows significant p- values for the sub-maximum P.T.M readings on the back and the V.A.S.1. (p= 0.02). The r value (r = -0.23) is low however.

Table 4.6 shows the correlation between the V.A.S. 1 and the maximum and sub-maximum pressure threshold meter readings in the retest group. Total n = 37. (non-painful areas and painful area).

Table 4.6 Maximum and sub-maximum pressure threshold readings correlated with the V.A.S. 1. n = 37.(Retest group).

	Maximum pressure threshold.			Sub-maximum pressure threshold.		
Area	Pearson's correlation coefficient (r)	p-value	Intra-class correlation coefficient (rho)	Pearson's correlation coefficient (r)	p-value	Intra-class correlation coefficient (rho)
Right deltoid	-0.05	0.76	0.00	0.16	0.34	0.12
Left deltoid	0.04	0.82	0.00	-0.12	0.01	0.40
Right shin	0.12	0.49	0.00	0.41	0.01	0.41
Left shin	0.06	0.73	0.00	-0.08	0.66	0.00
Back	-0.02	0.00	0.67	0.53	0.00	0.52

The above table shows that when the re-test was done, one day later, no correlation and no agreement was found in the maximum readings . (rho greater than 0.9 is regarded as having good agreement). The highest rho is 0.67 and was measured for the back.
This table also shows that for the sub-maximum readings, although the p- value for the left deltoid (p= 0.01), right shin (p= 0.01) and the V.A.S 1 is significant, the agreement is poor (rho= 0.40 and rho= 0.41 respectively).Pearson's correlation coefficients are also not high (r= -0.12 and r= 0.41 respectively).This shows that there is both a poor correlation and poor agreement between pressure threshold and the patient's rating of their pain.

Table 4. 7shows the correlation between the V.A.S. 1, the V.A.S. 2, the V.R.S. and the W.B.F. pain measure and the maximum and sub-maximum pressure threshold meter readings on the back (painful area). Total n=37.

Table 4.7 Correlation between maximum and sub-maximum P.T.M. readings of the back with the three scales .n=37.

	Maximum pressure threshold.		Sub-maximum pressure threshold.	
Scale	Pearson's correlation coefficient(r)	p-value	Pearson's correlation coefficient(r)	p-value
V.A.S. 1	0.69	0.00	0.53	0.00
V.A.S. 2	0.62	0.00	0.64	0.00
V.R.S.	0.53	0.00	0.48	0.00
W.B.F	0.66	0.00	0.70	0.00

This table shows moderate correlation between all three scales and the P.T.M.(maximum and sub-maximum readings) in the retest group. n=37. All p- values are significant.

Table 4.8 shows the correlation between the V.A.S. 1 and the maximum and sub-maximum pressure-threshold meter readings in the test group. Total n = 100. Education levels greater than and equal to grade9 (n= 47) and less than and equal to grade 8 (n= 53).

Table 4.8 Maximum and sub-maximum pressure threshold readings correlated with the V.A.S. 1 in education levels grade ≥9 (n=47) and ≤grade 8 (n=53). n = 100.

	Maximum pressure threshold.		Sub-maximum pressure threshold.	
Parameter	Pearson's correlation coefficient (r)	p-value	Pearson's correlation coefficient (r)	p-value
Right deltoid				
grade≥9	-0.29	0.05	-0.18	0.21
grade≤8	0.06	0.67	0.14	0.33
Left deltoid				
grade≥9	0.20	0.19	0.02	0.87
grade≤8	0.31	0.03	0.07	0.61
Right shin				
grade≥9	-0.16	0.28	-0.10	0.52
grade≤8	0.19	0.17	0.07	0.62
Left shin				
grade≥9	0.15	0.30	0.12	0.40
grade≤8	0.12	0.36	-0.13	0.37
Back				
grade≥9	-0.13	0.37	-0.24	0.10
grade≤8	-0.16	0.26	-0.21	0.13

Although this table shows a significant p-value for the P.T.M. maximum readings and the V.A.S.1 in grade≥ 9 group for the right deltoid (p= 0.05), the r value of -0.29 demonstrates a very low correlation. The same holds for the left deltoid measurement in the grade ≤8 where p= 0.03 and r = 0.31.This table also shows poor correlations for all of the maximum and sub-maximum readings.

Table 4.9 Maximum pressure and sub-maximum threshold readings correlated with the V.A.S. 1 in age groups less than and equal to 45 years(n= 57) and greater than 45 years (n= 43).

Table 4.9 The correlation between the V.A.S. 1 and maximum pressure and sub-maximum threshold meter readings in the test group. Total n = 100.

		Maximum pressure threshold.		Sub-maximum pressure threshold.	
Parameter		Pearson's correlation coefficient (r)	p-value	Pearson's correlation coefficient (r)	p-value
Right deltoid	age≤45 years	0.08	0.53	0.02	0.87
	age >45years	-0.32	0.03	-0.09	0.59
Left deltoid	age≤45 years	0.46	0.00	0.15	0.27
	age >45years	0.00	0.98	-0.07	0.64
Right shin	age≤45years	0.22	0.10	0.15	0.27
	age >45years	-0.25	0.10	-0.22	0.16
Left shin	age≤45 years	0.35	0.00	-0.04	0.80
	age >45years	-0.14	0.35	0.01	0.92
Back	age≤45 years	-0.01	0.93	-0.07	0.59
	age >45years	-0.42	0.00	-0.39	0.01

There were no moderate or good correlations seen in any of the above measurements. There are however a number of significant p- values.

