Original Article

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A Study on Factors Affecting Low Back Pain and Safety and Efficacy of NSAIDs in Acute Low Back Pain in a Tertiary Care Hospital of Western Nepal

Pharmacology Section

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ABSTRACT

Introduction: Low back pain is characterized by a range of symptoms which include pain, muscle tension or stiffness, and is localized between the shoulder blades and the folds of the buttocks, with or without spreading to the legs. Non-Steroidal Anti Inflammatory Drugs (NSAIDs) are the drugs of choice which provide an analgesic effect for acute low back pain.

Aim: To study the factors affecting low back pain, efficacy and safety of different non-steroidal anti-inflammatory drugs (aceclofenac, diclofenac, naproxen and nimesulide) in low back pain.

Methodology: Data collection form and numeric pain rating scale were used as study tools for studying patients' demographies and severities of pain respectively. Patients prescribed with aceclofenac 100 mg , diclofenac 100 mg, naproxen 500 mg and nimesulide 100 mg for acute low back pain at Orthopaedics Outpatients Department of Manipal Teaching Hospital, Nepal, were enrolled in this study. The decrease in pain scores was recorded on 5th and 10th days of follow-up and pain scores were calculated. Descriptive statistics and Kruskal Wallis non parametric test were used for analysis.

Results: Among 150 patients, 67.3% were females (n=101). Low back pain was more prevalent (24.7%) in age-group of 59-68 years and a positive correlation was seen. Similarly, low back pain was found to be high among people involved in agriculture, heavy weight lifters and non smokers. The decrease in average pain scores was more in the patients treated with aceclofenac (4.83 ± 0.537), followed by that in those who were treated with naproxen (4.13 ± 0.067) and diclofenac (3.84 ± 0.086). The decrease in pain scores was found to be lowest among patients who were treated with nimesulide (2.11 ± 0.148). Nimesulide presented more number of side-effects than the comparative drugs.

Conclusion: Different factors affect low back pain, such as age, gender, personal habit, posture, occupation, weight lifting. Aceclofenac showed greater decrease in pain scores with lesser number of side-effects.

Keywords: Low back pain, Non-steroidal anti-inflammatory drugs, Pain scale

INTRODUCTION

Low back pain is a symptomatic and a self-limiting condition which includes pain, muscle tension or stiffness, and is localized between the shoulder blades and the folds of the buttocks, with or without spreading to the legs (sciatica) [1]. In a national survey, 40% of the adults were found to have suffered from back pain which had lasted for more than one day and they had sought medical advice [1]. In general, 60-80% of the world's population experience low back pain during some point in their life [2]. Back pain is the second most common reason for visiting a physician [3]. Approximately 90% cases of back pain are idiopathic. In developed countries like the US, prevalence of back pain which had lasted for at least 1 month was 17.8%, whereas in developing countries, back pain was among the most frequently cited symptoms [4]. This might be because of large work forces, on heavy manual work. In the context of Nepal, the overall annual prevalence of low back pain was 71%, with a prevalence of 67.9% in males and of 74.3% in females. The total duration of back pain in one year was less than 15 days in 73% cases [5].

Acute low back pain is usually defined as the duration of an episode, which persists for less than 6 weeks; sub-acute low back pain which persists between 6 and 12 weeks; chronic low back pain which persists for 12 weeks or more [6]. The management of low back pain depends on cause of pain and it can be non-surgical or surgical treatment and medication therapy [7]. Non-Surgical treatment includes counselling, rest, medication, braces, spinal manipulation, exercise, stretching and proper lifting techniques. Surgical treatment is given when non surgical treatment fails. This includes spinal fusion and disc replacement [8]. Medications commonly used include NSAIDs and muscle relaxants [9].

The short-term symptomatic relief of uncomplicated low back pain provided by NSAIDs has already been established [10]. However, the rationale behind this study was to compare the analgesic effect of such NSAIDs and factors affecting low back pain, which are limited in the context of Nepal. So, this study will fulfill the gap and serve as a reference for the physicians, for choosing the most suitable NSAIDs for such patients.

