

## **Objectivity of Visual Analogue Scale in the Assessment Of Chronic Low Back Pain**

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### **ABSTRACT**

Background; One of the most critical important points to be determined in different medical fields are the assessment of pain. Adequate and accurate rehabilitation program requires a precise assessment of pain by an objective method. Objective; Evaluate the objectivity of using Visual Analogue Scale as an objective method in quantitating pain intensity for the patients with chronic low back pain and sciatica. Methods; Sixty chronic low back pain male patients with sciatica and twenty healthy subjects represent study group one and control group two respectively, participated in this study. Blood analysis for  $\beta$ -endorphin was done to objectively determine the intensity of pain .Pain intensity was recorded also by visual analogue scale for each subject then it was correlated with the level of  $\beta$ -endorphin. Results; showed no significant correlation between Visual Analogue Scale and  $\beta$ -endorphin level and the normal level of  $\beta$ -endorphin in the Egyptian male subjects of the fourth decade of life ranges from 1.4 ng/ml to 6.9 ng/ml. Conclusion; Visual Analogue Scale is a subjective method in the assessment of pain intensity of chronic low back pain patients due to disc bulge.

Key words: Chronic Low Back Pain -  $\beta$ -endorphin- Visual Analogue Scale.

## Introduction

Pain is a part of the body's defense system. It triggers mental and physical behavior to end the painful experience. Also, it is an important part of the existence of humans despite its unpleasantness. It is vital to healthy survival because pain can serve to indicate that an injury is coming up. Moreover, pain may also promote the healing process, since most organisms will protect an injured region to avoid further pain. It is considered the fifth vital sign (**Vinuela et al., 2007**).

Low back pain (LBP) is the second common cause of chronic pain, producing at least impairment in 70% to 80% of a general population. The prevalence of pain and the commonest type of pain were measured in one study. Cross-sectional survey by standardized structured questionnaire was used in that study. Subjects were recruited by random digit dialing sampling with the computer-assisted telephone interviewing system (CATI). It was concluded from that study that low back pain is the most common cause of pain. It is the most common reason that affects and has an impact on the working performance and daily

living especially the chronic type of low back pain (**Chung and Wong, 2007**).

Clinical observations indicated that diseases or injuries of similar severity could cause a wide range of pain experience. This variability is consequence to the differences in the central psychological processing of the peripherally generated pain data. Neural messages evoked by noxious stimulation ascend along peripheral nerves, spinal cord, brainstem and then rise to the cortex, where they reach consciousness. These messages can be modulated along this pathway at several points. The psychological part of the person plays a role in this modulation. Assessment of pain by many different methods of assessment depending on the subject reporting, which indirectly depends on his psychological state so most methods of assessment are subjective. Difficulty in the availability of the objective methods of assessment leads more to depend on these subjective methods (**Edwards, 2005**).

Visual analogue scale (VAS) is a common using method to assess the chronic pain as low back pain. It is 10-cm line, oriented vertically or

horizontally. It is formed of one end representing “no pain” and the other end representing “pain as bad as it can be”. The patient is asked to mark a point on the line corresponding to the current pain intensity. The distance from a point of no pain to the point the patient made is measured. The distance measured representing the intensity of pain of the patient (Van et al., 2002, Lord and Parsell, 2003).

Beta-endorphin is an endogenous opioid neurotransmitter. It is found in the neurons of both the central and peripheral nervous system like the hypothalamus, as well as the pituitary gland. It is an agonist of the opioid receptors. The evidences indicate that it serves as an endogenous ligand of the  $\mu$ -opioid receptor. This is the same receptor to which the chemicals extracted from opium, such as morphine and codeine, which have an analgesic effect. Beta-endorphin level in blood indicates the level of pain for the patients. It is frequently used in the research application but it is difficult to be used in the clinical application (Brack et al., 2004, Brian et al., 2007).

## Subjects, Instrumentations and Methods

### Subjects:

This study was conducted to evaluate the objectivity of using Visual Analogue Scale as an objective method in the assessment of pain intensity for the patients suffering from chronic low back pain and sciatica. The study was applied in out patients' clinic, Faculty of Physical Therapy, Cairo University.

### 1. Subjects Selection:

Sixty, male patients suffering from chronic low back pain (LBP) with sciatica and twenty healthy, matching male subjects were included in this study. The samples were represented as group one (G1) and group two (G2), the study group and the control group respectively, in this study. All the patients were diagnosed by neurologist or orthopedist. The diagnosis was confirmed by CT or MRI scan on the back. The patients (G1) were selected from the Outpatient Clinic of Kaser El Aini, Teaching Hospital, Cairo University and from the Out-Patient Clinic, Faculty of Physical Therapy, Cairo University. The control subjects (G2) were selected from the employees of Faculty of Physical Therapy, Cairo University who were free from any pain. The control group were selected for determining normal level of B-endorphin in Egyptian population. Subjects in both groups signed on an informed consent before beginning of the study. All the selected patients and healthy subject the age ranged from 40 to 55 years old.