Table 4.10 shows the correlation between the V.R.S. (first) and the V.R.S. (second) done in the test group. n = 100. Education levels greater than and equal to grade 9(n= 47) and less than and equal to grade 8 (n=53) as well as age group less than and equal to 45 years(n =57) and age group greater than 45 years (n =43).(This test was done twice on one day interspersed with the other tests). Total n =100.

Table 4.10 Correlation between V.R.S. (first) and V.R.S. (second) in test group. n=100.

Scale	Pearson's correlation coefficient (r)	p -value
V.R.S overall	0.49	0.00
grade≥9	0.46	0.00
grade≤8	0.50	0.00
age≤45 years	0.57	0.00
age>45 years	0.37	0.01

In this table a significant p- value for the>45 years age group (p= 0.01) is shown. The correlation coefficient r = 0.37 is however poor. The correlation for the grade≤8 group of r = 0.50 and that of the age≤45 years age group where r = 0.57 are both considered to be moderate. All p- values in the above table are significant.

Table 4.11 shows the correlation between the V.A.S. 2 and the maximum and sub-maximum pressure threshold meter readings on the back (painful area), for the test group (Total n=100) in education levels greater than and equal to grade 9 (n=47) and less than and equal to grade 8 (n=53) and for age group less than and equal to 45 years (n = 57) and age group greater than 45 years (n = 43).

Table 4.11 Maximum and sub-maximum pressure threshold readings on the back, correlated with the V.A.S. 2 in education levels ≥grade 9 (n=47) and ≤grade 8 (n=53) and for age groups≤ 45 years (n=57) and age > 45 years (n=43). Total n=100.

	Maximum pressure threshold.		Sub-maximum pressure threshold.	
Parameter	Pearson's correlation coefficient (r)	p-value	Pearson's correlation coefficient (r)	p-value
≥grade9	-0.10	0.50	-0.16	0.29
≤grade 8	-0.09	0.50	-0.19	0.17
age≤45years	0.09	0.52	-0.09	0.50
age>45years	-0.37	0.01	-0.27	0.08

The above table shows a significant p value in the age group>45 years for maximum pressure threshold readings (p = 0.01). The correlation coefficient however is very low and therefore does not show a good correlation for any of the maximum pressure readings. The results for the sub-maximum readings show a poor correlation in all of the groups (age and education).

Table 4.12 shows the correlation between the V.R.S. and the maximum and sub-maximum pressure threshold meter readings on the back (painful area), for the test group (n=100) in education levels greater than and equal to grade 9 (n=47) and less than and equal to grade 8 (n=53) and for the age group less than 45 years (n=57) and the age group greater than 45 years (n=43).

Table 4.12 Maximum and sub-maximum pressure threshold readings on the back, correlated with the V.R.S. in education levels ≥grade 9 (n=47) and≤grade 8 (n=53) and for age groups≤ 45 years (n=57) and age > 45 years (n=43). n=100.

	Maximum pressure threshold.		Sub-maximum pressure threshold.	
Parameter	Pearson's correlation coefficient(r)	p-value	Pearson's correlation coefficient(r)	p-value
≥grade9	-0.13	0.39	-0.05	0.75
≤grade8	-0.22	0.12	-0.11	0.44
age≤45years	-0.08	0.55	0.03	0.80
age>45years	-0.34	0.02	-0.20	0.20

The above table shows a low p-value in the age group>45 years (p = 0.02) for maximum pressure readings. The correlation coefficient however is very low and thus shows a poor correlation (r = -0.34). The sub-maximum readings do not show any correlation in any of the groups (age and education).

Table 4.13 shows the correlation between the Wong- Baker Faces pain measure and the maximum pressure and sub-maximum threshold meter readings on the back (painful area), for the test group (n=100) in education levels greater than and equal to grade 9 (n=47) and less than and equal to grade 8 (n=53) and for age group less than and equal to 45 years (n=57) and age group greater than 45 years (n = 43).

Table 4.13 Maximum and sub-maximum pressure threshold readings on the back, correlated with the W.B.F. pain measure in education levels ≥grade 9 (n=47) and≤grade 8 (n=53) and for age groups≤ 45 years (n=57) and age > 45 years (n=43).n=100.

	Maximum pressure threshold.		Sub-maximum pressure threshold.	
Parameter	Pearson's correlation coefficient(r)	p-value	Pearson's correlation coefficient(r)	p-value
≥grade9	-0.33	0.03	-0.14	0.34
≤grade8	-0.20	0.15	-0.17	0.21
age≤45years	-0.11	0.42	-0.00	1.00
age>45years	-0.54	0.00	-0.37	0.02

In this table, for the Wong-Baker Faces pain scale (maximum readings) a significant p-value (p = 0.00) in the older age group, is shown. The correlation coefficient (r = -0.54) is however moderate. The p-value (p = 0.03) for the ≥grade9 (maximum readings) is significant , however the correlation is poor(r = -0.33).

The sub-maximum values suggest that the Wong-Baker Faces pain scale seems to be best understood by the subjects in the >45 years age group (p = 0.02) but the correlation coefficient is once more poor (r = -0.37).

Scatter plots of the inverse relationship between the P.T.M. readings and the recording of the patient perception of pain on the various pain scales.
See appendix C.

No inverse relationship existed between the Pressure Threshold Meter readings and the three scales.

