Non-steroidal anti-inflammatory drugs in general practice: a decision-making dilemma

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ABSTRACT

Objectives: To examine the effect of the debate on the safety of non-steroidal anti-inflammatory drugs (NSAIDs) on decision making by Australian general practitioners and patients with osteoarthritis (OA), and to explore issues concerning the use of NSAIDs from both prescriber and consumer perspectives.

Design and setting: A qualitative study in which five focus groups (three for GPs, and two for patients with OA) were conducted between 15 May and 4 August 2006 in south-western Sydney.

Participants: Five advanced general practice registrars, six experienced GPs, and 20 patients with OA aged 54–85 years.

Main outcome measures: Key themes and issues identified by content analysis of focus group transcripts.

Results: GPs reported adopting a cautious approach to prescribing NSAIDs because of uncertainty about safety and medicolegal concerns. They were sceptical about information provided by the pharmaceutical industry and found the literature about the safety of NSAIDs confusing. Time was identified as a major barrier to adequate discussion with patients, and explaining the risk to patients in a meaningful way was perceived as a challenge. Patients wanted information and sought it from a range of sources, most commonly pharmacists and GPs. Most patients made active decisions about using or not using NSAIDs, with some favouring physical function over safety. Patients were also using other forms of treatment including alternative medicine.

Conclusion: Our findings reflect the need to provide clear, unbiased information about NSAIDs to help both GPs and patients negotiate this decision-making dilemma.

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Osteoarthritis (OA) is a chronic condition that affects 1.6 million Australians (7.8% of the population), and with ageing, this is expected to rise to 2.3 million (9.8%) by 2020.[1] Non-steroidal anti-inflammatory drugs (NSAIDs) are one of the commonest pharmacological treatments for OA prescribed in general practice. NSAIDs have been the subject of recent controversy following the worldwide withdrawal of rofecoxib, a cyclooxygenase-2-selective NSAID (COX-2 inhibitor), in September 2004.[2-5] This has generated concerns about the cardiovascular safety of all NSAIDs, and COX-2 inhibitors in particular.

In light of multifaceted evidence and a growing literature on the risks of NSAIDs,[6-8] safety concerns, and patients' wishes and expectations, general practitioners are challenged by the clinical decision making involved with prescribing NSAIDs for patients with OA.

In this descriptive study, we aimed to examine the effect of the safety debate on decision making by Australian GPs and patients with OA about the use of NSAIDs, and to explore issues concerning the use of these drugs from the perspective of both prescribers and consumers.

METHODS

We used a qualitative design based on focus groups.[9]

Three groups of participants were recruited, as described.

- Advanced general practice registrars, with less than a year of general practice experience and who were training with the Institute of General Practice Education, were invited by announcements at educational activities.
- Experienced GPs, with 3 to over 30 years' experience and working in training group practices in south-western Sydney, were invited by phone and/or letters.
- Patients with OA aged 18 years or older who were on the joint replacement surgery waiting lists (for shoulder, knee or hip replacements) at Whitlam Joint Replacement Centre, Fairfield Hospital, were invited by letter.

To ensure a range of general practice experience, maximum variation sampling[10] was used to select GP participants, while participating patients were purposefully selected for their extensive personal experience of using a wide range of therapies, including NSAIDs, to treat their OA (key informant sample[10]). There was no clinical relationship between participating patients and the researchers.

Data collection and analysis

The focus groups were run between 15 May and 4 August 2006, and were audiotaped and transcribed. Each one lasted for an hour and was facilitated by two investigators, one of whom collected field notes. Field notes were used to triangulate findings and ensure accuracy and completeness of transcripts. Topic guides were used to facilitate discussion in the doctor (Box 1) and patient (Box 2) focus groups.

A qualitative content analysis[11] was undertaken to identify and explore key themes arising from the discussions. Each transcript was independently manually coded by three of us (S S M, N A Z and S V). We then discussed similarities and differences in key themes, leading to a more complete and reflexive understanding of the factors involved. Based on the analysis of the first focus group, field notes and early discussions, a coding framework was developed to guide the analysis of subsequent transcripts. This framework was revisited in an iterative manner during the analysis process, with new themes added and existing ones amended. No new themes emerged after five focus groups had been conducted (three for GPs, and two for patients).

The Sydney South West Area Health Service Human Research Ethics Committee approved this study.

