

Patterns of Use and Public Perception of Over-the-Counter Pain Relievers: Focus on Nonsteroidal Antiinflammatory Drugs

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ABSTRACT. Objective. To assess the frequency and indications for over-the-counter (OTC) nonsteroidal antiinflammatory drug (NSAID) use and to what degree the public is aware of their side effects.

Methods. Two surveys totaling 9062 respondents were performed of the American public. The Roper survey, conducted in 1997, and the National Consumers League (NCL) survey, conducted in December 2002, were intended primarily to assess the public's use of and attitudes toward NSAID and OTC analgesics.

Results. Ibuprofen based drugs were the most frequently used OTC in both surveys (57% Roper, 33% NCL). In the Roper survey, 17% of respondents used NSAID, with 38% using both prescription and OTC. Forty-six percent of exclusive OTC users believed OTC were safer, while 56% of exclusive users of prescription NSAID believed they were safer. Sixty percent and 29% of exclusive OTC users were neither aware of nor believed they were at risk for side effects from NSAID, respectively. Twenty-six percent of respondents used more than the recommended dose on the label, while 22% believed warning symptoms would always precede any NSAID induced complications. In the NCL survey, 83% had used an OTC agent in the last year, with 15% reporting daily use, and 49% were not concerned about potential side effects. In this survey, 30% believed there was less risk with OTC analgesics, and 44% consumed more than the recommended dosage on the label.

Conclusion. OTC analgesics including NSAID are widely used, are frequently taken inappropriately and potentially dangerously, and users are generally unaware of the potential for adverse side effects. Educational intervention directed toward both patients and physicians appears warranted. (J Rheumatol 2005;32:2218–24)

Key Indexing Terms:

NONSTEROIDAL ANTIINFLAMMATORY DRUGS
PAIN RELIEVERS

OVER THE COUNTER DRUGS
ACETAMINOPHEN

Nonsteroidal antiinflammatory drugs (NSAID) are one of the most commonly used classes of medications. Prescriptions for generic ibuprofen and naproxen exceeded 500 million in each of the last 2 years; over 45 million prescriptions were written for cyclooxygenase-2 (COX 2) inhibitors in 2000, and in 2003, almost \$4 billion was spent on COX-2 agents alone¹⁻³. Gastrointestinal (GI) toxicities from NSAID, both over-the-counter (OTC) and prescription, continue to be reported⁴⁻¹⁰, increasingly in conjunction

with cardiovascular, hepatic, and renal complications^{11,12}. Despite the widespread use of OTC NSAID, there is little information on the characteristics of the population that use OTC and their attitudes toward an understanding of these drugs and their potential toxicity. Knowledge of such public attitudes and patterns of use is essential to develop and target appropriate educational interventions.

This study summarizes the findings from 2 recent surveys on OTC analgesia use, principally NSAID. The results confirm that these drugs are used frequently, often inappropriately, and that there is an alarming rate of ignorance regarding the potential side effects of NSAID and OTC analgesics.

MATERIALS AND METHODS

Two nationwide surveys of adult households in the United States form the basis of this report. The first survey was conducted by Roper Starch Worldwide Proprietary Telephone Research Center during the months of September and October 1997 and screened a national projectable sample of 799 adults for NSAID use. This survey was commissioned by the American Gastroenterological Association. The purpose of this survey was to determine, among NSAID users, their perceptions as to their effectiveness and safety, and knowledge regarding side effects and medical complications, personal risk of complications, safety of either prescription or OTC

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Accepted for publication June 9, 2005.

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NSAID, and the belief that there would be early warning symptoms before serious complications. NSAID users were defined as having used prescription or OTC pain relievers (to relieve any kind of pain such as pain, swelling, and/or inflammation in the joints or muscles, back pain, cramps, headaches, and the like) on at least 2 occasions in the past 12 months for at least 5 consecutive days at a time. Exclusive acetaminophen users were excluded from the results. Only those interviewees who reported use were interviewed further. The findings were projectable to the greater population of NSAID users as defined within a margin of sampling error of $\pm 3\%$.

The second survey, commissioned by the National Consumers League, was performed December 16 to 29, 2002, by Harris Interactive. This telephone survey contacted 4263 adult Americans age 18 years or over. The purpose of this survey was to determine the usage of OTC medications including NSAID, the extent to which the population understood the potential side effects of these medications and the doses that are used, and concern about side effects and whether Americans talk with health professionals about OTC medications. Prescription NSAID use was not recorded. The results were then weighted demographically using figures obtained from the US Census Bureau. An abbreviated portion of the results of this survey are available on the National Consumers League website.