#### 1.1. Group I (G1):

The age of the patients ranged from 40 to 50.5 years (yr). The BMI in this group ranged from 21.7 to 24.9 Kg/m<sup>2</sup>. All the patients had LBP

secondary to disc bulge only at the level of (L4-L5 or L5-S1) with or without radiating leg pain because they are the most common causes of LBP. The patients were free from any other neurological disorders. All the subjects in this group suffered from LBP for more than six months but not exceed the two years of complaining.

### **1.2. Group II (G2):**

The age and the body mass index (BMI) in this group were selected carefully to be matched with the patient group. The age ranged from 40 to 50 yr. The BMI in this group ranged from 21.07 to 24.9 Kg/m<sup>2</sup>. The muscle test for abdominal muscles were ranged from 4 to 5 grade muscle test

### **1.3. Exclusive criteria for G1:**

The patients with a history of:

- Any other neurological or orthopedic abnormalities of the back
- Acute low back pain patients.
- Previous back surgery or skin lesion at the site of the back or on the radiating leg pain( by asking patients and see MRI OR CT scan).
- Cognitive impaired patients after testing all the selected subjects by mini mental scale .
- Patients with history of epilepsy.
- Patients with cardiac pacemakers.
- Patients who are under analgesic drugs for less than three months.
- Patients with lost of tactile sensation in the painful area (area of applied electrodes).

## **2. Instrumentations:**

The data was collected through Visual Analogue Scale (VAS) and ELISA (Enzyme-Linked ImmunoSorbent Assay) reader for  $\beta$ -endorphin.

### **2.1. Visual Analogue Scale (VAS).**

It is a clinical evaluation method to determine the pain intensity. It is a ten centimeters tape with two perpendicular ends (the first end (zero) means no pain and the second end (ten) means the worst pain) to evaluate the intensity of pain. Patients determine the level of pain on this scale by marking a specific point on the tape. The distance from zero to the patients' point equal to the sense of pain on the most painful body part, which is either in the back or in the radiating leg pain (Adam et al.,2009).

### **ELISA (Enzyme-Linked ImmunoSorbent Assay) reader for $\beta$ -endorphin.**

ELISA is a specific quantitative assay for the determination of  $\beta$ -endorphin in the human by using ELISA reader apparatus. This product was supplied by Biosciences(Division of Morwell Diagnostics GmbH Gewerbestrasse 9,Postfach,8132 Egg b.Zurich,SwitZerland).

**Principle of enzyme immunoassay with this kit** (This is according to biochemistry lab analysis protocol of Kaser El Aini, Teaching Hospital, Cairo University):

This enzyme immunoassay kit is designed to detect a specific peptide and its related peptides based on the principle of competitive enzyme immunoassay. The immunoplate in this kit is precoated with secondary

antibody and nonspecific binding sites are blocked. The secondary antibody can bind to the Fc fragment of the primary antibody (peptide antibody) whose Fab fragment will be competitively bound by both biotinylated peptide and peptide standard or targeted peptide in the sample.

The biotinylated peptide is able to interact with streptavidin the substrate solution composed of 3,3',5,5'-tetramethylbenzidine (TMB) and hydrogen peroxide to produce a blue colored solution. The enzyme-substrate reaction is stopped by hydrogen chloride (HCL) and the solution turns to yellow. The intensity of the yellow is directly proportional to the amount of biotinylated peptide-SA-HRP complex but inversely proportional to the amount of the peptide in standard solutions or samples. This is due to the competitive binding of the biotinylated peptide and the peptide in standard solutions or samples to the peptide antibody (primary peptide). A standard curve of a peptide with known concentration can be established accordingly. The peptide with unknown concentration in the sample can be determined by extrapolation to this standard curve.

### 3. Procedures:

All the subjects participated in this study were informed and signed on a consent form before the application of any step of the study and the study was approved by ethical committee of the faculty of physical therapy, Cairo University. Both groups were subjected to a complete physical examination, which includes:

- Assessment of superficial and deep sensations.
- Assessment of muscle power of (back and abdomen).
- Identification of body mass index by using this equation (Stefan et al., 2009):

$$\text{BMI} = \frac{\text{Weight of the person in Kg}}{\text{Height of the person in M}^2}$$

All subjects involved in this study were classified as normal weight according to BMI. This means that all chosen subjects, their BMI ranged from 18.5-24.9 Kg/M<sup>2</sup>. Also all the persons chosen were of normal touch and deep sensation.