RESULTS

Eleven GPs (five registrars, six experienced GPs) participated in one of three doctors' focus groups, and 20 patients with OA (age range, 54–85 years; 10 women) participated in one of two patients' focus groups.

Themes identified in GP focus groups

While we assumed that diverse general practice experience could affect the views of GP

1 Topic guide for doctors' focus groups

- Since the withdrawal of Vioxx in September 2004, non-steroidal anti-inflammatory drugs (NSAIDs) and cyclooxygenase-2 (COX-2) inhibitors have been subjects of rigorous debate as a result of concerns about their safety as a drug class.
  - ➢ What are your views about this debate?
  - ➢ Did this impact on your management of osteoarthritis (OA) and your prescribing of NSAIDs and COX-2 inhibitors, and how?
- What are the factors that influence your decision-making process when considering NSAIDs or COX-2 inhibitors for patients with OA?
- What do you see as the expectations of your patients in regard to the use of NSAIDs?
- Given the current state of knowledge about NSAIDs as a drug class, how do you discuss with patients who have OA the benefits and risks of NSAIDs in treating their condition? ◆

2 Topic guide for the patients' focus groups

Non-steroidal anti-inflammatory drugs (NSAIDs) are commonly prescribed by general practitioners to treat your kind of arthritis. These medications include things like Nurofen, Voltaren, Celebrex, Mobic (and, previously, Vioxx). Most people taking these agents will not come to any harm, and they frequently provide relief of arthritis symptoms. However, the NSAID class of drugs has been a subject of recent debate because of safety concerns, particularly after the withdrawal of Vioxx in 2004 as a result of proven harmful side effects of the drug.

- Have you heard about these safety concerns?
  - ➢ What/who were your sources of this information?
  - ➢ What are your views on this debate?
  - ➢ Has this raised any concerns about the medications you receive for your arthritis? Explain.
- What are your experiences (including type and dosage) of medications for treatment of arthritis?
  - ➢ Has this debate affected your choice of treatment for your arthritis? Explain.
- Have you discussed your concerns about your treatment with your GP or another health care professional, such as a pharmacist?
  - ➢ What are your experiences of discussing these issues with your doctor?
- What are your expectations of your GP in managing your arthritis, in view of what you know or what you have heard about this class of medications? ◆

participants (thus the decision for maximum variation sampling), we were surprised by the commonality of their experiences and views.

Uncertainty: Uncertainty about the safe use of NSAIDs in general, and COX-2 inhibitors in particular, was evident across all three GP focus groups, regardless of years of experience.

> We are dealing with the uncertainty still, trying hard to keep the patients informed, but there is a lot that we don't know. (GP, 30 years' experience)

The medical literature debating the safety of NSAIDs and COX-2 inhibitors was described as confusing and difficult to interpret and apply.

> Which article is reliable? (GP, 3 years' experience)

Scepticism: Scepticism about medical information provided by some sources, particularly the pharmaceutical industry, was prominent.

> Drug reps promote studies that support their product. Some of them are biased but some are quite reasonable. (GP, 3 years' experience)

The reliability of advice from specialists, and talks by expert opinion leaders, particularly if sponsored by a drug company, was also questioned.

> Talks from experts can be very convincing, but I frequently find that the spokesperson is sponsored by the drug company. So I listen carefully to what they say; and unless they present evidence strong enough to change my views about my current treatment choices then I won't. (GP, more than 30 years' experience)

Safety concerns: All participants were very concerned about safe practice to ensure patients' wellbeing and protect against medicolegal liability.

> We reacted partly because of the safety concerns and partly because of medicolegal reasons. (GP, more than 30 years' experience)

Patients' acceptance of the risk was important in GPs' decisions to prescribe NSAIDs.

> People keep coming and asking for them [NSAIDs] despite knowing the risks, which makes you feel that you can accept the risk because patients do. (GP, 25 years' experience)

Impact on current management of OA: There was increased use of other pharmacological (eg, paracetamol) and non-pharmacological (eg, physiotherapy) alternatives for managing OA. Some GPs reported that patients themselves prefer these alternatives as an initial therapy.

