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Research article

PRESCRIPTION MEDICATION USE AMONG ADULTS WITH LOW BACK PAIN

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ABSTRACT

Low back pain is the most common cause of job related disability and about 80 percent of adults experience low back pain at some point in their lifetime. Combination therapy of neuropathic and nociceptive pain relievers are most effective in reducing chronic low back pain. Our study was a cross sectional population based study in which hundred patients suffering with low back pain were recruited. These patients fulfilled the following inclusion criteria : aged above 20 years and diagnosed with chronic low back pain who have a current valid prescription for the same. A structured data collection form was used to collect all the relevant data needed for the study. The pain score before the treatment and at second follow up after treatment was taken. Wong- Baker Faces Pain Rating Scale was used to compare the pain scores and from the scoring effectiveness of the drugs were found. We focused the study to four common drug combinations used in the treatment of low back pain which included Gabapentin+ Tolperisone, Gabapentin + Etoricoxib, Tramadol + Tolperisone , Tramadol + Etoricoxib. Among the Four drug combinations evaluated in the study, the combination of Gabapentin + Tolperisone showed more effectiveness in treatment of chronic low back pain. Our study revealed that combination therapy of neuropathic and nociceptive pain relievers are more effective in treatment of low back pain.

Key Words:- Chronic Low back pain, Pain Score, Medication use, Neuropathic pain, Nociceptive pain.

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INTRODUCTION

Low back pain is defined as the muscle tension or stiffness localized below the costal margin and above the inferior gluteal fold, with or without leg pain(sciatica), and is define as chronic when it persists for 12 weeks or more people in this have chronic low back pain(>12 weeks duration) (Anonymous 1).

Risk factors include heavy physical work, frequent bending, twisting, lifting, and prolonged static posture. Psychological risk factors include anxiety, depression, and mental stress at work. Having a previous history of low back pain and a longer duration of the present episode are significant risk factors for chronicity (Anonymous 1). By definition, this is pain that has persisted longer than 3 months. In addition to the pain, patients typically suffer physical disabilities and psychological distress. They may be unable to work and depressed. The prevailing approaches to chronic low back pain fall in three categories: Monotherapies, multidisciplinary therapy and reductionism. This include many classes of drugs such as simple analgesics, non-steroidal anti-inflammatory drugs, Opioids, antide pressants, muscle relaxants etc (Nikolai B, 2004). Pain intensity, pain related disability, pain duration and pain affect are the aspects that define pain and its effects. Pain scale used to assess the severity of pain in patients. Visual analogue scale/Graphic rating scale, Numerical

rating scale, pain drawing McGill pain questionnaires etc are used (Anonymous 2).

Low back pain is an extremely common problem that most people experience at some point in their life and estimates of 1 year incidence of first ever episode of low back pain range between 6.3%-15.4% while estimate of the 1 year incidence of any episode of low back pain range between 1.5% and 36%.Episode remission at 1 year range from 54% and 90% Prevalence range from 1.0%-58.1% (Hoy, 2010).

Among chronic conditions, chronic low back pain is noted to be the leading cause of job related disability. Despite no clear rationale medication use for chronic low back pain has significantly increased.

Short term (<4 months) treatment with Opioids provides moderate relief of chronic low back pain, but only minimal improvement function.

Chronic Low back pain remains a poorly understood condition that causes substantial disability,work absenteeism and health care costs. This warrants the need to implement appropriate therapeutic intervention for the treatment of chronic low back pain.

Aim

To assess the effectiveness and the side effects of various drugs used in treating chronic low back pain.

Objectives

- To enumerate the various drugs prescribed for chronic back pain
- To compare the effectiveness of various drugs used in treating chronic low back pain.

Hypothesis of the Study

Combination therapy of neuropathic and nociceptive pain relievers are most effective in treating chronic low back pain.

MATERIALS AND METHODS

Study design and data collection

A detailed data collection form with a bilingual patient Informed Consent was prepared. Data collection was done based on the inclusion and exclusion criteria. The detailed purpose of the study and benefits are explained in the local language to the individual patients and care takers before obtaining the informed consent without any force or compulsion.

All the patients with chronic low back pain with a valid prescription medication attending neurosurgery OPD had enrolled for the study. All the patients were examined and the demographic details, clinical features were documented and tabulated. The patients were evaluated with pain scale (VAS) before and after (1^{st} follow-up on 3^{rd} week and 2^{nd} follow up on 6^{th} week) of medication.

The details of the prescription were tabulated. The drugs prescribed were classified into various groups, age, dosage and duration was noted. The patients who attended the follow up sessions were examined for the pain score and the respective pain scores were noted in the annexure forms .Finally the pain scores of all the 100 samples were categorized in to before and after treatment and were then used as a criteria to describe the effectiveness of the drugs taken in the study. All the clinical details and drug related details were subjected to statistical analyses.

