Assessment of Efficacy of OTC Medication in Pain Management on Musculoskeletal Disorders among Adults from Selected Rural areas of central Karnataka: A Pharmacoepidemiological Study

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Abstract- Background: Medicines are important for treating diseases and they are responsible for improving the populations QOL. People may well continue to use OTC medicines extensively and inappropriately to mask severe symptoms and maintain function in their daily lives. Indiscriminate use of OTC medicines might cause health risks and abuse of these medications is a national issue. Methodology: This was a Prospective observational study in which selection of subjects is based on random sampling method subjects of different rural areas are included. Informed consent form will be provided to subjects with a brief explanation about study and its importance in local language. P value less than 0.05 was considered as statistically significant. Results: A total of 103 subjects were enrolled on the basis of randomized sampling in the study. Analgesic OTC usage pattern was common issue in literates as well as lliterates, the patterns of usage of these medications were observed to be more in workers than non-workers. There is no relation between sleep and hangover with alcohol intake. But the hang over is due to only analgesic intake. 4 subjects associated with CV problems which may be attributed either to NSAID usage or other conditions. Conclusion: The study concludes that workers are more prone to use analgesic OTC medications. Even though there is an option of home remedy subjects are still relaying directly on medications. CV risks associated with NSAID medications have observed but there is no clear evidence.

Keywords- OTC, Analgesics, Patient Education, CV, NSAID, QOL.

I. INTRODUCTION

"The person who takes medicine must recover twice, once from the disease, and once from the medicine" —William Osler [1]

World Health Organization (WHO) defines self-medication (SM) is the selection and use of medicines to treat symptoms and self-reported diseases without the counseling of a qualified health professional for a certain function, comprising a stage of self-care. ^[2] The National Survey on Drug Use and Health (NSDUH) definesnon-medical use of prescription medications (NMUPM) as "use of at least one (prescription-type psychotherapeutic) without a prescription belonging to the respondent or use that occurred simply for the experience or feeling the drug caused". ^[3]

Medicines are important for treating diseases, and they are responsible for improving the population's quality of life. ^[4] People may well continue to use OTC medicines extensively and inappropriately to mask severe symptoms and maintain

function in their daily lives.^[5] However, indiscriminate use of medicines might cause health risks. ^[6] The practice of SM is worrisome because of the easy access to therapeutic products and potential damages to health caused by such practices. ^[3] The abuse of these medications is a national issue. ^[6]

SM is an important aspect in health-care delivery system especially in a developing country like India. Making the individuals responsible for their own health through health education and make them aware that professional care for minor ailments is not necessary are the keys that lead to this relatively newer concept. ^[7] The WHO promotes the practice of responsible SM so that patients can get desired benefits without overburdening the health-care delivery system especially in rural and remote areas. ^[8]

But SM can be described as a double-edged sword for its users, because it has both beneficial and harmful effects. SM has advantages like it facilitates better use of clinical skills,

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increases access to medication to the needy, and also to better utilization of funding in public health program. ^[4] However, there are potential risks of SM, *e.g.* incorrect self-diagnosis, delays in seeking medical advice when needed, severe adverse reactions, dangerous drug interactions, masking of a severe disease, risk of addiction, and abuse. ^[9] One benefit of SM may be the active role of the patient in his/her own health care. ^[10]

Therefore, it is suggested that the public has to be educated on the type of illnesses to be self-diagnosed and medicated, dangers of OTC on misuse which would possibly lead to delay in detection of more serious underlying ailment and timely medication. And also it is a known fact that clinical trials are done on healthy volunteers exceptional among special population (geriatrics, pediatrics, pregnant and lactating women).

It is requisite to accomplish an exploration on analgesic OTC usage pattern and creating awareness among rural areas in compliance with the above statements.

Section 1 Definition of Self medication.

Section2 about the OTC medicine usage.

Section 3,4&5 about self medication practices.

Section 6 issues related to self-medication.

Section 7&8 Importance of the study.

