



USE OF NSAIDs AND PATIENT SAFETY

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ABSTRACT

OBJECTIVE To assess the pattern of use of non-steroidal anti-inflammatory drugs (NSAIDs) and propose methods whereby pharmacists can help to improve patient safety when these drugs are used.

METHOD A psychometrically-evaluated questionnaire was administered to 261 patients aged 18 and over who visited 13 different community pharmacies, 1 from each electoral district in Malta and Gozo, chosen by stratified random sampling. Information about the socio-demographic status, symptoms and disease states and the drugs taken in the past 6 months was collected. Analysis of data was carried out using Microsoft Office Excel 2007 and the Biomedical Data Package (BMDP) Software.

KEY FINDINGS Results show a high prevalence of analgesic (>80% per district) and NSAID use (about 50% per district). The first drug of choice to relieve analgesia was paracetamol (67.1%) followed by diclofenac (37.2%). Ibuprofen was the fourth drug of choice (7.3%). About 65% of patients who took diclofenac stated that they self-prescribe the medication. Statistical analysis of data showed an association between the use of NSAIDs, musculoskeletal pain and menstrual pain (both $p=0.010$). A number of patients at risk of gastro-intestinal bleeds, cardiovascular events and those suffering from asthma reported taking NSAIDs occasionally. The presence of risks of drug interactions was identified with various drugs.

CONCLUSION NSAIDs are overused in Malta and are often administered indiscriminately. Pharmacist intervention could ensure the rational and safe use of NSAIDs. This could be achieved by having a shared protocol between pharmacists and prescribers for appropriate prescribing and dispensing and by identifying scenarios where pharmacist prescribing can be carried out to ensure that the analgesic used is appropriate for the individual patient.

KEYWORDS NSAID use, patient safety, community pharmacists, physicians.

INTRODUCTION

Non-steroidal anti-inflammatory drugs (NSAIDs) are mostly used to relieve pain of musculoskeletal origin since they exhibit both analgesic and anti-inflammatory effect.¹ These drugs must be used with caution since they can cause serious adverse drug reactions that range from gastro-intestinal (GI) upsets and bleeding to cardiovascular events, damage to the kidneys and stroke.^{2,3,4,5} NSAIDs may interact with various other drugs including anticoagulants⁶, corticosteroids⁷ and selective serotonin reuptake inhibitors⁸ where in all these cases the risk of GI bleeding increases. They also reduce the effect of antihypertensive drugs since they can cause fluid retention.⁹ Patients on angiotensin-converting enzyme inhibitors will be at a greater risk of kidney damage¹⁰ if they take NSAIDs concurrently.

Various NSAIDs are available in Malta; however no national statistics exist on the actual quantities of different NSAIDs imported locally. No protocols on the use of NSAIDs in specific patients are established in primary care.

The aims of this study were to assess the pattern of NSAID use in the community pharmacy setting, to identify gaps leading to improper use of these drugs and to propose measures to help improve patient safety in relation to NSAIDs administration.

METHOD

The study was approved by the University Research Ethics Committee. An extensive literature review on the use and safety of NSAIDs was undertaken. A questionnaire was formulated, adapted from similar work done in Italy in 2004.¹¹ The developed questionnaire was divided into 3 parts; socio-demographic information, symptoms suffered from over the past 6 months and drugs taken over the past 6 months, including corresponding information on these drugs, for example the route of administration, reasons for which the drugs in question were taken, interval and frequency of drug intake and the source of prescription. The questionnaire was validated and tested for reliability by statistical 'Kappa Testing'. The questionnaire was delivered in the form of an interview. An 'Inter-Rater Kappa Test' was performed to ensure that no bias was introduced by the interviewer during the interview.