Study Materials

Informed consent form, patient data collection form , pain scale, medication history are the essential aids used for the study.

Study site

The study site selection was done based on the availability of resources like the specific departments and study subjects so this prospective cross sectional observational study was conducted in the Neurosurgery Department , Sri Venkateswara Institute Of Medical Sciences ,SPMC(W)-Tirupati, Andhra Pradesh.

Study population

A total of 100 patients with Chronic Low back pain were enrolled in to the study from the Neurosurgery department, SVIMS, SPMC (W) according to the inclusion and exclusion criteria.

Study Period

This study was carried out for duration of 6 months from the 16 August 2018 to 16 January 2019.

Study Design

This is a hospital based cross sectional prospective observational study.

INSTITUTIONAL ETHICAL CLEARANCE

The study protocol along with patient data collection form and informed consent form were submitted to the institutional ethical committee of Sri Venkateswara Institute Of Medical Sciences, SPMC (W)-Tirupati, a 1500 bedded tertiary care hospital for the approval. The study was approved by the institutional ethical committee held on 14 August 2018.

STUDY CRITERIA

Inclusion Criteria

- Patients of either sex of the age group of 20 years and above diagnosed with chronic low back pain (> 12 weeks) are in possession of a current valid prescription for the same, are eligible to enroll in the study.
- Patients with complete follow up

Exclusion criteria

- Patients under the age of 20 years
- Pregnant women
- Patients lost to follow up
- Patients who are not willing to participate in the study

STASTISTICAL TOOLS

Sample size

Sample size was determined for a paired Comparision of pain scores before and after the treatment using an anticipated effect size of 0.20(Cohen's d) and using online calculator we got n=100 as minimum size. Therefore we carried out the study with 100 patients.

Statistical methodology

Data on continuous variables was summarized as descriptive statistics mean and standard deviation. Comparision of means was made by paired t-test. Categorical data was presented as number, percentage and Comparision was done by chi-square test. Results with $p<0.05$ were considered as significant.

The collected data was initially entered in to Microsoft excel spreadsheet ten it is transferred to SPSS 20.0.The major analytical method to find the significance of the p value is paired student t test. The different variables from the obtained data such as gender, age, diagnosis, before and after pain scores were collected and analyzed using paired student t test. The obtained results were presented in tabular and graphical form using Microsoft word and excel.

RESULTS

GENDER DISTRIBUTION

Out of 100 subjects included in our study, total number of female patients were 57(57%) and the total number of male patients were 43(43%).This indicates that there is higher incidence of chronic low back pain was among females as per our study.

In our study , out of 100 patients ,12 patients were under the age group of 20-29,24 patients were under the age group of 30-39,30 patients were under the age group of 40-49,24 patients were under the age group of 50-59,6 patients were under the age group of 60-69 ,4 patients were under the age group of 70-79.The higher incidence of chronic low back pain was among the age group of 40-49 .

ACCORDING TO TREATMENT

Numbers of male and female patients receiving gabapaentin+ tolperisone were 10 and 15 respectively. Numbers of male and female patients receiving gabapentin+ Etoricoxib were 12 and 13 respectively. Numbers of male and female patients receiving Tramadol+ Tolperisone were 11 and 14 respectively. Numbers of male and female patients receiving Tramadol+ Etoricoxib were 11 and 14 respectively.

STATISTICAL ANALYSIS

Statistical evaluation for change in pain score for Gabapentin+ Tolperisone has been done with help of statistical to SPSS 20 .The statistical method used to find the p value and t value in paired t test with degree of freedom 24 at the level of significant o.o5%.

Paired sample statistics: Gabapentin and Etoricoxib:

The obtained p valve <0.0001 found less the 0.05% is showing the significant for two tailed student-t test. The mean difference between the before and after pain Acores related to Gabapentin+ Etoricoxib was found to be 3.08.

Paired sample statistics: Gabapentin and Tolperisone

Statistical evaluation for change in pain score for Gabapentin and Etoricoxib has been done with help of statistical to SPSS 20 .The statistical method used to find the p value and t value in paired t test with degree of freedom 24 at the level of significant 0.05%.

The obtained p valve 0.0010 found less the 0.05% is showing the significant for two failed student t test. The mean difference between the before and after pain scores related to Gabapentin+ Tolperisone was found to be 4.44.

Paired sample statistics: Tramadol and Tolperisone

Statistical evaluation for change in pain score for Tramadol and Tolperisone has been done with help of statistical to SPSS 20 .The statistical method used to find the p value and t value in paired t test with degree of freedom 24 at the level of significant 0.05%.

The obtained p valve 0.0002 found less the 0.05% is showing the significant for two failed student test. The mean difference between the before and after pain scores related to Tramadol+ Tolperisone was found to be 3.64.