#### 3.1. Assessment of pain intensity by VAS:

Each patient was asked to mark on the line of the VAS to a point which best representing the intensity of pain. The distance from the zero point to the point of the patient was determined by a ruler and measured by the researcher. This distance determines the intensity of patient's pain by VAS. The same sequences applied for the healthy group to insure that there was no pain in the control group. All subjects in this group chose the zero point (the absence of pain at the time of collection of the samples).

#### 3.2. Measuring the level of $\beta$ -endorphin in the blood:

The sample of the blood was collected in a clean tube containing few milligram of EDTA to determine plasma level of  $\beta$ -endorphin. The blood sample drawn was about three cm<sup>3</sup>. The collection and analysis of the selected sample were done at biochemistry lab in Kasr El-Aini hospital.

- From a half, lying position a sample of blood was drawn from the antecubital fossa before measuring pain intensity by VAS.
- The antecubital fossa was cleaned by alcohol before taking the blood sample.

### **Statistical analysis:**

**Data is summarized and analyzed by using:**

- The arithmetic mean as an average description of central tendency for the observations.
- The stander deviation as a mean of dispersion of results.
- Pearson rank correlation test. Values of r ranged from +1 (perfect positive correlation), through 0 (no correlation), to -1 (negative correlation).

The alpha point of 0.05 was used as a level of statistical significance (when  $p < 0.05$ , the difference is significant and when  $p \leq 0.01$ , difference is highly significant); (MINITAB V-15) was the used statistical program (Kirkwood and Stern, 2003).

## **RESULTS**

### **1. General chronological features of the subjects:**

The general chronological features of the study group (G1) are shown in table (1). The patients age ranged from 40 to 50.5 years (yr) with a mean value of  $46.03 \pm 2.88$  yr. Their height ranged from 155 to 188 centimeter with a mean value of  $169.96 \pm 6.48$  cm. Their weight ranged from 55 to 80 kilogram with a mean value of  $69.59 \pm 5.43$  kg. The BMI in this

group ranged from 21.7 to 24.9 Kg/m<sup>2</sup> with a mean value of  $24.15 \pm 0.68$ .

The general chronological features of the control subjects (G2) are shown in table (1). The healthy subjects age ranged from 40 to 50 yr with a mean value of  $45.05 \pm 2.83$  yr. Their height ranged from 160 to 179 centimeter with a mean value of  $169.98 \pm 6.92$  cm. Their weight ranged from 60 to 77 Kg with a mean value of  $68.48 \pm 6.07$  Kg. The BMI in this group ranged from 21.07 to 24.9 Kg/m<sup>2</sup> with a mean value of  $23.81 \pm 0.89$ .

Table (2) and (Fig.1) show that the percentage of patients with pain mainly in the lower back was 96.7% while those with pain mainly in the radiating leg was 3.3%.

## 2. Results of laboratory data analysis:

The mean values of  $\beta$ -endorphin level in G1 and G2 are analyzed and compared in table (3) and (Fig. 2). As seen in (table, 3), the mean values of  $\beta$ -endorphin level in G1 and G2

are  $12.03 \pm 1.79$  and  $4.44 \pm 1.77$  respectively. The results indicate that there is a highly statistically significant increasing in the mean values of  $\beta$ -endorphin in (G1) comparing to (G2) ( $P=0.01$ ). Also according to (table, 3) the normal level of  $\beta$ -endorphin in the Egyptian male subjects of the fourth decade of life ranges from 1.4 ng/ml to 6.9 ng/ml.

**Table (1):**General features of the study group (G1) and control group (G2).

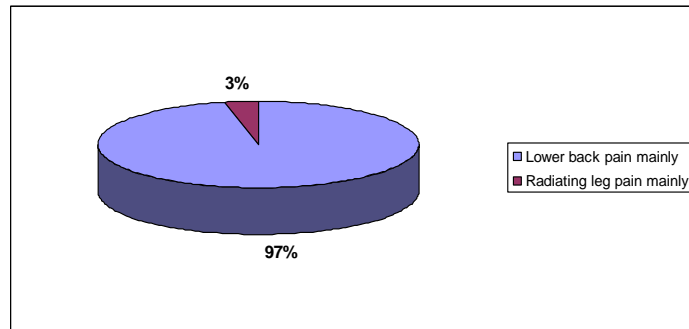
Variables	Mean $\pm$ SD	
	G1	G2
Age	46.03 $\pm$ 2.88	45.05 $\pm$ 2.83
Height	169.96 $\pm$ 6.48	169.98 $\pm$ 6.92
weight	69.59 $\pm$ 5.43	68.48 $\pm$ 6.07
BMI	24.15 $\pm$ .68	23.81 $\pm$ .89