The setting involved 13 pharmacies, 1 from each electoral district in Malta and Gozo chosen by stratified random, sampling. One afternoon was spent in each pharmacy to carry out the interviews. Subjects were recruited on a voluntary basis and with their informed consent. The collection of data was confidential and anonymous. Analysis of data was carried out using Microsoft Office Excel 2007 and the Biomedical Data Package (BMDP). Safe use of NSAIDs were identified from the reviewed literature.^{1,2,12,13}

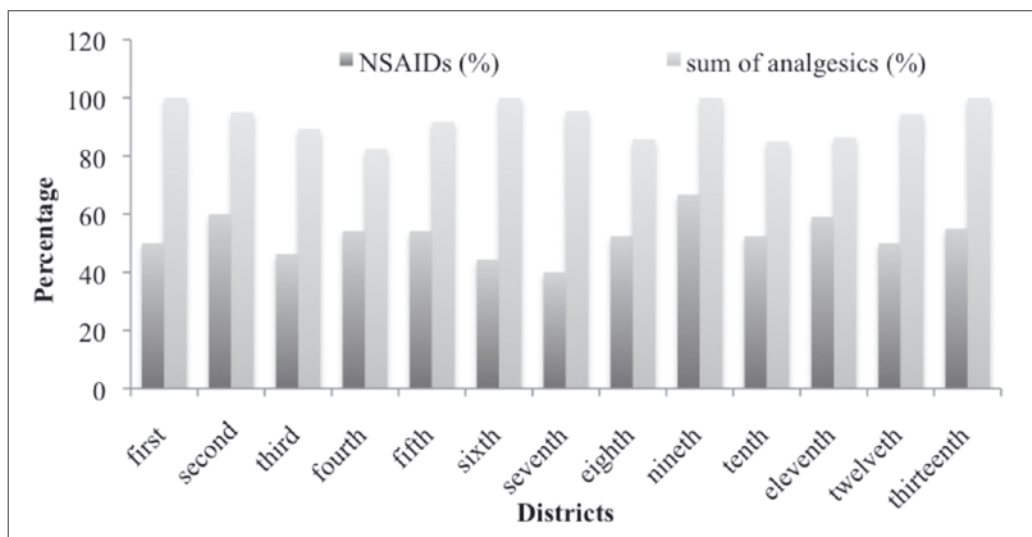


Figure 1: Frequency of different analgesics used by patients by district over the past six months (n=261)

RESULTS

A total of 261 questionnaires were collected. Seventy one percent (n=186) of the respondents were female. The average age was 48 years and the range was 18-79 years. Both Kappa tests performed gave values of over 0.75 indicating reliability of the questionnaire.

Results show that during the study period, more than 80% (n=241) of patients per district had used analgesics for the past 6 months and about 50% (n=131) of these patients had been using NSAIDs (Figure 1).

About 78% of the NSAID users reported taking the drugs for over 6 months, 55% of these stated that they take the drugs

every now and then and 65% stated that when they do take NSAIDs they take them only for a day or two.

Looking at the prevalence of NSAID use it was found that 9% more females than males make use of NSAIDs. It was established that 11% more of the younger generation administer NSAIDs when compared to the elderly. Both these facts were also reported in the Italian survey.¹¹

When ranking analgesic use (Figure 2) it was found that the first drug of choice as an analgesic was paracetamol with a frequency of 67% (n=175), followed by diclofenac with 37% (n=97).