MATERIAL AND METHODS

This study was conducted at Orthopaedics Out Patients Department (OPD) at Manipal Teaching Hospital, Pokhara, Nepal. It was approved by the ethical comittee of the hospital and fully abided by Helsinki's declaration. Written consent (annex II) forms were read and signed by all the participants before enrolling themselves in the study. A prospective comparative study was done between months of April 2012 to September 2012, for a period of 6 months. However, data collection was done for a period of only one month (April 15, 2012 to May 20, 2012). So, patients with the complaint of acute low back pain were enrolled in the study according to the below mentioned inclusion criteria. Among 179 acute low back pain patients, 150 were selected for the study. Remaining 29 patients were excluded from the study, as they didn't come for the follow-up. Depending upon the results of a pilot study which was done; aceclofenac,

diclofenac, naproxen and nimesulide were among the NSAIDs most frequently used orally for the treatment of acute low back pain in Manipal Teaching Hospital. Hence, the drugs were chosen for study purpose, to compare their analgesic effects.

Prescriptions were taken from the patients only after they had visited the orthopaedician. Doctors were not influenced. So, based on the prescriptions of the orthopaedician, the drugs were grouped into four comparative groups and patients were sampled accordingly.

Inclusion Criteria

- Out - patients who were more than 18 years of age
- Low back pain with duration of less than 6 weeks
- Patients prescribed with aceclofenac 100 mg, diclofenac 100 mg, nimesulide 100 mg or naproxen 500 mg only.

Exclusion Criteria

- Age less than 18 years
- Patients with back pain caused by malignancy, infection, abnormal metabolism, osteoarthritis
- Back pain referred from other organs
- Pregnancy and lactation patients
- Non complying patients who had mental retardation and drug addiction.
- Patient allergic to NSAIDs.

A questionnaire (annex I) and numeric pain rating scale (annex III) were used as research tools. To validate the questionnaire, a pilot study was conducted among 30 patients with acute low back pain. Questionnaire consisted of demographic details, previous and past medication histories, literacy statuses, socio-economic statuses and other parameters. Pain score consists of twelve standard questions on low back pain. Each question allowed the patients to rate their severities of pain from zero to ten. Zero indicated no pain, whereas ten indicated worst pain. Demographic details of the patients were noted and average pain score was rated for each question on low back pain. Patients were called for follow-up on 5th and 10th days respectively, to rate the pain scores again. Any adverse effects of the drugs were also noted, based on to patient's descriptions. Severity of pain was interpreted as follows:

0=1	1-2 = 2	3-5 = 3	6-7 = 4	8-9 = 5	10 = 6
No pain	Mild pain	Moderate pain	Severe pain	Very severe pain	Worst pain

Data analysis was done by using SPSS, version 15. Descriptive statistics was used to study the demographics. To determine the analgesic effect of non steroidal anti inflammatory drugs, Kruskal Wallis test (non parametric test) was used.

RESULTS

One hundred and fifty patients were selected for this study. Among them, 42 were prescribed aceclofenac (100 mg), followed by diclofenac (100mg) 37, naproxen (500 mg) 37 and nimesulide (100 mg) 34.

Socio-Demography of Low Back Pain

In our study, more number of patients were from 59–68 age-group. A significant positive corelation (p value= 0.027) between age and low back pain was found. Similarly, female patients were more in number than males. We found that 48 patients were from agricultural background, who were relatively higher in number than those from other professions. Similarly, 88 of them had lifted heavy weights and 89 were non-smokers. The details of medicine-wise distribution has been given in [Table/Fig-1].

