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Original Research Article

Study of utilisation pattern and adverse reaction monitoring of drugs used for relief of musculoskeletal pain in a tertiary care teaching hospital in Eastern Odisha

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ABSTRACT

Background: Musculoskeletal conditions are the most common cause of long-term pain and physical disability. The burden of musculoskeletal conditions is not only in terms of global numbers but also in terms of physical and psychosocial disability. Pain arising from musculoskeletal conditions of the major joints like back, neck, shoulder, knee or multi-site involvement results in diminished quality of life. Evidence for the effectiveness and safety of the various drugs used to alleviate MSP is uncertain.

Materials and Methods: The present study was an observational, cross-sectional study which included patients with complaints of musculoskeletal pain attending Regional Spine Injury Centre, S.C.B Medical College and Hospital. A total of 100 patients were included in the study. Demographic data of all the patients was collected and their level of significance in the causation of musculoskeletal pain was assessed. The prescription pattern of the drugs for musculoskeletal pain was analysed. All the patients taking the drugs were monitored for any adverse drug reaction and the same was documented.

Conclusion : Low back ache (28%) was the most common type of musculoskeletal pain observed. Aceclofenac was the most common analgesic prescribed, followed by paracetamol and etoricoxib. Aceclofenac and paracetamol was the most common combination used. Pain abdomen was the most common ADR encountered.

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1. Introduction

Musculoskeletal conditions are the most common cause of long-term pain and physical disability. They range from acute and short-lived conditions like fractures, sprains, strains to long-term debilitating conditions like chronic low back ache, osteoarthritis. They have diverse pathophysiology but are related anatomically. Musculoskeletal pain (MSP) may arise from the joints (osteoarthritis, spondylosis, rheumatoid arthritis), bones (fractures, osteoporosis) or muscles (neck and back pain,

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fibromyalgia). Low back pain is the most prevalent of musculoskeletal conditions and affects nearly everyone at some point of time. ¹ The burden of musculoskeletal conditions is not only in terms of global numbers but also in terms of physical and psychosocial disability it creates.

Pain is the most prominent symptom in most people and is the most important determinant of disability. Pain arising from musculoskeletal conditions of the major joints like back, neck, shoulder, knee or multi-site involvement results in diminished quality of life. ^{1,2} MSP is managed by a wide range of treatment options which include pharmacological, non-pharmacological approaches or a combination of both. Prognosis is often poor and may

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impact physical, psychological and socio-economic aspects when the pain is persistent or recurrent.³ Evidence for the effectiveness and safety of the various drugs used to alleviate MSP is uncertain.

An episode of acute musculoskeletal pain (duration less than 3 months) may resolve effectively with analgesics or may recur or change into chronic pain syndrome. Successful management of acute pain reduces the risk of its development into chronic pain. Non-steroidal anti-inflammatory drugs (NSAIDs) are mainstay in relief of pain of musculoskeletal origin. Without a doubt, they also comprise one of the largest group of pharmaceutical agents known to cause adverse reactions. Other drugs like opioids, corticosteroids are often used too. Due to the heterogeneity and diversity of the disease, it is important to manage MSP with a holistic approach.

There is lack of enough evidence as to what are the various drugs used for relief of MSP. Hence, this study aims to summarise the current pattern of various drugs used in the management of pain of musculoskeletal origin and response to it.

2. Materials and Methods

The present study was conducted with the aim to evaluate the current prescribing pattern for patients presenting with musculoskeletal pain to the Regional Spine Injury Centre in S.C.B Medical College and Hospital, Cuttack and to determine the various adverse drug reactions encountered. The study was carried out over a period of 18 months from January 2007 to June 2008.

The present study was an observational, cross-sectional study which included all the patients attending the OPD of Regional Spine Injury Centre with complaints of musculoskeletal pain. The subjects were explained the purpose of the study and an informed consent was taken prior. Patients who were terminally ill and unlikely to adhere to the study protocol were excluded.

Demographic data of all the patients was collected and their level of significance in the causation of musculoskeletal pain was assessed. The prescription pattern of the drugs for musculoskeletal pain was analysed. All the patients taking the drugs were monitored for any adverse drug reaction and the same was documented.

Ethical approval was taken from the institutional ethics committee prior to start of the study [IEC Ref no. 47/dated 18.11.2009].

3. Results and Discussion

A total of 100 patients suffering from musculoskeletal pain were included in the study, out of which 49(%) were males and 51(%) were females. Most of the patients belonged to 40-49 years (30%) and 50-59 years of age (30%). Males were in majority in all the age groups except in the two

categories, where females were predominant i.e. 63.3% and 56.7% in age group 40-49 years and 50-59 years respectively. Table 1. shows the age and gender distribution of the study participants.

Table 1 describes the type of pain encountered by the patients. It was considered as acute if the duration was less than 3 months and chronic if the duration was more than 3 months. 72% of total study participants suffered from chronic type of pain, among which 34 (47.2%) were males and 38 (52.8%) were females. On the contrary, among the 28% patients with acute pain, majority (53.6%) were males.