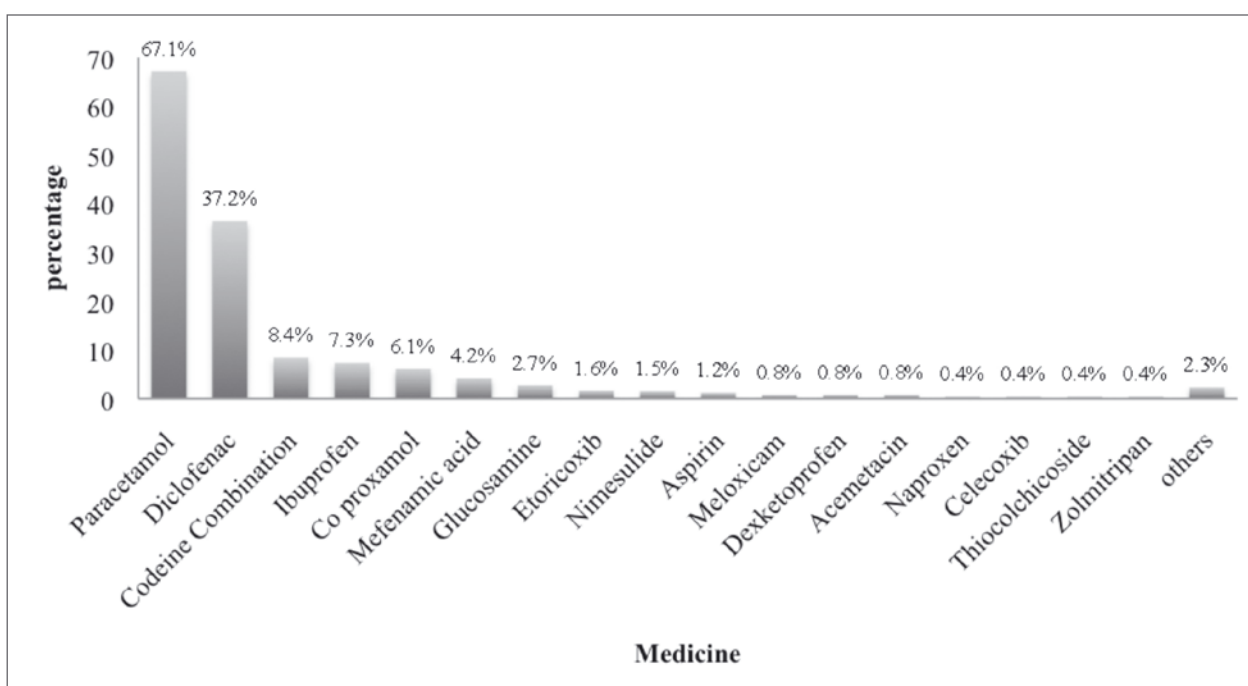


Figure 2: Ranking list of analgesics used in the study (n=261)

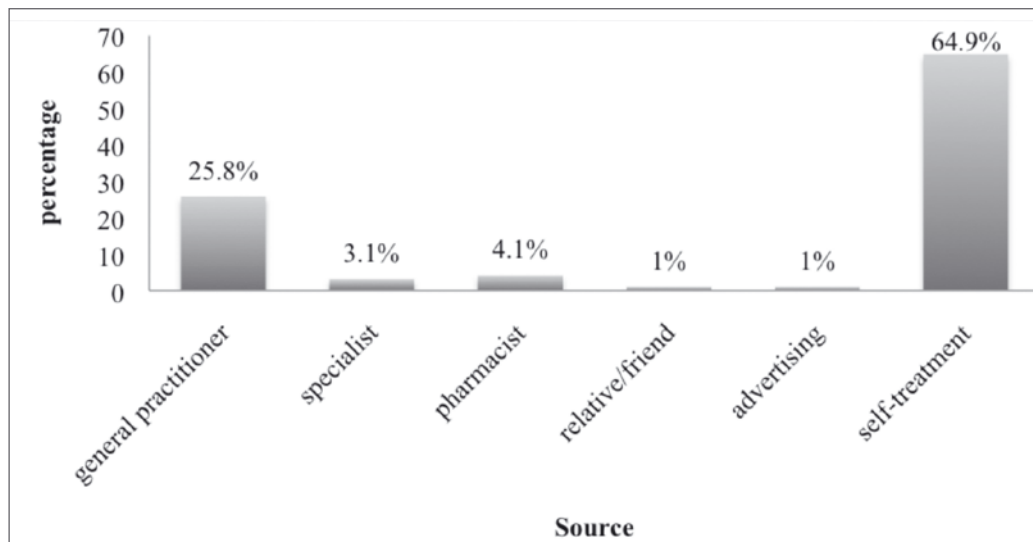


Figure 3: Source of diclofenac prescription and advice (n=97)

Ibuprofen was the fourth commonly used drug with 7% (n=19), aspirin was the tenth commonly used drug with 1% (n=3) and naproxen ranked in the fourteenth place with 0.4% (n=1). About 65% (n=63) of patients taking diclofenac admitted to self-prescribe the drug (Figure 3).