Decrease in Pain Score

Kruskal Wallis (non parametric ANOVA) test was performed to find out significantly effective NSAIDs. From the test statistics, we found that there was a significant reduction in pain by all four NSAIDs in the first follow-up (p=0.000). Similarly, there was also a significant reduction in pain by all four NSAIDs in the second follow-up (p=0.000). However, among all four comparator drugs, decrease in average pain score was higher with aceclofenc, followed by naproxen, diclofenac and nimesulide. Details regarding decrease in average pain score of each individual drug has been given in [Table/Fig-2].

Severity of Pain

As for the pain severity, aceclofenac decreased the pain from very severe to no pain. Diclofenac and naproxen decreased the pain from very severe to mild pain, while nimesulide decreased the pain from very severe to moderate pain.

Adverse drug Reaction of NSAID's

List of adverse drug reactions of comparator drugs has been given in [Table/Fig-3]. All the ADRs were recorded and documented in ADR reporting form of the hospital. Furthur, such ADRs were also reported to the National ADR Reporting Centre of Nepal (Department of Drug Administration).

Demographics	Range	Aceclofenac	Diclofenac	Naproxen	Nimesulide	Total
Age	19 – 28	7	3	6	9	25
	29 – 38	4	9	6	2	21
	39 – 48	10	7	6	3	26
	49 – 58	9	7	8	12	36
	59 – 68	11	8	10	8	37
	68 and above	1	3	1	0	5
Gender	Female	32	25	21	23	101
	Male	10	12	16	11	49
Occupation	Housewife	12	10	16	9	47
	Student	3	2	1	4	10
	Govt. Service	4	0	1	5	10
	Businessman	4	1	10	2	17
	Pensioner	2	1	2	0	5
	Agriculture	14	18	6	10	48
	Unemployed	2	3	0	2	7
	Others	1	2	1	2	6
Heavy wt. lift	Yes	25	21	22	20	88
	No	17	16	15	14	62
Smoking	Yes	18	11	13	19	61
	No	24	26	24	15	89

[Table/Fig-1]: Socio-demography of Low Back Pain

Drugs	Before treatment	1st f/u	2nd f/u	Difference (before trt and 2nd f/u)
Aceclofenac	5.83±0.537	2.45±0.504	1.00±0.000	4.83±0.537
Naproxen	5.51±0.559	3.16±0.501	1.38±0.492	4.13±0.067
Diclofenac	5.46±0.767	3.38±0.492	1.62±0.681	3.84±0.086
Nimesulide	5.29±0.906	4.09±0.753	3.18±0.758	2.11±0.148

[Table/Fig-2]: Decrease in Pain Score by Different Nsaid's
*NSAID's: Non steroidal anti inflammatory Drugs *f/u: follow-up

Drugs	Nausea	Vomitting	Abdominal Pain	Headache	Dyspepsia	Vertigo	Gastritis	Total number of side-effect
Aceclofenac	√					√	√	3
Diclofenac	√	√					√	3
Naproxen	√				√	√	√	4
Nimesulide	√		√	√	√	√	√	6

[Table/Fig-3]: Adverse Drug Reaction of the Drugs

DISCUSSION

In our study, low back pain was most commonly seen in elderly patients, which was also supported by several literatures. Study done by Paul in 2008 concluded that the incidence of lower back pain increased with age [11]. Similar findings was seen in workers who were between the ages of 45 and 64 years, with highest prevalence of back pain being seen in both sexes [4]. A national survey conducted in US among patients who were aged 75 years or older, revealed back pain as the third most frequently reported symptom [12]. The reasons for this may be lack of adequate physical activity, muscle weakness and some degenerative factors [13]. In the present study, more number of female patients complained of low back pain than males. This study was similar to the study done in Taiwan by Manek [4]. The reason might be osteoporosis. In osteoporosis, the hormonal changes of menopause result in a decrease in bone density or a "thinning" of the bones of the lumbar spine (low back) [14]. Some other causes like anxiety, genetic factors also may play roles in female patients.