Analyses were restricted to tabulations provided by the agencies that conducted the surveys. Statistical analyses were performed among responses in each survey with Fisher's exact tests to compare dichotomous variables and Student's *t* tests for continuous variables. A *p* value < 0.05 was considered statistically significant.

RESULTS

Roper survey. Of the 4799 people surveyed, 807 (17%) reported NSAID use; of these, 240 (30%) used only pre-

scription, 258 (32%) only OTC (Table 1), and 309 (38%) reported use of both. Of these 309 dual users, 94 (30%) used more prescription, 108 (35%) more OTC, and 107 (35%) the same amount. Ibuprofen based NSAID were the most frequent OTC drug used (Table 2). No significant differences were noted for type of NSAID used for dual users and exclusive OTC users (data not shown). Although NSAID were mostly taken for arthritis (36%), 15 patients (2%) reported taking an antiinflammatory pain reliever for relief of stomach problems or ulcers.

Of the 807 NSAID users in this survey, 439 (54%) were not aware of the potential side effects of these drugs, and 144 (18%) had previously experienced side effects, including 82 prescription and 62 OTC users. When asked which type of antiinflammatory pain reliever was most effective in relieving pain and swelling, 439 respondents (54%) considered prescription NSAID most effective in relieving pain, 205 (25%) believed OTC to be more effective, 12% believed that there was no difference, and 17 (9%) did not know. Prescription NSAID were reported as very effective in relieving pain in 132 respondents (55%) and somewhat effective in 81 (34%). Among all NSAID users, prescription NSAID were believed to be safer (33% of users), while 32% believed OTC were safer, 20% believed there was no difference, and 15% did not know (Table 3).

Table 1. Characteristics of the survey populations exclusively using over-the-counter pain relievers.

	Roper [†]	National Consumers League*
Number	258	3557
Age, yrs	46.5	44.3 \pm 6.8
Female, n (%)	171 (66)	1916 (54)
Caucasian, n (%)	221 (86)	2646 (74)
High school graduate, n (%)	84 (33)	1276 (36)
College graduate, n (%)	57 (22)	594 (17)
Married, n (%)	146 (57)	—
Household income \leq \$35,000, n (%)	116 (45)	887 (25)
Current health good to excellent, n (%)	209 (81)	3044 (86)
Alcohol use \leq 3 drinks past month	—	2160 (61)
Duration of use < 2 years, n (%)	18 (7)	—
Use more than recommended dose, n (%)	66 (26)	1570 (44)
Taking a corticosteroid, n (%)	9 (3)	—
Types of pain in past 3 mo, n (%)		
Arthritis/joint pain	86 (33)	1478 (42)**
Back pain	40 (15)	1449 (41)
Headache	57 (22)	1416 (40)
Sports/exercise related pain	—	742 (21)
Other	75 (29)	NA
Frequency of use, n (%)		
Daily	69 (27)	531 (15)
Several times/week	—	505 (14)
Several times/mo	—	964 (27)
Less than several times/mo	—	1528 (43)
As needed	189 (73)	—

[†] Exclusive users of acetaminophen included; 79 respondents reported acetaminophen use. * Exclusive users of acetaminophen included; 1639 respondents reported acetaminophen use. ** Total number higher than the total as patients could report more than one cause of pain.

Table 2. Most frequent over-the-counter pain reliever taken. Values expressed as number (%).

	Roper, n = 567*	NCL, n = 3557
Ibuprofen based	325 (57)	1347 (33)
Advil	142 (25)	564 (16)
Motrin	49 (9)	154 (4.3)
Tylenol/acetaminophen	79 (14)	1172 (33)
Aspirin	55 (10)	563 (16) [†]
Aleve	61 (11)	314 (8.8)
Naproxen	—	10 (0.3)
Other	21 (4)	82 (2)
No response/Don't know	9 (2)	69 (2)

* Includes respondents who used prescription and OTC pain relievers.

[†] Includes Excedrin, Bayer, Ascriptin, Ecotrin.

Table 3. Attitudes about side effects (SE) from pain relievers for exclusive OTC medication users. Values expressed as number (%).

	Roper, n = 258*	NCL, n = 3557
Aware of SE	100 (39)	—
Concern about SE	47 (18)	2107 (49)*
OTC are safer than prescription medications	119 (46)	1278 (36)
Read directions of OTC medicines	—	2066 (58)
Discussed risk of stomach bleeding/ulcer with health professional	—	714 (20)
Safe to combine with prescription medications if follow label instructions	—	1163 (33)
Safe to drink alcohol with OTC	—	630 (18)
Experienced SE	95 (37)	—

* Very concerned/somewhat concerned.