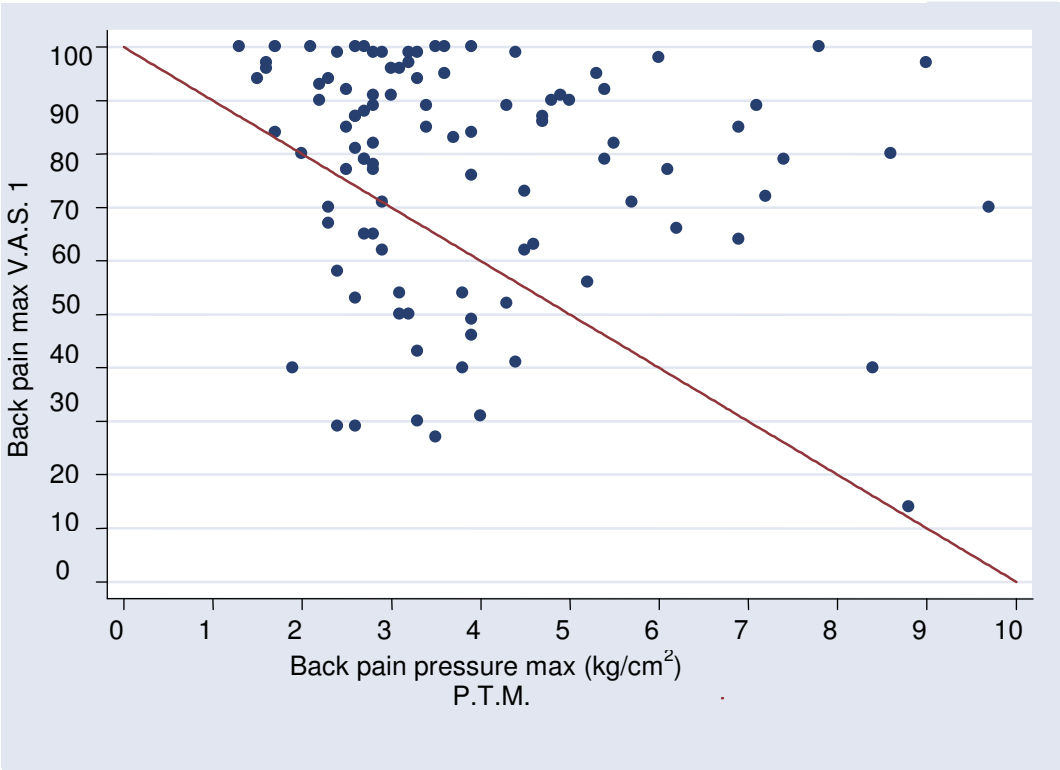

Figure 1: Scatter plot of the maximum pressure pain vs the patient perception on theV.A.S. 1.

Figure 1 shows no inverse relationship exists between the maximum pressure threshold readings and the V.A.S.1.

CHAPTER FIVE

DISCUSSION

5.1 Introduction.

In this chapter the findings, presented in the previous chapter are discussed and their relevance to the research question, is commented on.

The statistics were displayed in table form and showed the correlation between the pressure threshold meter readings and the scale measurements. Although several significant p-values ($p \leq 0.05$) were found, none of the correlations were high i.e. in excess of $r = 0.5$ and preferably greater than $r = 0.7$.The Spearman's correlation coefficient (rho) agreement was mostly poor (rho was not > 0.9).The scatter plotting of all graphs, as was to be expected following the above findings, showed poor inverse relationships between the various scales and the maximum and sub-maximum P.T.M. readings.

5.2 Interpretation of findings.

After statistical analysis of all the data it became apparent that not one of the scales used for the target group of subjects was more suitable than the next. It was established from the results that the group of subjects in this research study did not do particularly well in any of the scales tested, although certain scales seemed to be better understood by certain subjects. The correlation for the V.A.S. 1 and the sub-maximum P.T.M. measurements on the back appeared to be better than that for the other scales. This could be explained by the fact that the subjects had more practise in the use of this scale and due to this familiarity, fared better. In the retest group the V.A.S.1 also seemed to fare better than the other three scales. Not one scale was overall, the best understood scale for our target group. The results were on the whole, not statistically significant and it appears to be that

the tested subjects were unsure of what was expected of them and did not understand the entire process. When looking at the results of the re-test, moderate correlation was seen between all three scales and the P.T.M readings.(Sim and Wright,2002). This indicates that although the second test results were better than the first, the subjects still did not show an understanding of the scales.

Some of the scales seemed to be better understood by some of the subjects .The correlation between the W.B.F. pain scale and the maximum P.T.M. readings on the back showed moderate correlation .This could be explained by the fact that the subjects after having gone through all of the previous testing in the normal, non-painful areas were now familiar with what was expected of them. Another explanation could be the fact that the back was painful and that they could better feel the pain and therefore record it more accurately.

The Wong -Baker Faces pain scale was best understood by subjects in the age group>45 years (sub-maximum readings).The Wong-Baker Faces pain scale also seems to be best understood by the subjects in the >45 years age group (maximum readings) .These findings could be attributed to the fact that the older subjects, who probably had a poorer education due to their socio-demographic characteristics, had more life education and experience, a better understanding of the entire process, patience and most probably took more time and care in completing the scales. A study by Jelsma, et al. ,(2000) found that pictorial scales were better understood by individuals of low education levels and that verbal and numerical scales are best understood in subjects of higher education and literacy levels.

In addition, factors contributing to the poor results in this research study, could be that the subjects tested all come from the previously disadvantaged sector of our country and because of this had inferior education in the old Bantu Education system. These poor results occurred despite the correct procedure being followed for the translation and cross-cultural adaptation of scales.

Another problem could have arisen from the fact that the subjects did not truly understand what was expected of them in spite of the fact that the entire procedure was explained to them in their own language. They may have lacked functional health literacy which is defined as a person's ability to function in the health care setting using their skills in literacy and numeracy. Low functional health literacy may limit a patient's ability to comprehend, retain, recall and act on written health care measures (scales or questionnaires) of both literary and numerical content. (Teutsch, 2003).