More number of patients who complained of low back pain were from agricultural sector, in this study. Kar and Dhara found similar results in 2010. This may be caused by adoption of a strongly bent posture for a long period. Farmers or agricultural people are involved in works like reaping, transplantation and uprooting operations, which are continous and repetitive processes. They are also highly involved in frequent twisting of their waists, by taking much physical effort. When such activities and stooping postures are sustained for long periods, they will definitely result in significantly higher proportions of disc disease [15]. Activities that require long periods of sitting, lifting heavy objects, bending or twisting, repetitive motions, or constant vibrations can be a predisposing factors for acute low back pain [16]. Though low back pain is also found among patients leading sedentary lifestyles, Nepal being an agricultural country, more number of low back pain patients come from agricultural background. The fact that those who lift more heavy weights are more likely to get acute low back pain, which was seen in this study, was similar to the findings of Manchikanti [17]. This study concluded that 15% to 64% of low back pain occurrences took place after lifting heavy weights. In the same study, some harmful activities were also noted, like sudden lifting of objects by making unexpected maximum efforts, lateral bending and twisting. Those who lift heavy weights manually, have eight times higher incidences of low back pain problems as compared to those involved in sedentary work. So, heavy weight lifting, bending and twisting frequently at work can be risk factors for the development of low back pain [18].

Though the number of non smokers was high in this study, literature suggested that smoking was one of the risk factors in development of low back pain. Study done by Otani et al., concluded that smoking had a negative effect on bone mineral density in young adult men [19]. Smoking also reduced vertebral blood flow. When vertebral bodies and intervertebral discs receive decreased blood supply, this can lead to depressed levels of oxygen and nutrients in these components, which can make them vulnerable to mechanical stress and to low back pain [19].

In the present study, all four NSAIDs were effective in reducing low back pain, which is similar to the findings of another study done by Koes et al., It concluded that NSAIDs were the drugs of choice for acute uncomplicated low back pain [20]. As for the pain severity, in our study, aceclofenac decreased the pain severity from very severe to no pain; diclofenac and naproxen decreased it from very severe to mild pain, while nimesulide decreased it from very severe to moderate pain. Findings of study done by Schattenkirchner and Milachowski also showed better safety and tolerability profiles of aceclofenac in low back pain patients, which were similar to our findings [21]. Another study which compared the efficacy of aceclofenac 100 mg and diclofenac 75 mg in acute lumbago, resulted in a more efficacy profile of aceclofenac. In the same study, assessment was done by physicians, with reported efficacy of 85% in aceclofenac-treated patients and of 76% in diclofenac. The average change in pain scores after 8 to 10 days was greater with aceclofenac i.e., 61.6 mm and with diclofenac, it was 56.7 mm. In the aceclofenac treated group, improvement in functional impairment and routine activities were noted [22]. However, a review study done by Tulder et al., reported that there did not seem to be a specific type of NSAID which was clearly more effective than others. Furthur, the study suggested a need for RCTs with high methodologic standards, to evaluate the effectiveness of NSAIDs in acute low back pain. They also seemed to be useful for evaluating the most effective dose with a comparatively lowest risk of (serious) side-effects [23].

Our study showed that GI related side-effects were less with nimesulide than the other comparator drugs. Though NSAIDs are effective for short-term relief of back pain, they can cause uncomfortable gastrointestinal side-effects. Such GI side-effects are most common with both aceclofenac and diclofenac, mostly because of potential inhibition of both COX-1 and COX-2. Inhibition of COX-1 is responsible for potentially serious adverse effects of NSAIDs. Common reactions to diclofenac that affect the GI tract, include epigastric pain, nausea, vomiting, and diarrhoea. Although they are less frequent, peptic ulcer and GI bleeding have also been reported. Headache occurs in about 3-9% cases and dizziness occurs in 1-3% of patients receiving diclofenac. Adverse nervous system effects occurring in less than 1% of patients receiving the drug, include drowsiness, depression, insomnia, anxiety, malaise and irritability. The incidence of gastrointestinal side-effects seems to be lower with nimesulide than with other NSAIDs, which is because of its preferential inhibition of COX – 2 pathway [24]. Withdrawal rates caused by adverse events among NSAIDs was 2% in diclofenac treated patients [25]. The present study provided various important issues related to safety and efficacy of NSAIDs in acute low back pain. From this study, we can conclude that all NSAIDs are effective in lowering acute low back pain. Only the difference lies in decrease