A previous injury to the muscles and bones can lead to the pain of musculoskeletal origin. Table 3 shows that only 14% of participants had an injury in past with male predominance.

Musculoskeletal pain is an umbrella term that includes all the pain originating from bones, joints, ligaments, tendons or muscles Table 4. shows the diverse range of ailments encountered among the study participants. Low back ache (28%) was the most common ailment with equal prevalence among men and women. Next in the row were cervical spondylosis (16%) and osteoarthritis where females were found to be majorly affected.

The approach towards treating a case of musculoskeletal pain could be pharmacological, non-pharmacological like physiotherapy, life-style modification or a combination of both. As evident from Table 5 all the acute cases needed pharmacological approach with or without others but not non-pharmacological approach alone. Few cases of chronic pain could be dealt with physiotherapy and appropriate lifestyle modification and counselling. Most frequent approach was a combination of both (86%).

The number of drugs prescribed per prescription varied from one to five. The average number of drugs prescribed was 2.8±0.16. Maximum number of prescriptions (42%) had 3 drugs.

Aceclofenac was the most common analgesic used, followed by paracetamol and etoricoxib. Aceclofenac and paracetamol was the most common combination used. There were many concomitant drugs used, most commonly the antacids, followed by micronutrients and muscle relaxants.

Depending on the severity of the pain, drugs were prescribed for different durations. Most of the people (69%) recovered with a treatment of 2 weeks or less. Only of 3% cases required a treatment lasting more than a month. Table 9 shows the adverse drug reaction seen in the study participants. 18.4% males and 11.8% females encountered adverse drug reactions. Most of the ADRs (53.3%) were found in the age group of 40-49 years.

The present study was conducted on 100 patients suffering from acute or chronic musculoskeletal pain. The prevalence was equivalent among middle-aged men and women (49% and 51% respectively). Others studies

Table 1: Demographic profile of the study participants

Age group (years)	Gender distribution (n=100)		Total (%)	Count within	p-value	
	M (%)	F (%)		\mathbf{M}	\mathbf{F}	
20-29	7 (14.3)	1 (1.96)	8	87.5	12.5	
30-39	6 (12.2)	5 (9.8)	11	54.5	45.5	
40-49	11 (22.5)	19 (37.3)	30	36.7	63.3	
50-59	13 (26.5)	17 (33.3)	30	43.3	56.7	
60-69	9 (18.4)	8 (15.7)	17	52.9	47.1	
>70	3 (6.1)	1 (1.96)	4	75	25	
Total	49	51	100			

Table 2: Duration of pain among the study participants

Duration of pain	Gender distribution (n=100)		Total (%)	Count within type of pain (%)		p-value
	M (%)	F (%)		M	\mathbf{F}	
Acute pain (< 3 months)	15 (30.6)	13 (25.5)	28	53.6	46.4	
Chronic pain (≥3 months)	34 (69.4)	38 (74.5)	72	47.2	52.8	
Total	49	51	100			

Table 3: History of injury among the study participants

History of injury	Gender distribution (n=100)		Total (%)	p-value
	M (%)	F (%)		
Present	10 (20.4)	4 (7.8)	14	
Absent	39 (79.6)	47 (92.1)	86	
Total	49	51	100	

 Table 4: Types of musculoskeletal pain encountered among the participants

Type of illness	Total (%)	M (%)	F (%)	p-value
Low back ache	28	14 (28.6)	14 (27.5)	
Cervical spondylosis	16	7 (14.3)	9 (17.7)	
Neck sprain	2	0	2 (3.9)	
Knee pain/ OA	13	3 (6.1)	10 (19.6)	
Traumatic causes	5	3 (6.1)	2 (3.9)	
PID	8	6 (12.2)	2 (3.9)	
Sciatica	2	2 (4.1)	0	
Hyperlordosis spine	1	1 (2)	0	
Trigger finger	1	0	1 (1.9)	
Fracture/ dislocation/ malunion	3	2 (4.1)	1 (1.9)	
Periarthritis shoulder	6	4 (8.2)	2 (3.9)	
Lumbar spondylosis	2	1 (2)	1 (1.9)	
Spondylolisthesis	1	0	1 (1.9)	
Ankylosing spondylitis	1	1 (2)	0	
Multiple site OA	11	5 (10.2)	6 (11.8)	
Total	100	49 (100)	51 (100)	

Table 5: Types of therapy prescribed

Duration of pain	Only pharmacological therapy	Only Non-pharmacological therapy	Both	Total (%)
Acute pain (< 3 months)	8 (28.6)	0	20 (71.4)	28
Chronic pain (≥3 months)	3 (4.2)	3 (4.2)	66 (91.7)	72
Total	11	3	86	100

Table 6: Number of drugs per prescription

Number of drugs per prescription	Frequency (%) (n=100)
None	3
One	1
Two	35
Three	42
Four	17
Five	2
Total	100