Exclusive OTC NSAID users. Of the 258 exclusive OTC NSAID users, the median duration of use was 5 years; 18 (7%) reported using these agents for less than 2 years, and 40 (16%) were reported using agents for 15 or more years. Sixty-nine respondents (27%) used OTC NSAID daily, with 189 (73%) using them on an as-needed basis. Consuming more than the recommended amount on the package instructions was reported in 66 respondents (26%), while 148 (57%) used the exact dosage. As with prescription NSAID, most respondents believed OTC NSAID were effective; 148 (57%) of the exclusive OTC users believed these drugs were very effective, with 100 (39%) reporting them as somewhat effective. Of the 247 OTC NSAID users who were aware of side effects, 95 had previously experienced side effects, most commonly heartburn (34%), stomach pain (23%), and indigestion (22%). Seven percent reported bleeding ulcers, 6% internal bleeding, and 5% ulcers. The most common side effects or medical complications these exclusive OTC NSAID users were aware of were stomach pain (19%), followed by internal bleeding (16%) and bleeding ulcers (15%). Of the exclusive OTC users, 29% considered them-

selves at no risk for side effects, 51% as ordinary risk, 15% as moderate risk, and 3% as high risk. Only 100 (39%) of the exclusive OTC users were aware of side effects from these drugs, and of these, only 47% were concerned. When asked, what if anything had you done in the past 12 months to reduce your risk for ulcers or gastrointestinal (stomach) bleeding from OTC NSAID, 18 (39%) had done nothing, while 1% had taken something to prevent or treat the side effects. Only 2% discussed this issue with their doctor and 11% changed their behavior (better diet, more exercise).

Beliefs in warning symptoms and signs. NSAID users were specifically queried about their belief in the occurrence of warning symptoms or signs that may antedate any complications from these drugs. Of the 258 exclusive OTC users, 57 (22%) thought that warning symptoms/signs would always be present, 60 (23%) thought that symptoms/signs would never be present, and 9% did not know. For those who felt that warning symptoms/signs would occur, stomach pain was the most commonly reported warning (65%), followed by nausea and vomiting in 14%, and heartburn in 10%; only 3% reported bleeding as a possible sign. As noted, 14 (5%) of the OTC users had previously been hospitalized for an ulcer or ulcer condition.

Prescription NSAID users. This survey also allowed examination of prescription NSAID users. The mean duration of prescription NSAID use in 549 prescription NSAID users was 6.6 years (median 4 yrs) and 44% reported daily use. Forty-four (8%) reported that they frequently consumed more than the exact dosage prescribed. Of these 549 prescription NSAID users, only 247 (45%) were aware of potential side effects, 48 (19%) did not know what they were, and 110 (20%) had previously experienced side effects. Fifty-six percent of exclusive prescription users believed these medications were safer than OTC. However, of the 247 prescription NSAID users who were aware of side effects, 80 (32%) were not concerned about potential side effects. The side effects experienced most frequently included stomach pain in 32 (24%), upset stomach 24 (21%), nausea 22 (20%), internal bleeding and bleeding ulcer 5 (3%). Only 89 (65%) of those who had experienced side effects were warned of these by their physician, while 71% were informed by their pharmacist. Although side effects were commonly experienced, discussion of these with their physicians was infrequent. Only 37 (27%) of the prescription users who had experienced side effects or medical complaints had discussed these with their physicians, while 12% ignored the side effects and 40 (29%) took something to prevent or treat the side effects.

Of the 549 prescription NSAID users, 131 (24%) considered themselves at no risk for side effects, with a similar number for those using both prescription and OTC; 35 (6%) did not know the risk. One hundred sixty-nine of the 549 total prescription NSAID users (31%) believed warning signs would never be experienced if a complication were to

occur, while 158 (29%) believed there would always be warning signs. The most common warning signs that were believed to occur included stomach pain (54%), nausea/vomiting (11%), and bleeding (10%); 15% did not know. Selected comparisons between exclusive OTC and prescription NSAID users are shown in Table 4.

National Consumers League survey. Of the 4263 interviewees, 3557 (83%) reported OTC analgesic use in the past year, 531 (15%) daily use, and 1036 (29%) daily to several times per week use. Women were more likely to report using OTC pain medications in the past year than men (87% vs 80%; $p < 0.001$). The most common reported causes of pain in OTC users, presumably the reason for use of these agents, were arthritis or joint pain in 42%, followed by back pain in 41%, and muscular ache in 40%. Of the daily OTC users, the frequency of daily use ranged from once (44%) to 5 or more (5%), with a median of 2. Of the 27% of respondents who reported monthly usage, the median uses per month were 2, with 24% using these drugs 5 or more times per month. Of those consuming OTC analgesics, 2235 (63%) respondents used an NSAID most often. When asked if they ever took an OTC when they otherwise could have taken a prescription medication, the most common reasons for doing so were that OTC pain medications were easy to purchase (61%), that they felt OTC pain medications worked just as well as prescription or that they did not need prescription strength (47%), or because OTC agents cost less (44%). Thirty percent felt there was less risk of potential side effects with OTC drugs.