in pain scores, caused by each of them. Among four comparator drugs, though aceclofenac decreased pain from very severe to moderate pain, diclofenac and naproxen decreased it from very severe to mild pain, while nimesulide decreased it from very severe to moderate pain, but it is still unclear as to which NSAID is more effective than others.

LIMITATIONS

This study was monocentered, it involved limited sample size and inability in patients' follow-up. Similarly, duration of study period was also limited. Therefore, further studies need to be done on large populations and at different centres, to extrapolate the findings of the safety and efficacy of NSAIDs.

CONCLUSION

Lower back pain is associated with a myriad of factors. NSAIDs are the mainstay of treatment for such pain. In the most common medications which were prescribed, aceclofenac proved to be more effective in alleviating the pain.

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ANNEX I: PHARMACIST: PATIENT DATA COLLECTION: QUESTIONNAIRE

Personal History

Patient Name: ..... Age: Sex:

Address: ..... Contact no. .....

History of Disease

Diseasee occurrence : Less than six weeks ☐ More than six weeks ☐

Type of disease : Acute ☐ Chronic ☐

Medication History

1. a. Have you used any NSAID,s before? : Yes ☐ No ☐
   b. If yes what?
      Aceclofenac ☐ Diclofenac ☐ Naproxen ☐ Nimesulide ☐ Others ☐
   c Dose details .....
   d. How long back?
      Before 3 days ☐ Before 2 days ☐ Before 1 day ☐ Today ☐
   e. Any allergies to NSAID's: Yes ☐ No ☐
2. a. NSAID's prescribed now
   Aceclofenac ☐ Diclofenac ☐ Naproxen ☐ Nimesulide ☐
   Dose details .....
3. Other concurrent drugs given: Gatric acid lowering drugs ☐ Muscle relaxant ☐ topical gel ☐

4. Use of anticoagulants : Yes ☐ No ☐

Socio-economic Status

a. Marital status: Single ☐ Married ☐
b. Religion: Hindu ☐ Muslim ☐ Christian ☐ Buddhist ☐ Other ☐
c. Caste: Brahmin ☐ Chhetri ☐ Newar ☐ Others ☐
d. Family income/month (in Rs.):
e. Occupation: .....
f. Heavy Weight Lifting: Yes ☐ No ☐
g. Number of hours of work: 2-4 ☐ 4-8 ☐ 8-12 ☐ 12-16 ☐ 16-20 ☐ more than 20 ☐
i. Literacy status: Illiterate ☐ Primary ☐ Secondary ☐ High School ☐ College ☐

Side-effects

1. Nausea ☐ 2. vomitting ☐ 3. rashes ☐ 4. angioedema ☐ 5. headache ☐ 6. dizziness ☐ 7. dyspepsia ☐ 8. abd pain ☐ 9. drowsiness ☐ 10. insomnia ☐ 11. vertigo ☐ 12. tinnitus ☐ 13. photosensitivity ☐ 14. Gastritis ☐

Personal Habit

1. Smoking habits: Yes No
2. Alcohol consumption : Yes No
3. Quantity: 30-60ml 60-100ml >100ml
4. Exercise / physical activity: Yes No
5. How often? everyday twice a week thrice a week once a week

Name of Prescribing Physician: Name of Data Collector:

ANNEX II: INFORMED CONSENT FORM: WRITTEN CONSENT

Part I : Explanation of research:

Hello, Namaskaar, Good morning!