Some of the subjects were confused and did not understand how to use the V.A.S. They thought that if the pain was on the right side of their body they needed to record this on the right side of the scale and that if the pain was on the left side of the body that this should be recorded on the left side of the scale. If their pain was situated centrally they would record it in the middle of the ten centimetre line. This could be attributed to fact that their abstract thinking ability was not well developed.

Anecdotal evidence suggests that others equated their worst pain as one out of ten explaining their choice of one meaning the best, the most supreme pain ("number one") i.e the most (pain) and ten was regarded as more inferior i.e the least pain. Another trend noticed was when the subjects were filling in the Wong-Baker Faces pain scale they would often say that their pain was severe but would only mark the middle face which represented a six out of ten instead of the face representing a ten out of ten .The interpretation of this could be that they were trying to be stoical and although their pain was severe, they did not want to admit it.

There were also a few subjects where the opposite was true. They were less stoical and were in fact overly sensitive. They would rate their pain verbally as being severe and yet when it came to filling in the scales they would not mark their pain as ten out of ten. These subjects also complained of the sub-maximum pressures as being just as painful as the maximum pressures and some of them equated the sub-maximum pressures with more pain than the maximum pressures. This could be due to the fact that the subjects did not understand what was expected of them or could possibly be due to an element of

malingering. This possibility is supported by anecdotal evidence of subjects asking that, if they had pain, would they get off work.

The scale which was thought to cause much confusion was the Verbal Rating Scale. The majority of subjects asked repeatedly during the ordering of the cue cards as to whether they were doing the right thing. Some subjects even put the cards in the wrong order i.e. arranged them from ten to nought instead of from nought to ten even after the process was explained to them more than once in their home language. Many of the subjects could be seen to become frustrated by the entire procedure and others were embarrassed by the fact that they were not managing very well. The V.R.S**.** appears to be the worst understood of all the pain scales.

The subjects had difficulty in understanding the nuances in the verbal description of their pain. In the retest group, the V.R.S. appeared to be too complicated for this group of subjects. When comparing the correlation between the V.R.S. (first) and the V.R.S. (second) done in the test group in education levels less than grade 9 and greater than grade 8 as well as in age group less than and equal to 45 years and age greater than 45 years the correlation was found to be poor. A different trend was seen in the research done by Gagliese, et al, (2003) where they established that in order to determine age differences in pain intensity, verbal descriptions of pain qualities are more reliable than non-verbal measures.

As could be expected, the scatter plotting of all the graphs showed that no inverse relationship existed between the pressure threshold meter readings and the pain scales. This holds true for the maximum and sub-maximum readings and the patient perception of pain as recorded on the pain scales.

In summary this study did not show that the objective measure of pain was inversely related to the subjective measure. This could be explained by the fact that the subjects did not understand what was expected of them and did not know how to use the different

scales correctly. It can be concluded therefore that these scales are not useful scales to be used in this group of subjects.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS.

6.1 Introduction.

In this chapter a conclusion is formulated based on the discussion in the previous chapter and recommendations for future research are made. The clinical implications of the findings are discussed.

6.2 Conclusions.

The main findings of this study are as follows: Statistical analysis of all the data suggests that not one of the scales used for the target group of subjects was more suitable than the next. It was established from the results that the group of subjects in this study did not do particularly well in any of the scales tested, although certain scales seemed to be better understood by certain subjects. Not one scale was overall, the best understood scale for our target group .The results were on the whole, not statistically significant and it appears to be that the tested subjects were unsure of what was expected of them and did not understand the entire process. Subjects in the older age category (greater than forty five years of age) and of a higher educational level (greater than and equal to grade nine) fared better than those in the younger age category (less than and equal to forty five) and in the lower education group(less than and equal to grade eight).

6.3 Recommendations.

6.3.1 Research recommendations.

Future research needs to be done to develop entirely different outcome measure for the South African population. More relevant and better understood outcome measures should be developed for our population in order to include persons of different languages and different educational levels. This will assist in a better understanding of the health care process and will by so doing, improve their health care and management.

6.3.2 Clinical recommendations.

Clinically these results suggest that the pain scales which are presently being used in South Africa, are not being understood by persons of varying cultures and ethnicity. If the ways of quantifying pain (scales) are not fully understood this can impact negatively on the assessment and management of our patients and as already stated, other more appropriate methods of measuring pain need to be developed.It is the researcher's recommendation that therapists continue to use the historically used outcome measures until better and more appropriate ones have been developed for our local population of varying cultures and ethnicity.

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APPENDIX A

Ethical clearance.

Patient consent form (English and Tswana).

Consent form from hospital management.

APPENDIX B

Patient information sheet.

Scales, questionnaires and pressure threshold measurements. (Research instruments used) English version and Tswana version.

APPENDIX C

List of figures.