> Now, more alternative medicine is used as first-line therapy, and that's the change in strategy. The patients themselves nowadays prefer more natural treatments. (GP, more than 30 years' experience)

Caution in prescribing NSAIDs: Uncertainty and safety concerns led to a cautious approach in prescribing NSAIDs. This involved prescribing the lowest effective dose, short-term use, shorter intervals between follow-up of patients, recommending breaks in taking NSAIDs, and use of other therapies.

> I am certainly more cautious about not prescribing them [NSAIDs] on a long-term basis, and I encourage patients to have breaks in between. (GP, 25 years' experience)

The decision to prescribe NSAIDs is complex, with patient-related issues being the most influential factor. The decision-making process involves balancing potential benefits and potential side effects of precribing NSAIDs.

> I think one has to balance the quality of life at one end as opposed to side effects, and, more importantly, the other medical conditions that interact with the drug that one prescribes. (GP, 3 years' experience)

Impact on the consultation: The NSAIDs safety debate has generated more dialogue between doctors and patients. There was consensus that patients sought more information, particularly in response to media reports.

> We're more cautious and more communicative about it. (GP, 30 years' experience)

Time was identified as a major barrier to providing sufficient information to patients.

> Time is always an issue. (All participants except one experienced GP)

Strategies identified for managing time pressures included: tailoring the information to the patient's clinical presentation, perception and interest in decision making; and providing the essential information in

the first consultation and the rest in follow-up sessions.

> I tell the patients the essential things first and ask them to return in 2 weeks to see how they are going with the medication. This seems to be an incentive for them to return and a good opportunity for me to discuss the other issues. (GP, 25 years' experience)

Presenting the risk in a patient-friendly way was perceived as a challenge.

> The real challenge is to describe the risk in a meaningful way to the patient. (GP, 30 years' experience)

Patients' expectations from the doctors' perspective: The general perception was that patients expected doctors to prescribe a safe and effective drug, with regular monitoring for side effects, and to provide essential information.

> They expect you to take responsibility for giving them a safe drug that would make them feel better. (GP, 25 years' experience)
>
> Patients do expect you to properly discuss risk/benefit stuff. (GP, 30 years' experience)

Themes identified in patients' focus groups

Insightfulness: All patients were aware that OA had no cure, and that all treatments were mainly for symptoms. While most were quite well informed, one patient had no knowledge of the side effects of NSAIDs and the safety concerns. Nonetheless, they all acknowledged that no drug is 100% safe.

> We know there is no cure for osteoarthritis. Just take what helps the pain; it's going to be a pain-killing procedure all the time. (Man, aged 78 years)
>
> I haven't heard about these safety concerns. I just take what the doctor gives me. (Woman, aged 58 years)

Dealing with the pain of OA: Most patients had tried various NSAIDs and other treatments, such as paracetamol, cortisone injections, herbal remedies and diets, with varying degrees of success.

> I've been on four different types [of NSAIDs] over 16 years. My doctor took me off Vioxx and put me on Celebrex, and to be perfectly honest, I don't know how bad the pain would be if I didn't take the Celebrex. I just take them every morning. (Man, aged 78 years)
>
> Anti-inflammatories don't stop the pain, they just make it better. (Woman, aged 67 years)

Many used glucosamine without noticeable benefit. Duration of use varied between 3 months and 2 years.

> Glucosamine makes no difference. (Woman, aged 85 years)

Importance of function and risk taking: Function was unanimously stated as a very important factor in their choice of treatment.

> Mobility is the most important factor. There's no point in being a cripple. (Man, aged 63 years)

While some were willing to take risks for the benefit of function, others preferred relatively safer treatments.

> Every medicine has side effects. You've got to weigh up whether it's worth taking that little bit of risk to make the pain all right. (Man, aged 78 years)

Need for information: Patients actively sought information from various sources, including GPs, pharmacists, medical books, consumer medicine information (CMI) leaflets, the Internet and the media. Although pharmacists were perceived as reliable sources of information, sometimes in preference to doctors, patients were displeased at the variability of the provision of CMI leaflets from pharmacies. Despite satisfaction of most with their GPs, some patients complained that their GPs did not provide them with enough information.

> The doctor doesn't have the time to tell you. Sometimes, you're better off asking the chemist. (Woman, aged 85 years)
>
> Doctors are telling you more if you ask them. But you have to ask them. (Man, aged 72 years)

Patients' expectations of their GPs: Despite recognition that the doctors themselves were dealing with a decision-making dilemma, patients wanted the GPs to be more attentive, providing more care and information.