Paired sample statistics: Tramadol and Etoricoxib

Statistical evaluation for change in pain score for Tramadol and Etoricoxib has been done with help of statistical to SPSS 20 .The statistical method used to find the p value and t value in paired t test with degree of freedom 24 at the level of significant 0.05%.

The obtained p valve 0.0005 found less the 0.05% is showing the significant for two failed student test. The mean difference between the before and after pain scores related to Tramadol+ Etoricoxib was found to be 3.84.

Based on the mean difference values of all the drug combinations the one with highest value is considered as more effective. The mean difference value of Gabapentin+ Tolperisone was found to be 4.4 and is highest among all the four combinations of drugs which are more effective.

Fig 1. Gender distribution of the patients

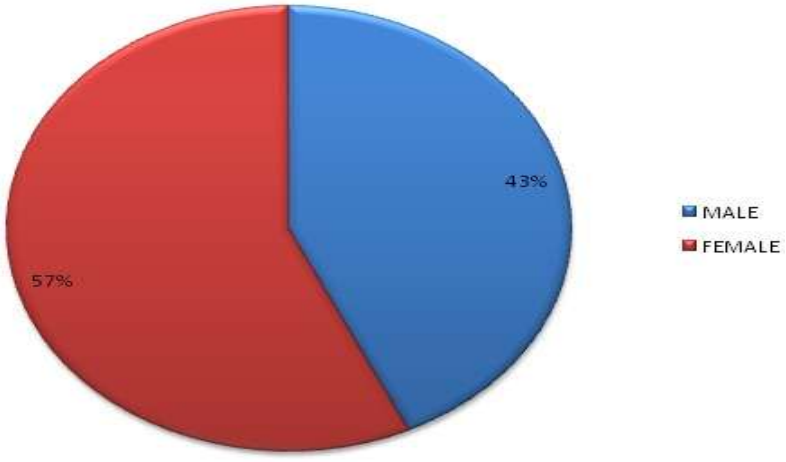

Table 1. Age distribution of the patients

S.No	Age (year)	No.of patients	Percentage (%)
1	20-29	12	12
2	30-39	24	24
3	40-49	30	30
4	50-59	24	24
5	60-69	6	6
6	70-79	4	4

Table 2: Patient distribution according to the treatment

S.NO	TREATMENT	MALES	FEMALES
1	Gabapentin+ Tolperisone	10	15
2	Gabapentin + Etoricoxib	12	13
3	Tramadol+ Tolperisone	11	14
4	Tramadol + Etoricoxib	11	14

Table 3. Comparision of efficacy of Gabapentin and Etoricoxib in terms of P value

	Mean	S D	Mean difference	Confidence interval	D F	T	*P*
Before	6.44	1.26	3.08	95%	24	-18.956	0.0001
After	3.36	0.81					

Table 4. Comparision of efficacy of Gabapentin and Tolperisone in terms of P value

	Mean	S D	Mean difference	Confidence interval	D F	T	*P*
Before	7.92	0.81	4.44	95%	24	-25.52	0.0010
After	3.48	0.59					

Table 5. Comparision of efficacy of Tramadol and Tolperisone in terms of P value

	Mean	S D	Mean difference	Confidence interval	D F	T	*P*
Before	7.56	1.04	3.64	95%	24	-21.157	0.0002
After	3.92	0.70					

Table 6. Comparision of efficacy of Tramadol and Etoricoxib in terms of P value

	Mean	S D	Mean difference	Confidence interval	D F	T	*P*
Before	7.84	0.85	3.84	95%	24	-24.00	0.0005
After	4	0.81					

Table 7. Statistical analysis of the drug combinations used in treatment of Chronic low back pain

S.NO	Treatment	Mean Difference	T value	*p* Value
1.	Gabapentin+ Etoricoxib	3.08	-18.956	<0.0001
2.	Gabapentin+ Tolperisone	4.44	-25.521	0.0010
3.	Tramadol+ Tolperisone	3.64	-21.157	0.0002
4.	Tramadol + Etoricoxib	3.84	-24.00	0.0005

DISCUSSION

The present study was carried out with 100 patients who were presented to Neurosurgery OPD of SVIMS hospital, Tirupati.

We have taken up this study as Chronic low back pain is the most common cause of disability in developing countries. Although there are many treatment options are available to treat this condition but there is limited evidence for perfect choice of drugs in treating this. This study is aimed at assessing the effectiveness of various drugs used in treating chronic low back pain.

Among the 100 patients studied we have observed that the incidence of low back pain in females (56%) is more when compared to males (44%). Our observation is consistent with those of other studies (Chronic pain in a geographically defined general population conducted by Andersson HI *et al*.,).