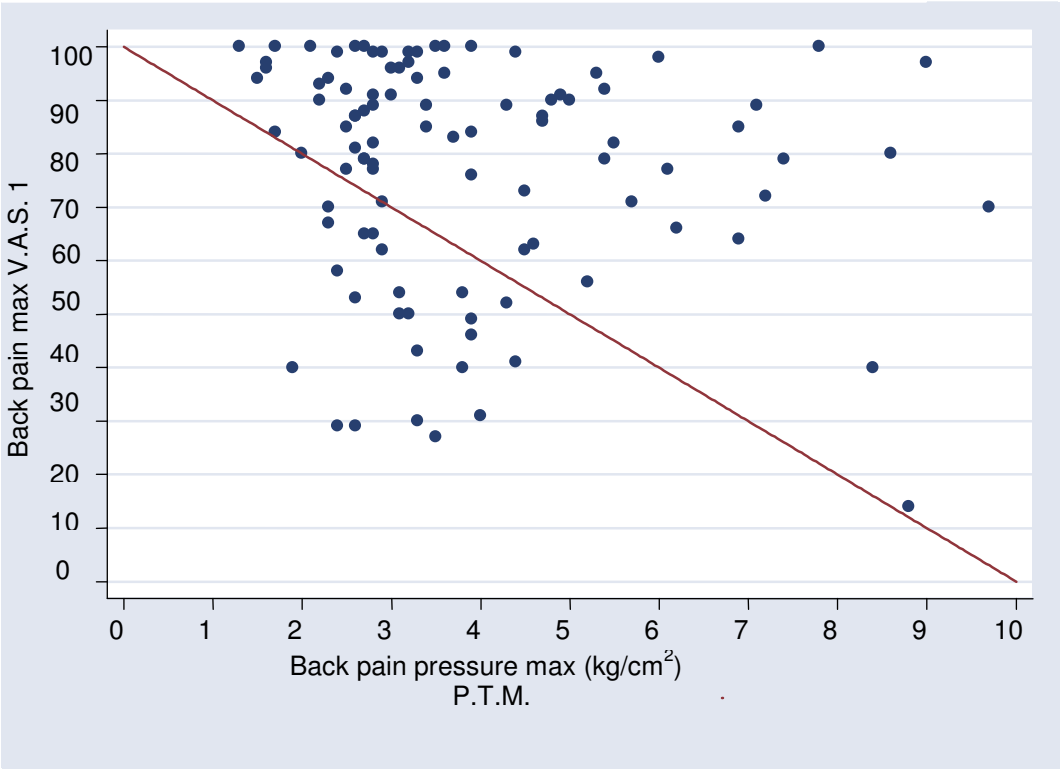

Figure 1: Scatter plot of the maximum pressure pain vs the patient perception on the V.A.S. 1.

Figure 1 shows no inverse relationship exists between the maximum pressure threshold readings and the V.A.S.1.

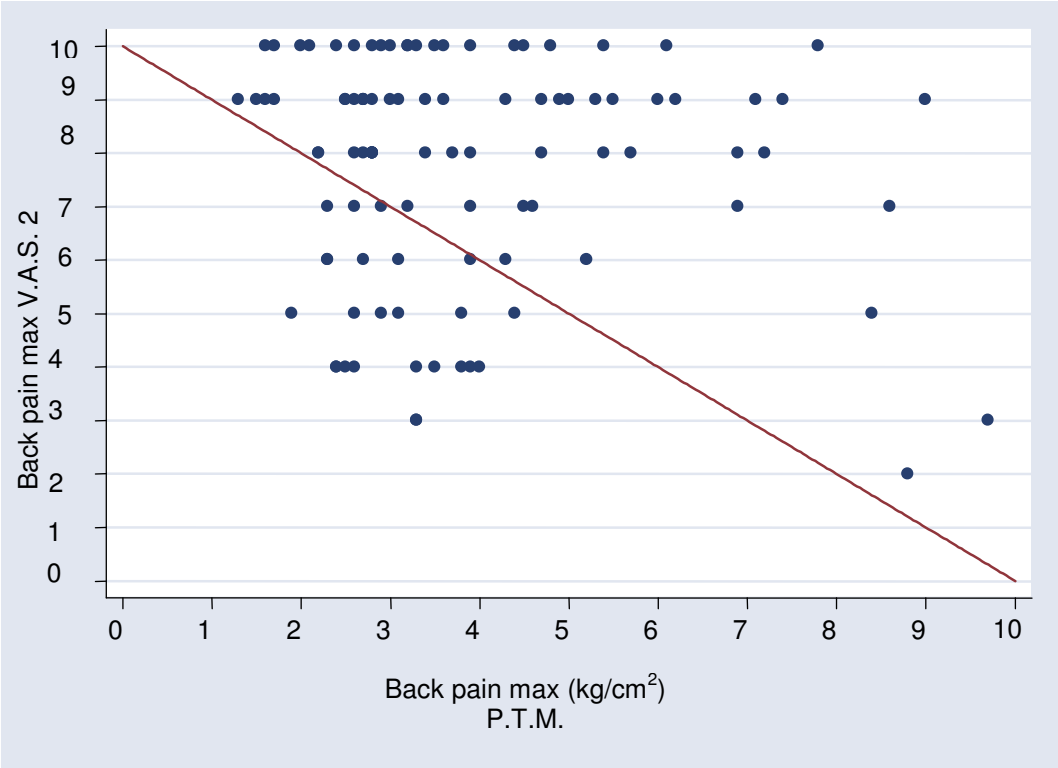

Figure 2: Scatter plot of the maximum pressure pain vs the patient perception on the V.A.S.2.

Figure 2 shows no inverse relationship exists between the maximum pressure threshold readings and the V.A.S.2.