II. RELATED WORK

- In our study profoundly, literates 76 (73.7%) were more than illiterates 27 (26.3%), which was very similar to the study conducted by **Jain P** *et al.* ^[13] in which 70.8 % were literates and 29.2 % were illiterates.
- Response given by the subjects for the question asked "When do you feel to take OTC medication?" majority of subjects (70.9%) given response for moderate and severe pain. Similar study has conducted by **Manohar** *et al*; in which the maximum study (57%) subjects take medicines for body pain. ^[14]
- When the subjects have been asked "From where you get the source of information for OTC for pain management?" maximum subjects 68(66%) have given response "from neighbors" similar study has conducted by **Mohammed** *et al;* in which the subjects responded as from pharmacists 265(40.4%). [15]
- Among 103 study subjects, 53 subjects have procured medicines from provisional stores, 46 from pharmacy (medical) stores and 4 from friends and neighbors. Similar study conducted by **Haramiova H** et al; from pharmacy (50.4%) and from shopping centers (27.2%). [6] Of these, 25 subjects got information regarding medicines they procured from pharmacy and 15 from those who have procured from provisional stores respectively.
- When the subjects have been questioned "Have you felt anytime these symptoms after taking OTC medication?"

few subjects 4(2.9%) have given response "Cardiovascular (CV) problems", and maximum 27(26.2%) have given response as "abdominal pain". Similar study was conducted by **Nissen SE** *et al* in which they concluded that subjects aged ≥ 18 years with increased CV risk who required daily NSAID treatment due to pain from osteoarthritis and rheumatoid arthritis. [16]

• When the patients have been questioned "Anytime have you taken medication before or after taking alcohol?" 14(13.6%) subjects has response as "Yes" this will be the conclusive point for sleep and hang over. We concluded that there is no relation between sleep and hangover with alcohol intake. But the hang over is due to only medicine (Analgesic) intake. Similar study was conducted by **Heresh EV** *et al* [17]

III. METHODOLOGY

Study design: It is a prospective observational study.

Study site: The study was conducted in selected rural areas of central Karnataka.

Study period: The study was conducted over a period of three months from October 2017 to December 2017.

Study subjects: The study will include the subjects who matches the inclusion and exclusion criteria.

INCLUSION CRITERIA

- 1. Subjects who are between 25-65yrs age group
- 2. Both gender
- 3. Those diagnosed with or without musculoskeletal disorders.
- Those who are on prescribed as well as OTC medications.

EXCLUSION CRITERIA

- 1. Subjects who are not willing to participate in study
- 2. Pregnant and lactating women
- 3. Those who are on travelling jobs

Vide number: SJMCP/IEC/PHARM D/17-18 (ANNEXURE -1)

Sources of data:

- •Interaction with the subjects.
- Evaluation of questionnaires.

Study procedure

A three months prospective observational study was carried out in the selected rural areas of Chitradurga taluk. Selection of subjects is based on random sampling method in which the subjects of different rural areas are included. Informed consent form will be provided to subjects with a brief explanation about study and its importance in local language. A self-designed data collection form with a self-designed questionnaire is provided to obtain patient details.

Statistical analysis:

Descriptive statistics, Chi square test and Paired t-test was used for statistical significance. P value less than 0.05 was considered as statistically significant.

IV. DISCUSSION AND RESULTS

- Classification of the subjects is similar to the Marak et al [11]
- The categorization of age groups in our study was similar to **Meenambal S** *et al.* ^[12]
- Out of 103 subjects 49(47.5%) were males and 54(52.5%) wer females.
- Of this, 56(54.2%) were working and 47(45.8%) were non working.
- It was the first kind of study in which we categorized the
 occupational status of the subjects into working and nonworking, we have not come across the much similar
 studies which are related to this parameter for analgesic
 drug usage pattern.
- Similar study has conducted by **Manohar** *et al*; ^[14] in which the maximum study (57%) subjects take medicines for body pain the hang over is due to only medicine (Analgesic) intake. Similar study was conducted by **Heresh EV** *et al* ^[17]
- In our study, we found that most of the analgesic OTC
 users for pain management were workers. By conducting
 this study, we also concluded that even though there is
 add-on of non-pharmacological therapy but the subjects
 still relaying on medications (Pharmacological therapy).
- Time saving and heavy expenses (doctor fees, distance of the hospital,) are the main reasons for choosing on OTC medications.
- From our study we also concluded that 4 subjects associated with CV problems which may be attributed either to NSAID usage or other conditions.
- From present study we concluded that 7 subjects were found having hangover effect who have used single drug for their pain management. This hangover may be attributed to either NSAID (Which is new finding) or any antipsychotic medications. Also concluded that there is no relation between sleep and hangover with alcohol intake. But the hangover is due to only medicine (Analgesic) intake.
- In our study analgesic OTC usage pattern was common issue in literates as well as illiterates, this showed that health education is very important for all patients in community set ups and private clinics or so called trade clinics.
- Another important aspect regarding choosing OTC medication is clinician/physician/doctor/prescriber and patient ratio, shortage of trained health care professionals, limited role of clinical pharmacist.
- Apart from the above factors as the saying goes on "a pill for every ill" will lead to drug misuse and addiction

- especially in case of CNS acting (Narcotic) analgesics which shows its severe potential effects on the individuals.
- Subjects were educated regarding the effects of OTC medications and their usage pattern through structured counseling along with specially designed patient information leaflets.