I am a Pharm D student from the Kathmandu University conducting a comparative study on the A Prospective Study to Compare the Analgesic Effect of different NSAID's in Low Back Pain patients in a Tertiary Care Hospitals of Western Nepal. I need a little bit of your time. I will be asking some questions relating your problem in low back pain and severity of pain that you are going through. Additionally I also need some information about your demographics, drugs being prescribed and side-effects experiencedwhich I will be asking through a questionnaires. I will also be asking you 12 different questions on the severity of pain that you are going through on the first day and at each follow-up. This will be done through a VAS scale. This is a complete comparative study on different kinds of NSAID's that is being prescribed by the physician to you. I request you to cooperate and give us a little bit of your time and at the same time ask for information as far as possible. We assure that your information will be used only for study purpose and that your identity unrevealed.

PART II: Certificate of Consent

I have read all the information in this form. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant ..... Address .....

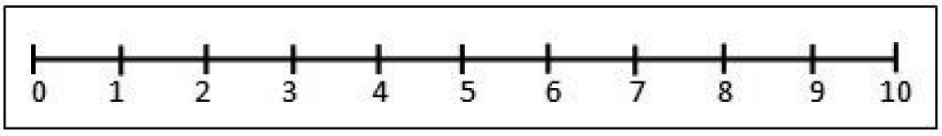
Date ..... Contact no. .....

Name of the witness if participant cannot (read and write) .....

ANNEX III: RATING SCALES FOR LOW BACK PAIN

1.Do you have any pain in the back? How severe is it?

No pain Intolerable

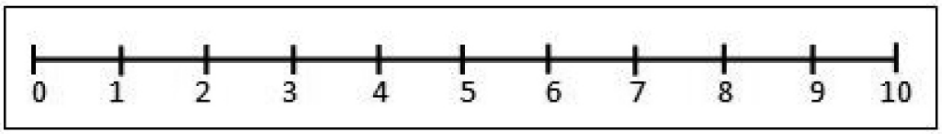


Visit	1st	2nd	3rd
score			

2.Do you have any pain in the night? How severe is it?

2.Do you have any pain in the night? How severe is it?