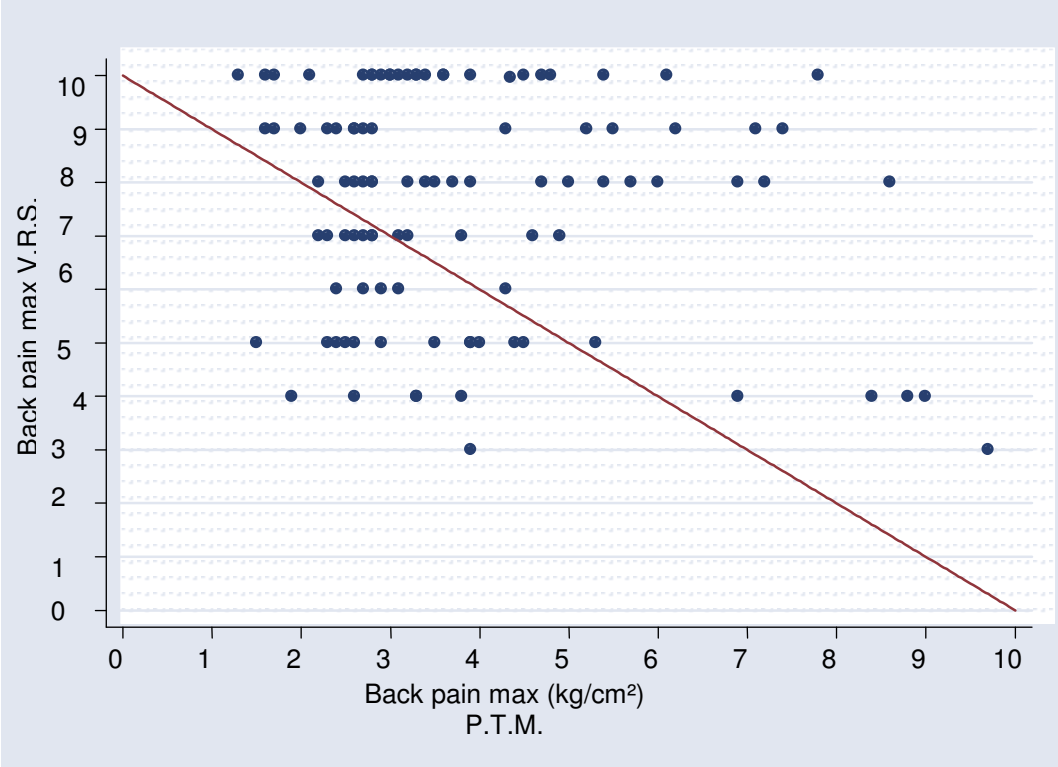

Figure 3: Scatter plot of the maximum pressure pain vs the patient perception on the V.R.S.

Figure 3 shows no inverse relationship exists between the maximum pressure threshold readings and the V.R.S

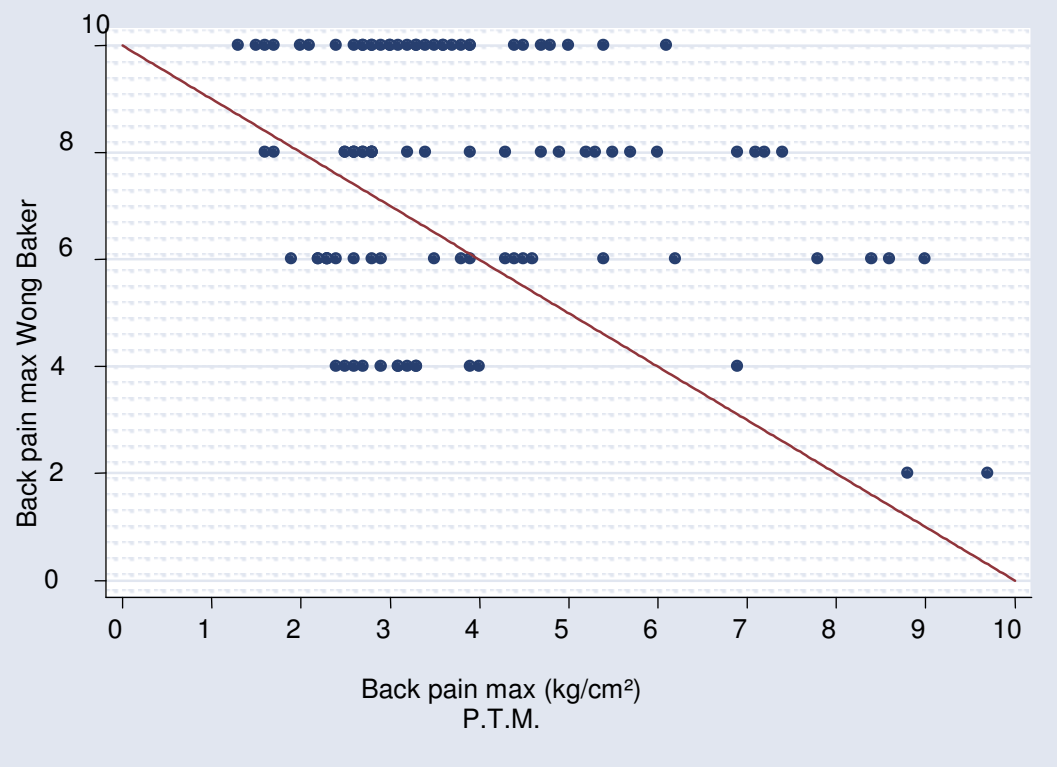

Figure 4: Scatter plot of the maximum pressure pain vs the patient perception on the Wong- Baker Faces pain measure.

Figure 4 shows no inverse relationship exists between the maximum pressure threshold readings and the Wong- Baker Faces pain measure.