SD=standard deviation

BMI: body mass index

**Table (2):**Frequency distribution of the most painful site in G1

Variables	Numbers of patients	Percentage
Lower back pain mainly	58	96.7%
Radiating leg pain mainly	2	3.3%
Total	60	100%



**Fig.(1):** Frequency distribution of the most painful site in G1.

**Table (3):** Comparison between the mean values of  $\beta$ - endorphin level in the patient group (G1) and the healthy group (G2)

Groups	Mean $\pm$ SD	Minimum	Maximum	P	T
G1	12.03 $\pm$ 1.79	9.22	14.6	.01	16.44**
G2	4.44 $\pm$ 1.77	1.35	6.99		

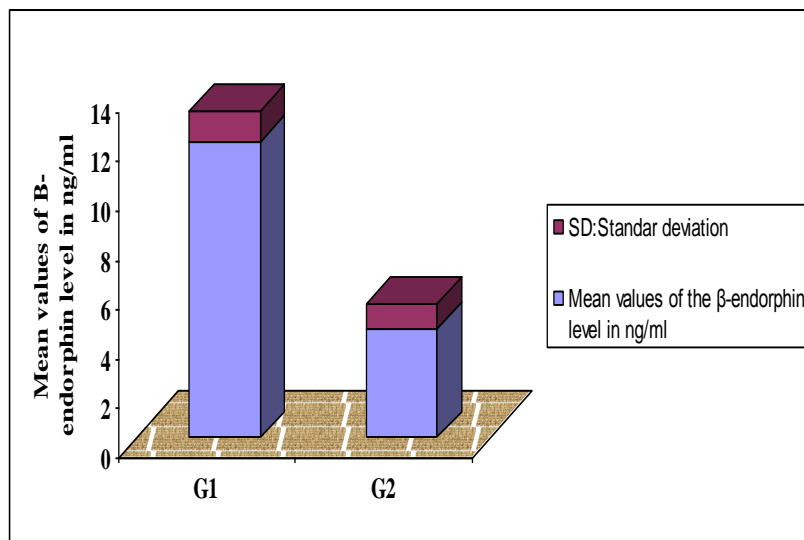
P: probability level.

T: t-test.

\* Sign: significant.

\*\* Sign: highly significant.

NS: non significant.



**Fig. (2):** Comparison between the mean values of  $\beta$ -endorphin level (in ng/ml) in both groups (G1 and G2).



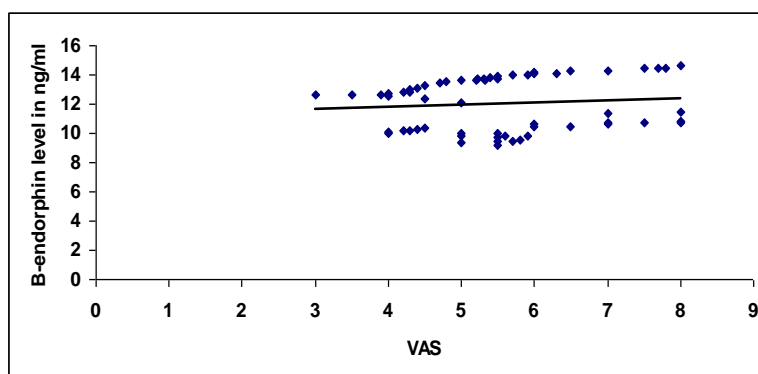
The correlation between the level of  $\beta$ -endorphin and the intensity of pain measured by VAS in G1 is shown in table (4) and (Fig.3). The Pearson rank correlation (r) is .045. The results indicate that there is a non-significant correlation between the level of  $\beta$ -endorphin and the intensity of pain measured by VAS in G1 (P=0.458).

**Table (4):** The correlation of the level of  $\beta$ -endorphin to the intensity of pain measured by VAS in the patient group (G1)

Variables	VAS	$\beta$ -endorphin
Mean $\pm$ SD	5.54 $\pm$ 1.26	12.03 $\pm$ 1.79
R	.045 NS	
P	.458	

P: probability level. \* Sign: significant. \*\* Sign: highly significant

NS: non significant.r: Pearson rank correlation. SD: stander deviation



**Fig. (3):** Scatter plot to show the correlation of  $\beta$ -endorphin level to pain intensity level measured by VAS in the patient group (G1).