ANSWERS GIVEN BY THE SUBJECTS FOR THE QUESTIONS ASKED:

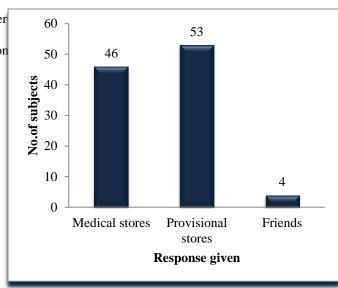


Fig. no 1: "From where do you take these medications?"

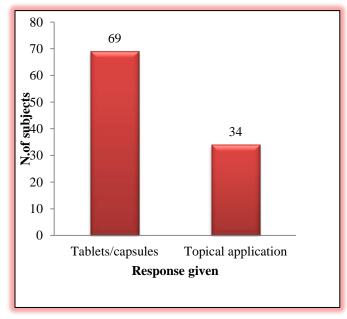


Fig no.2: "What type of OTC medication you prefer?"

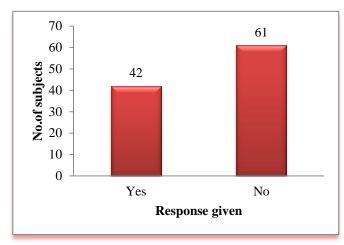


Fig.no 3: "Have your chemist /provisional stores person gave any suggestion regarding your medication?"

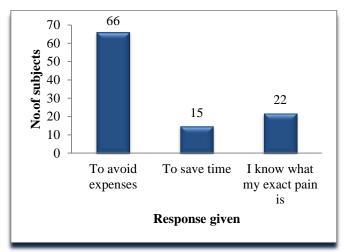


Fig.no 4: "What made you to take OTC medication for pain management?"

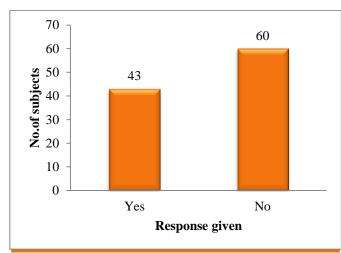


Fig.no 5: "Are you aware that apart from useful effects of OTC medication there are some side effects too?"

V. CONCLUSION & FUTURE SCOPE

- In our study, we found that most of the analgesic OTC users for pain management were workers. By conducting this study, we also concluded that even though there is add-on of non-pharmacological therapy but the subjects still relaying on medications (Pharmacological therapy).
- Time saving and heavy expenses (doctor fees, distance of the hospital,) are the main reasons for choosing on OTC medications.
- From our study we also concluded that 4 subjects associated with CV problems which may be attributed either to NSAID usage or other conditions.
- From present study we concluded that 7 subjects were found having hangover effect who have used single drug for their pain management. This hangover may be attributed to either NSAID (Which is new finding) or any antipsychotic medications. Also concluded that there is no relation between sleep and hangover with alcohol intake. But the hangover is due to only medicine (Analgesic) intake.
- ♣ In our study analgesic OTC usage pattern was common issue in literates as well as illiterates, this showed that health education is very important for all patients in community set ups and private clinics or so called trade clinics.
- ♣ Another important aspect regarding choosing OTC medication is clinician/physician/doctor/prescriber and patient ratio, shortage of trained health care professionals, limited role of clinical pharmacist.
- Apart from the above factors as the saying goes on "a pill for every ill" will lead to drug misuse and addiction especially in case of CNS acting (Narcotic) analgesics which shows its severe potential effects on the individuals.
- Study should extended to various class of drugs used for pain management among OTC medications.

FUTURE DIRECTIONS

- ♣ Prevalence of different types of musculoskeletal disorders should be studied.
- Telephonic conversations, community pharmacist, clinical pharmacist should play a major role in follow up of the patients.
- ♣ Study should be extended to geriatric populations (>65 yrs) which is very essential as the chances of misuse is high.
- ♣ Similar studies need to be carried out on pregnant woman's which will be very helpful.

LIMITATIONS

- ♣ The follow up and patient counseling for patients were limited to single time.
- The present study was qualitative study, whereas quantitative study may give more insight.

- In our study, Medication Adherence was judged on predictors but not on adherence scales related to clinical outcomes

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Dr. Ravi Chandra Yadav is currently working in IQVIA (clinical research). He has completed his Pharm D (2019) from Rajiv Gandhi University of health science, Bangalore. He has attended 67th Indian Pharmaceutical Congress held at Mysore (2015) 70th Indian Pharmaceutical



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