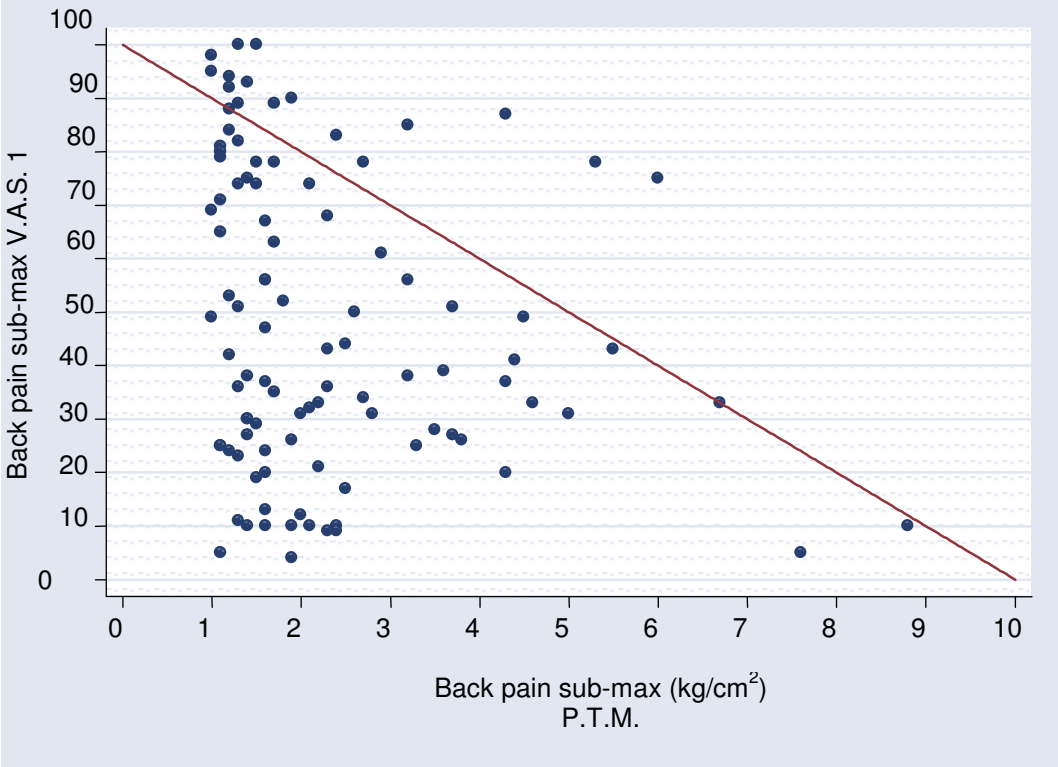

Figure 5: Scatter plot of the sub- maximum pressure pain vs the patient perception on the V.A.S. 1.

Figure 5 shows no inverse relationship exists between the sub- maximum pressure threshold readings and the V.A.S.1.

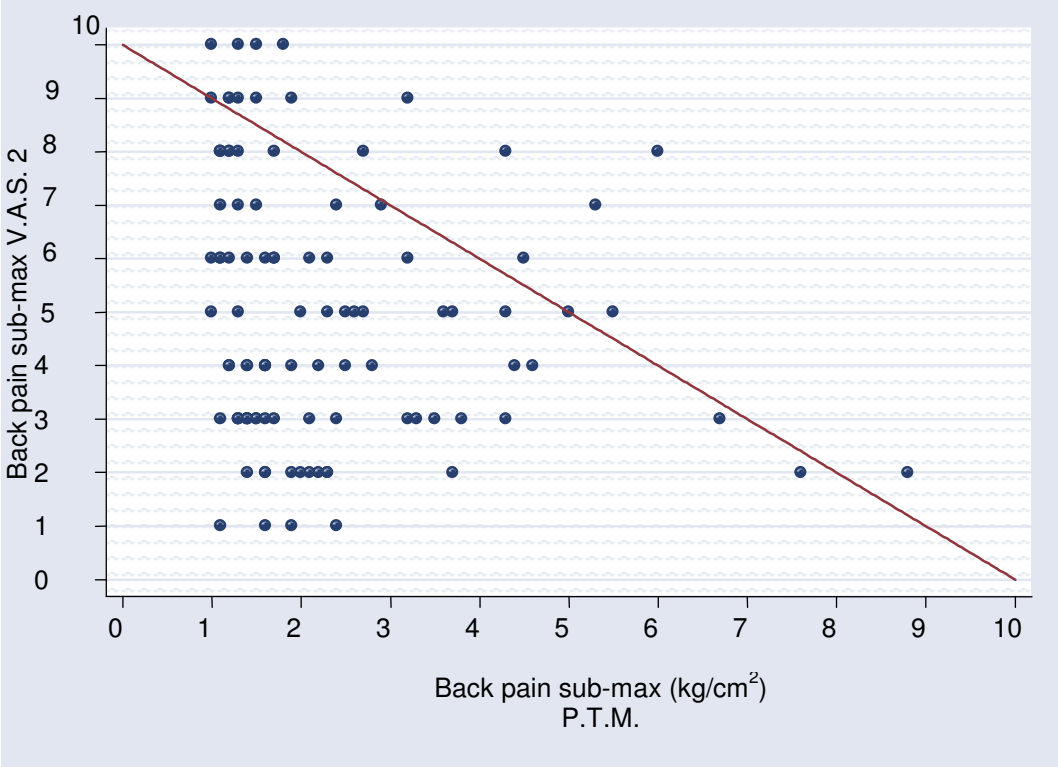

Figure 6: Scatter plot of the sub- maximum pressure pain vs the patient perception on the V.A.S.2.

Figure 6 shows no inverse relationship exists between the sub- maximum pressure threshold readings and the V.A.S.2.