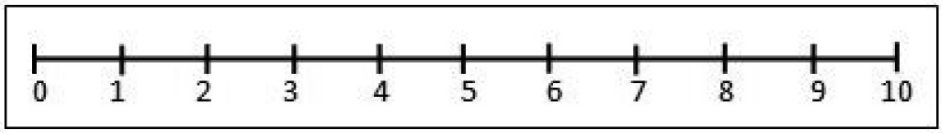
No pain Intolerable



Visit	1st	2nd	3rd
score			

3. Do you get relief from pain killers?

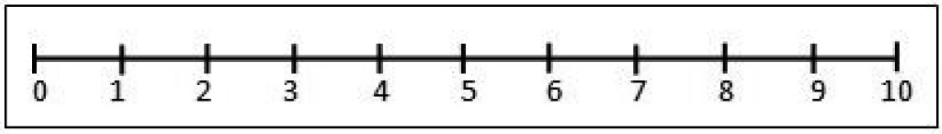
Complete relief– No relief



Visit	1st	2nd	3rd
score			

4. Do you have any stifness in the back?

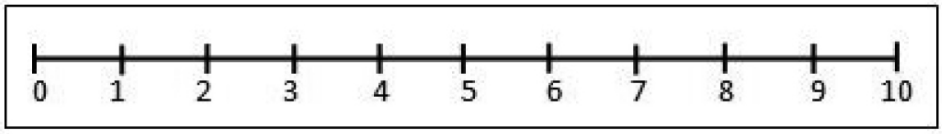
No stiffness- Intolerable stiffness



Visit	1st	2nd	3rd
score			

5. Do you have discomfort when walking?

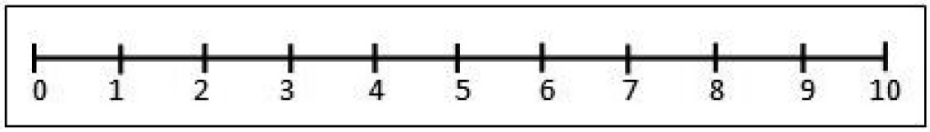
None at - Intolerable



Visit	1st	2nd	3rd
score			

6. Does your pain interfere with your ability to stand still?

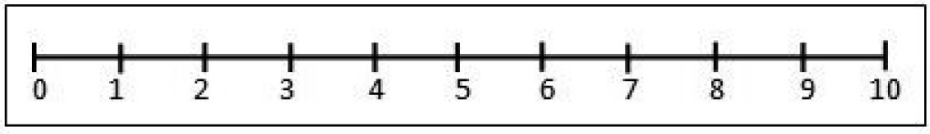
Stand still for a long time, that is an hour Not able to stand still at all



Visit	1st	2nd	3rd
score			

7.Does your pain prevent you from turning and twisting?

Complete freedom to twist– Completely incapable of twisting



Visit	1st	2nd	3rd
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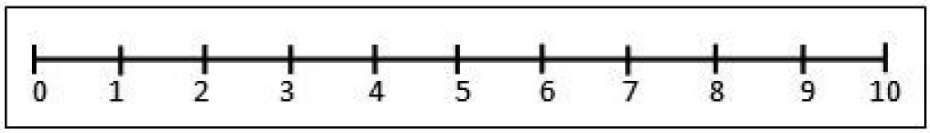
8.Does your back pain allow you to sit on an upright hard chair?

Complete freedom to sit on a hard chair So much pain that cannot sit on such a chair at all



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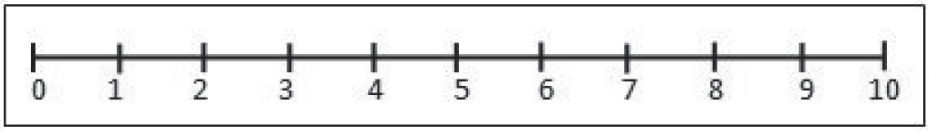
9. Does your back pain prevent you from sitting in a soft armchair?

Complete comfort– Such discomfort that cannot sit in a soft chair at all



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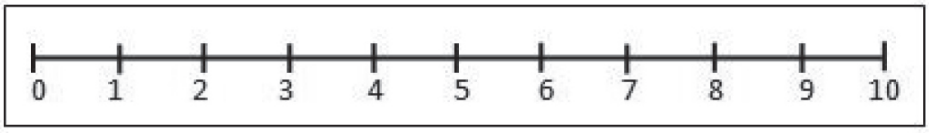
10. Do you have back pain when lying down in bed?

Complete comfort- Not comfort at all



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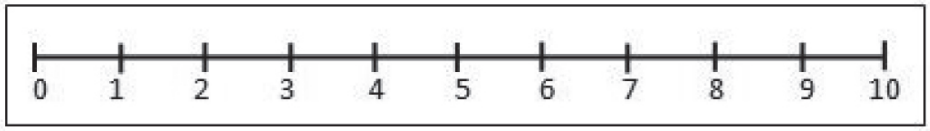
11. To what extent does your pain interfere with your work?

No interference at all– Totally incapable of work



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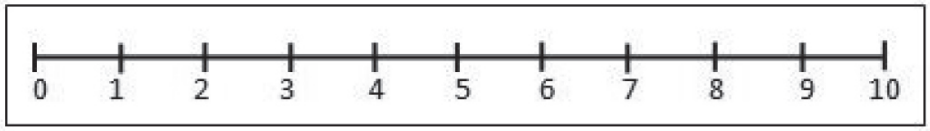
12. To what extent does your work have to be modified so that you are able to do your job?

No adjustment to work - So much adjustment that you have had to change your job



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