All the patients were grouped in to 4 types, i.e., GBN-NT+TLP, GBN -NT+ETR, TRM+TLP, TRM+ETR.

In our study, visual analog scale scores were 6.4(day 1) and 3.3(day 14) so they recommended Gabapentin is as effective as other drugs in treating chronic low back pain. Consistent to previous studies to assess the effectiveness of drugs in low back pain our study also concluded that Gabapentin is very effective in treatment of low back pain (Dr.James MC *et al*., 2016 to help regain and then maintain your quality of life, devoid of spine and extremity pain). Our research reflects on the fact that back pain has neuropathic components and that the nervous system is involved particularly when back pain turns chronic. The spinal nerves are affected. As with most pain intervention researches share the good and the bad on the positive side of the neuropathic pain relievers. Gabapentin was found to be fast and effective, visual analog scale scores were 9.3 (pre-treatment) dropping to 5(day 1) and 2-6 (day 7). So they recommended Gabapentin as the first line medication for pain in patients with specific neuropathic pain involvement.

The results of previous studies that assessed the effect of Tolperisone on treatment of low back pain was in support of our finding during the study (Tolperisone: A Typical Representative of a class of Centrally Acting Muscle Relaxants with Less Sedative Side Effects conducted by Stefan Quasthoff *et al*., Our study concluded that Tolperisone is effective in relieving low back pain and has less side effects.

The combination of Gabapentin+ Etoricoxib have also shown some effectiveness in treating chronic low back pain which is evidenced by the pain score values but less than that of Gabapentin + Tolperisone .But the prolonged usage of NSAID'S may cause epigastralgia when compared to other related studies like Pregabalin, Celecoxib and their combination for treatment of chronic low back pain conducted by Carlo LR *et al*., Included 42 patients and reported that 6 patients refused to continue the treatment with in first two weeks due to reported epigastralgia and/nausea.

In our study visual analog scale scores related to Opioids 7.9(day 1) and 5.4(day 14) and have shown a questionable effect in treating chronic low back pain when compared to other related studies like Opioids for chronic low back pain articles conducted by Amol D *et al*., in 2007 include 90% participants on average, those receiving tramadol an atypical weak Opioid reported on difference in pain relief and performing daily activity.

The results of previous studies that assessed the effect of Non steroidal anti inflammatory drugs in treating chronic low back pain in support of our finding the study Non steroidal anti inflammatory drugs for low back pain ; an updated Cochrane review conducted by Pepjin DDM, Roelofs., concluded that the evidence from the 65 trails included in this review suggests that NSAIDS are effective for short term pain relief but the effect sizes are small and should be given cautiously as they are associated with increased cardiovascular risks in specific population.

Tolperisone have shown more effect in treating the back pain when given in combination with Gabapentin. when compared to other studies like "Muscle relaxants for chronic low back pain conducted by Mauritis WVT *et al.*, concluded that Tolperisone is effective in treating chronic low back pain but should be

given cautiously if used for long term it can produce adverse effects relating to central nervous system.

The results previous studies like Ant neuropathic and Antinociceptive drugs combination in patients with chronic low back pain; a systematic review conducted by Carlo luca Romano, Delia R *et al*., suggested the use of combination therapy is more effective than immunotherapy as chronic low back pain involves both nociceptive and neuropathic pain .Therefore, an individualized, multimodal therapy, combining drugs with different mechanism of action represents a rational approach. In particular ,combination of Pregabalin and buprenorphine has be demonstrated to b more effective than either Monotherapies and relatively safe .This study supports our study in the aspects such as we included the combination therapy of Gabapentin and Tolperisone which is reported to be more effective decreasing both neuropathic and nociceptive pain respectively .

LIMITATIONS OF THE STUDY

- Less time period of the study (6 months).
- Small sample size (n=100)
- Limited interaction with the patients

SCOPE FOR FURTHER STUDY

A large scale study with greater sample size and longer duration can help in getting into a greater understanding about the best choice of drugs for treatment of lower back pain.

CONCLUSION

The study **"Prescription Medication Use among Adults with Chronic low back pain"** in patients presented to SVIMS hospital, Tirupati, Andhra Pradesh, India concludes that:

- Gabapentin+Tolperisone,Gabapentin+Etoricoxib,Tramadol+Tolperisone,Tramadol+Etoricoxib are effective in the management of chronic low back pain but Gabapentin+ Tolperisone are clinically more effective when compared to others.
- Gabapentin + Tolperisone achieve earlier reduction in the pain and improved the daily activities of the patient with minimal adverse effects.
- Hence we suggest that Gabapentin+ Tolperisone be used as an initial choice as pain reliever for Chronic low back pain because of its effectiveness and minimal toxicity.

ACKNOWDEGEMENT

None

CONFLICT OF INTEREST

None declared.

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