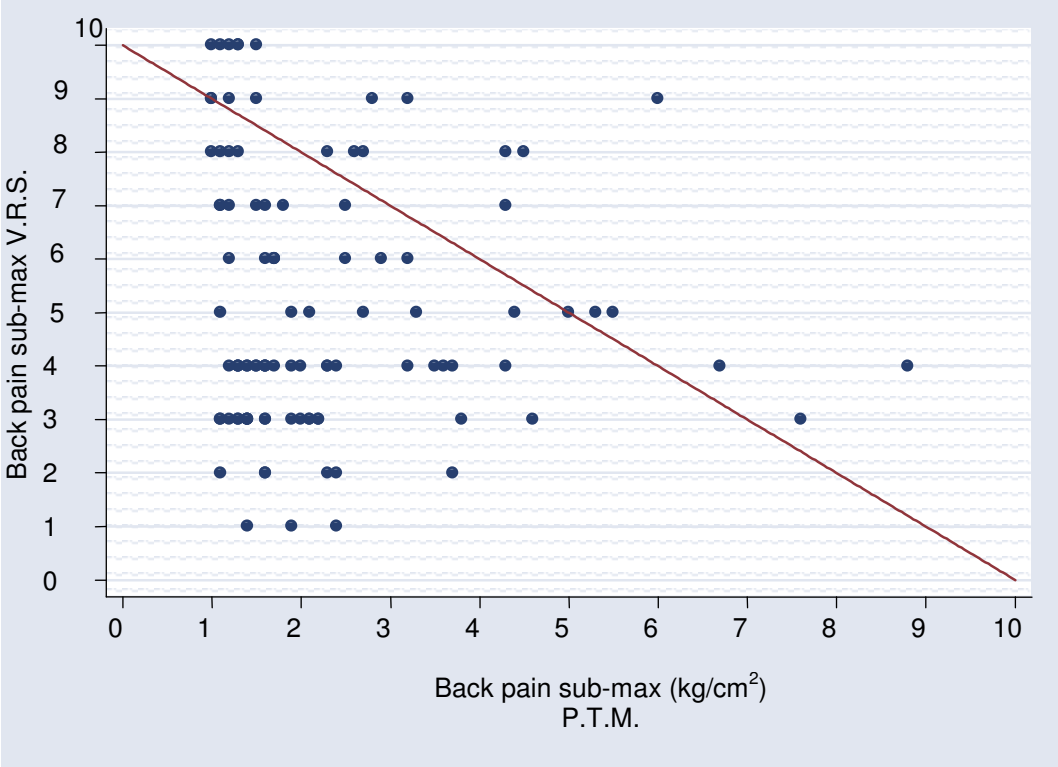

Figure 7: Scatter plot of the sub- maximum pressure pain vs the patient perception on the V.R.S.

Figure 7 shows no inverse relationship exists between the sub- maximum pressure threshold readings and the V.R.S.

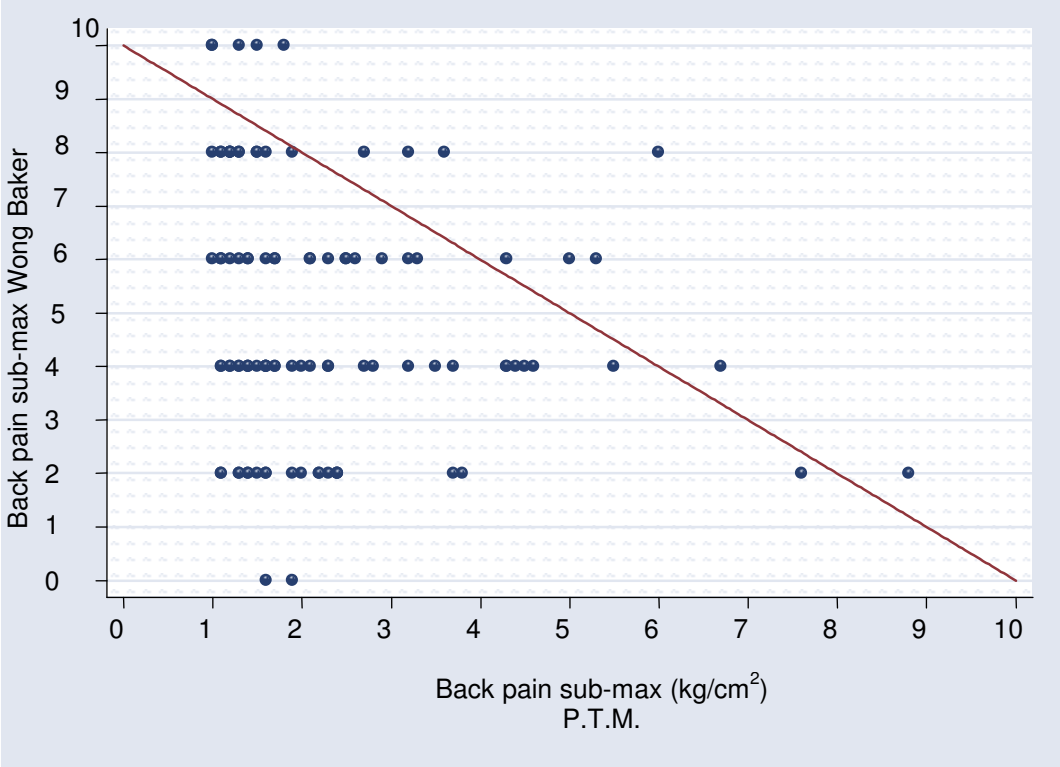

Figure 8: Scatter plot of the maximum pressure pain vs the patient perception on the Wong- Baker Faces pain measure.

Figure 8 shows no inverse relationship exists between the sub- maximum pressure threshold readings and the Wong- Baker Faces pain measure.

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