Table 7: Drugs used in the study population

Tuble 1. Brugs used in the study population	
Specific drug	Frequency (%) (n=100)
Aceclofenac	22
Paracetamol	13
Diclofenac	9
Etoricoxib	13
Etodolac	4
Piroxicam	3
Indomethacin	1
Ketoprofen	1
Aceclofenac + Paracetamol	20
Ibuprofen + Paracetamol	8
Diclofenac + Paracetamol	3
Tramadol + Paracetamol	12
Concomitant medications	Frequency (%) (n=100)
H ₂ antagonists/ PPIs	92
Muscle relaxants	44
Vitamins and Minerals	48
Diacerein	14
Serratiopeptidase	2
Glucosamine, Chondroitin SO4	15

Table 8: Duration of treatment

Duration (in days)	Frequency (%) (n=100)
<7	5
7-15	69
16-30	33
>30	3
Total	100

revealed female preponderance.^{4,5} However, a study done among various physicians showed male predominance with the mean age of 46 years.⁶ The mean age in a study by Perruccio et al⁵ was 51.9 years.

Chronic pain due to musculoskeletal conditions is a major social concern which significantly affects the day-to-day activities depending upon the pain duration, rhythm and affected sites. Most of the cases in the present study suffered from chronic pain which lasted for 3 months or more. In such a situation, a multimodal approach of treatment including both pharmacological and non-pharmacological modalities is more appropriate. In the present study, 92.1% of patients suffering from chronic pain were treated with dual modalities. Non-pharmacological therapies include lifestyle modification, cognitive behavioural therapy for

acupuncture, massage among others. The transition from acute to chronic pain is not well understood. 9

In the present study, pain around the lower back, neck and knee was most prevalent. Results were consistent with other studies where lower back ache was the most prevalent followed by pain around the neck, knee, shoulders ⁴ and upper back. ¹⁰

As per the guidelines by The American College of Physicians (ACP) and American Academy of Family Physicians (AAFP), patients with acute pain from non-low back musculoskeletal injury should be treated with topical non-steroidal anti-inflammatory drugs (NSAIDs) with or without menthol gel as first line therapy. Another recommendation (2a) was to use oral NSAIDs or oral acetaminophen. With rising cases of musculoskeletal pain

Table 9: Adverse drug reactions encountered

	ADR encountered
Gender	
Male	9 (18.4%)
Female	6 (11.8%)
Age group	
20-29	2 (13.3%)
30-39	0
40-49	8 (53.3%)
50-59	2 (13.3%)
60-69	2 (13.3%)
>70	1 (6.7%)
Types of ADR	
Loose motion	3
Head reeling	3
Pain abdomen	8
Vomiting	3
Loss of appetite	2
Fatigue	1

Table 10: ADR profile of various drugs used in MSP.

Specific drug	ADR reported					
	Loose motion	Head reeling	Pain abdomen	Vomiting	Loss of appetite	Fatigue
Aceclofenac			3			
Diclofenac			1			
Etoricoxib	1	1	1	1		1
Aceclofenac + Paracetamol	1		1		1	
Ibuprofen + Paracetamol			1			
Diclofenac + Paracetamol + Tramadol			1	1		
Diclofenac + Paracetamol		1		1	1	
Tramadol + Paracetamol	1	1				
Total	3	3	8	3	2	1

as per 2016 Global Burden of Disease data, ¹² NSAID use is evidently increasing and unavoidable. NSAIDs and opioids reduce pain in the short-term but their effect size is moderate.³ Owing to the potential for adverse effects, long- term use of both NSAIDs and opioids should be limited. ¹³ In 1986, the World Health Organization (WHO) published the pain ladder system. Since then, the ladder has guided clinicians all over the world in treating pain. ¹⁴ An updated WHO ladder, a four-steps ladder as opposed to the 1986 "ladder", reflects the advances in non-opioid modalities for achieving better pain relief. A systemic review by Babatunde et al was of the similar opinion that NSAIDs and opioids (where appropriate) offer short-term benefit with potential for adverse effects which needs careful consideration.³

According to WHO, musculoskeletal conditions are the leading contributor to disability worldwide and need for rehabilitation. ¹⁵ Although they encompass disorders with extensive variety and prognosis, together they pose a substantial burden on the patient, society and

healthcare system. Considering such heterogeneity, the treatment options may range from non-pharmacological conservative modalities (especially for chronic pain) to pharmacological drugs prescribed in an appropriate manner. With drug therapy, the associated risks are inevitable which mandates risk-benefit analysis before prescribing the drug. To conclude, curing and rehabilitating a case of musculoskeletal pain must be comprehensive i.e., it must include conservative approach, psychological support and counselling and pharmacological aid along with patient commitment.

4. Conclusion

Pain due to musculoskeletal conditions is a major social burden and diminishes the quality of life. Owing to the great heterogeneity of the condition, it is important to formulate a management, including both pharmacological and nonpharmacological approaches for better cure and improving the quality of life and productivity of the patients and society as a whole.

5. Conflict of Interest

None.

6. Source of Funding

None.

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