A statistically significant association was found between the use of NSAIDs and musculo-skeletal pain and the use of NSAIDs and menstrual pain (both $p=0.010$). Patients reported using NSAIDs mainly to treat back pain, sciatica, joint pain and menstrual pain.

Results show that 52% (n=34) of the patients suffering from GI symptoms, 47% (n=50) of the patients suffering from cardiovascular disorders, 35% (n=8) of the patients exhibiting respiratory disturbances and 43% (9) of those with diabetes reported taking NSAIDs. Risk of drug interactions was encountered in patients taking: anti-thrombotics (50%, n=12), the anti-hypertensive drugs including beta blockers, calcium channel blockers and alpha-adrenergic blockers (45%, n=17), diuretics (44%, n=14), angiotensin converting enzyme inhibitors (38%, n=19) and neuroleptics (50%, n=10).

DISCUSSION

This study shows that the overall use of NSAIDs in Malta (50.2%) is nearly double the usage reported in the Italian study (23.1%). Chronic NSAID use, that is daily use of NSAIDs for 4 weeks or more, is similar in Italy (4.2%) and in Malta (5%). Locally, NSAIDs are being used frequently but for short periods of time.

In other studies ibuprofen and aspirin are the most commonly used NSAIDs.^{11,14,15} The difference could be attributed to the lack of protocols for NSAID use in Malta. Naproxen, which according to the British National Formulary (BNF)¹ is "one of the first choices as an NSAID because it combines good efficacy with a low incidence of side-effects" has shown very low frequency of use. Most patients self-prescribe the drugs and this indicates the need for framework where pharmacists can undertake prescribing activity so as to guide patients to more rationale options of therapy.

The study indicates that the female population administer more NSAIDs compared to males. Reasons for this could be since females are more prone to conditions for which NSAIDs are indicated such as osteoarthritis, rheumatoid arthritis, dysmenorrhea and menorrhagia.

NSAID use among the younger generation was higher compared to the elderly. One reason for this could be that young people resort immediately to medication that relieves pain fast. Moreover, they may have a lower tolerance to pain. The responsibility of a pharmacist in such circumstances is to recommend non-pharmacological treatment to control pain before resorting to any medications and to remind them that whenever they do self-administer a medicine they should first read the patient information leaflet.