> Constant appraisal of what your ailment is and regular follow-up of how it's going. (Man, aged 73 years)

DISCUSSION

Early large-scale adoption of COX-2 inhibitors by Australian GPs has been criticised as not being in accord with quality use of medicines principles.[12] The withdrawal of rofecoxib, and the studies questioning the safety of NSAIDs in general and COX-2 inhibitors in particular,[2-8] have affected GPs' prescribing patterns. To our knowledge, ours is the first Australian study to examine the reasons behind this change in prescribing. It not only provides insights into the responses of GPs and patients to the recent controversy over NSAIDs, but also into how complex issues such as interpretation of risk and management of uncertainty are communicated and negotiated in general practice.

Confusion about the debate on the safety of NSAIDs in the medical literature caused uncertainty and medicolegal concerns among the GPs. They questioned the reliability and applicability of the peer-reviewed literature, and were sceptical about information provided by the pharmaceutical industry. Previous research examining the influence of specialists' recommendations on GPs' prescribing decisions has shown that specialists, particularly if hospital-based, can be influential opinion leaders.[13-16] However, the GPs in our study received advice and recommendations from specialists cautiously, particularly if they were thought to be influenced by the pharmaceutical industry.

The NSAIDs safety debate has created more dialogue between doctors and patients. While some patients took a passive role in decision making, others took more active roles.[17-19] As in other studies,[20,21] time was a major barrier to providing adequate information to patients, and presenting the information meaningfully was perceived as a challenge. Patients' acceptance of the risk was an important factor in GP's decisions to prescribe NSAIDs. Practical tools, such as graphical aids developed by an unbiased source, might help GPs convey complex information to patients in a meaningful way and assist informed decision making.

Patients wanted information and sought it from a range of sources, most commonly pharmacists and GPs. That some pharmacists did not provide CMI leaflets was a problem for patients who relied on this in the absence of sufficient information from GPs. As it did with participating GPs, the NSAIDs controversy increased patients' preference for alternative pharmacological and non-pharmacological therapies. In support of a recent study,[22] this reluctance of prescribers and consumers to use NSAIDs in preference to safer alternatives highlights the need to develop safer medicines and

further evaluate these preferred alternative treatments. Although many of the patients in our study used glucosamine, none of them found it effective. Meta-analyses of glucosamine studies have raised doubts about its efficacy.[23,24]

Two previous reports concluded that patients were not knowledgeable enough to make informed choices about their treatment for OA.[19,25] One reported that, if given the choice, all patients would prefer a safer albeit less effective option.[25] In contrast, our study found that most of the participating patients made an active choice about using or not using NSAIDs, based on the information available to them, with some favouring their continuing ability to function over safety.

The results of our study should be interpreted within the context of it being small and descriptive. Despite using maximum variation sampling to select a broad range of experience across GP participants, our analysis indicated a commonality of perspectives. Given that participating GPs came from training practices, including GPs from non-training practices may have enhanced the study. It is also noteworthy that, while no new themes emerged by the third GP focus group, it is possible that the sample selected represented a specific point of view. The study may have also benefited from including pharmacists, who are likely to add another perspective to this debate.

Controversies over the safety of medicines, like the NSAIDs safety debate, lead to prescribing dilemmas. Despite the efforts of organisations such as the National Prescribing Service to provide resources to help prescribers, our findings suggest that clear, unbiased information is still needed for both GPs and patients. Our findings also reflect the need for simple tools that help GPs deliver complex information to patients in a meaningful way. Further research into the effectiveness of information and tools provided to prescribers and patients is needed.

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COMPETING INTERESTS

Richard Day has received fees for being a speaker at drug company-sponsored educational meetings. He is or has been a member of advisory boards for NSAIDs (Merck Sharpe & Dohme, Pfizer, Novartis, Boots, GlaxoSmithKline Consumer, AstraZeneca) and is a member of the advisory board to sponsors for adalimumab, infliximab, and anakinra in Australia. The St Vincent's Hospital Clinical Trials Unit, with Richard Day as chief investigator, has also been contracted to undertake clinical trials of NSAIDs, COX-2 inhibitors, etanercept, infliximab, adalimumab, and anakinra. Recompense for these activities is placed in audited hospital trust funds for use in the research activities of the Clinical Pharmacology Department, St Vincent's Hospital, Sydney.

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