### DISCUSSION

This study examined the objectivity of using VAS in the assessment of pain intensity in chronic LBP patients .Objective and valid method of pain assessment provides means of assessing the efficacy of response to the treatment and determining the prognosis of the condition. The limitations in the

treatment of pain as a general and chronic LBP as a specific coming from the method used for the assessment and follow up the course of treatment. Inaccurate assessment leads to inaccurate treatment so many studies are recommended to search for new valid and reliable method to assess pain.

Sixty, male, chronic LBP patients with sciatica in addition to

twenty healthy subjects were participated in this study. ELISA test for  $\beta$ -endorphin was used as an objective method in determining the level of pain intensity as well as to find its correlation with VAS .

The present study proved that VAS is a subjective method in the assessment of pain. The study did not find a significant correlation between pain intensity measured by VAS and the level of  $\beta$ -endorphin determined by ELISA test (the most objective and reliable method to assess pain). VAS rating depends on the subject comparing the current pain intensity with the previous pain. That makes it one of the subjective measurements of pain. The result of the present study is consistent with the result of **Oddmundet al., (2003)**. The authors found no correlation between the level of  $\beta$ -endorphin and cortisol and the rating of pain measured by VAS. Our finding is also consistent with the findings of **Kane et al., (2005)** and **Massy-Westropp et al., (2005)**.

This result contradicts with the results obtained by **Cork et al., (2004)**. The authors concluded that both VRS and VAS are reliable and objective methods in the assessment of pain perception. This difference is due to, the current study depended on the laboratory analysis of  $\beta$ -endorphin, the most objective method in the assessment of pain but the study of **Cork et al., (2004)** assessed the reliability with an analysis of the correlation between the two tests and the authors found a significant correlation.

The present result disagrees also with the findings of **Lida et al., (2009)**, **Salo et al., (2003)**, **Katz, and Melzack, (1999)**. In addition, it is not

consistent with the findings of **Gallagher et al., (2002)**. The authors concluded that VAS is a reliable and valid method in the assessment of pain because patients in that study were asked to contrast their current pain severity with their pain in the preceding 30 minutes using one of 5 graded verbal descriptors: "much less pain," "little less pain," "the same pain," "little more pain," and "much more pain.". Validity was assessed by performing an analysis of variance for linear trend on the association between the five categorical pain descriptors and the change in VAS scores. Reliability and objectivity were assessed using the intra-class correlation coefficient (ICC) between VAS scores taken one minute apart, supplemented by a Bland-Altman analysis but our study depend on the  $\beta$ -endorphin analysis (the most objective tool in the assessment of pain).

#### **Conclusion:**

Visual Analogue Scale is a subjective method in the assessment of pain intensity of chronic low back pain patients due to disc bulg.

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## الملخص العربي

### موضوعية القياس التناظري البصري في تقييم آلام أسفل الظهر المزمن

واحدة من أكثر النقاط أهمية لكي تحدد في مختلف المجالات الطبية هنتقييما للألم. البرنامج العلاجي الدقيق والمناسب يتطلب تقييم دقيق للآلام بوسيلة موضوعية. ومن هنا يهدف هذا البحث الى تقييم موضوعية المقياس البصري للآلام في تقييم شدة الآلام عند مرضى آلام أسفل الظهر المزمن وعرق النساء. شارك في هذا البحث ستون مريضا بالآلام أسفل الظهر المزمن وعرق النساء وعشرون شخصا لا يعانون من أى ألم قد مثلوا المجموعة الأولى والثانية على التوالي. وقد تم قياس مستوى مادة  $\beta$ -endorphin في الدم لتقييم شدة الآلام بموضوعية في المرضى الذين يعانون من الآلام وقد تم تحديد شدة الآلام أيضا بواسطة المقياس البصري للآلام ومقارنتها بمستوى مادة  $\beta$ -endorphin في الدم. ولم تظهر النتائج أياً ارتباط بين قياس شدة الآلام بالمقياس البصري للآلام ومستوى مادة  $\beta$ -endorphin. كما أظهرت النتائج ان مستوى مادة  $\beta$ -endorphin في الدم عند المصريين الذكور يتراوح بين 1.4 نانوغرام/ملي إلى 6.9 نانوغرام/ملي. نستخلص من هذا البحث ان المقياس البصري للآلام لا يعتبر وسيلة موضوعية في قياس الآلام عند مرضى آلام أسفل الظهر المزمنة.

الكلمات الدالة: الآلام أسفل الظهر المزمنة -  $\beta$ -endorphin - المقياس البصري للآلام