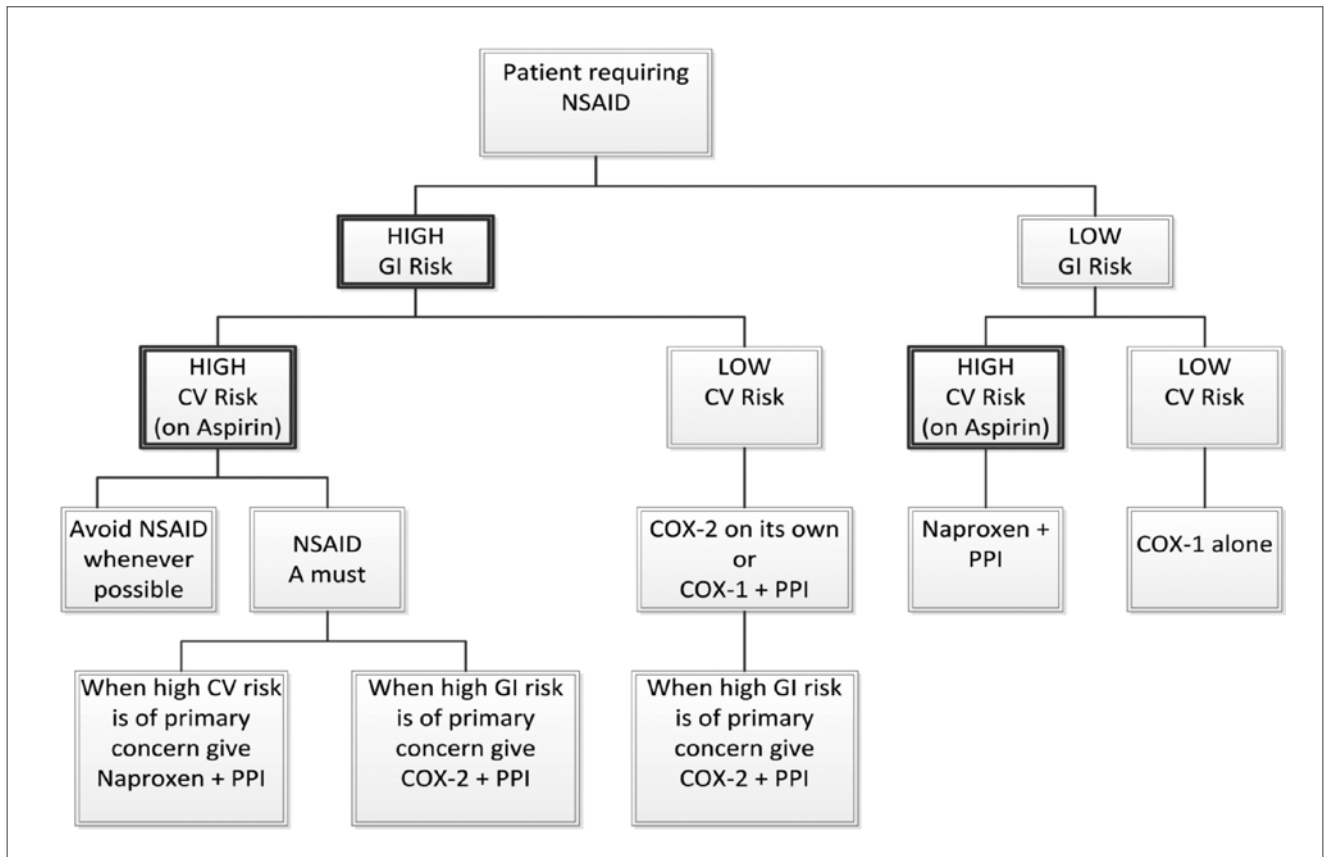


Figure 4: Protocol for NSAID use (Adapted from the Canadian Association of Gastroenterology: Rostom et al, 2009)

This study has shown that the Maltese public are using NSAIDs for their appropriate indications. Yet, there is a high prevalence of NSAID use by patients whose co-morbidities entail caution in the administration of this drug class. Various possibilities of drug interactions were identified indicating that patients need to be better advised about the use of their medication by physicians and pharmacists.

To enhance patient safety with regards to NSAID administration, this study proposes the use of a protocol based on a protocol developed by the Canadian Association of Gastroenterology.⁹ This protocol includes recommendations about the use of different NSAIDs depending on the presence or absence of GI and cardiovascular risk factors (Figure 4).

The introduction of a pharmacist prescribing scheme, which could be initiated within a supplementary prescriber model, is suggested wherein doctors and pharmacists work in voluntary partnership to ensure that medicines are being administered properly and safely to all patients.¹⁶

CONCLUSION

This study has shown that although NSAIDs are used for a short timeframe, they are still being overused by the Maltese general population. More advice is required regarding rationale use, cautions and interactions. To rectify such a situation this study is proposing the introduction of a protocol for the dispensing and prescribing of this class of drugs and the possibility of introducing a pharmacist prescribing scheme where physicians and pharmacists work in collaboration to ensure optimisation of the risk/benefit ratio of these drugs in each individual patient.



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