Perceptions and concerns regarding risk of side effects. As with the results from the Roper survey, there was marked lack of awareness and concern regarding potential complications of OTC medication use. Half the adults described themselves as either not too concerned (25%) or not at all concerned (25%) about potential side effects of OTC pain medication. Women were more likely to report being very or somewhat concerned about side effects than men (57% vs 43%; $p < 0.001$). Further, those who used NSAID daily were less likely to be concerned about potential side effects from OTC medications than those taking OTC several times per month or less (41% vs 50%; $p < 0.001$).

When asked what side effects consumers were concerned about, only one in 5 (21%) reported stomach problems; 21% cited liver damage, 12% kidney problems, 5% ulcers, and 4% GI bleeding. Interactions with other OTC or prescription medications had been previously discussed with a doctor or pharmacist by 29%, and only 23% had discussed the proper length of time to take OTC pain medications or continuous use of these agents. These discussions were generally initiated by the respondent in the majority of cases. Less than one in 5 adults had talked with a healthcare professional about the risk of kidney or liver damage associated with OTC use (19%) or the risk of stomach bleeding or ulcers (18%). However, when presented with specific information about the risks associated with OTC medications, most respondents were concerned. Consistently, when facts regarding side effects from NSAID were discussed, 75% or more then expressed concern. For example, after reading the

Table 4. Selected comparisons between exclusive OTC and prescription NSAID users in the Roper survey. Values expressed as number (%).

	OTC	Prescription	Both	p [†]
Number	258	240	309	—
Mean age, yrs	46.5	52.5	47.5	—
Female, n (%)	171 (66)	156 (65)	236 (76)	0.78; 0.009; 0.004
Duration of use, mean (median), yrs	8.5 (5)	6.6 (4)	8.1 (5)	
Chronic use*	69 (27)	126 (53)	118 (38)	0.01; 0.004; 0.001
Experienced side effects	28 (11)	39 (16)	57 (18)	0.34; 0.01; 0.57
Which is safer?				< 0.01; 0.26; 0.07
OTC	119 (46)	30 (13)	110 (36)	
Prescription medication	51 (20)	135 (56)	79 (26)	
No difference	45 (17)	39 (16)	76 (25)	
Don't know	43 (17)	36 (15)	44 (14)	
Aware of side effects				0.17; 0.15; 1.0
Yes	100 (39)	108 (45)	139 (45)	
No	155 (60)	126 (53)	158 (51)	
Don't know	3 (1)	6 (3)	12 (4)	
Belief in warning signs/symptoms				< 0.01; 0.1; 0.02
Always	57 (22)	61 (25)	97 (31)	
Sometimes	117 (45)	61 (25)	90 (29)	
Never	60 (23)	76 (32)	93 (30)	
Don't know	24 (9)	42 (18)	29 (9)	
Used more than recommended amount	66 (26)	17 (7)	99 (32)	0.03; 0.1; < 0.01

* Usually on a daily basis. † p values expressed as OTC vs prescription; OTC vs both; prescription vs both.

statement, “serious side effects such as stomach bleeding are associated with some OTC pain relievers and can occur without warning,” 77% reported being very or somewhat concerned about NSAID use.

Adherence to label instructions. When taking a nonprescription pain reliever for the first time, only 30% read the dosage level, 21% read directions for usage, 12% responded that they did not read anything on the label, and 568 respondents (16%) read everything on the label. No significant differences were detected between men and women in regard to reading the entire label for first-time NSAID users (data not shown). Consuming more than the recommended dosage was common (44%), with a variety of reasons reported (Table 5). In addition, OTC medications were frequently combined with other medications that could contain an NSAID. For example, 31% reported taking cold or flu medications at the same time as OTC agents, and 32% consumed alcohol the same day as taking an OTC agents. However, heavy drinkers were more likely to agree that it was “okay” to drink alcohol with OTC medications if only the recommended amount of medication was taken (37% vs 15%; $p < 0.001$).

Patterns of use in alcohol users. Respondents who regularly consumed large amounts of alcohol, defined as at least 3 alcoholic beverages a day for greater than 5 days per month, commonly reported OTC misuse. Such heavy drinkers were more likely to take more than the recommended dose of pain reliever than non-heavy drinkers (54% vs 43%; $p < 0.001$). For example, 41% of heavy drinkers said they had taken the next dose of an OTC sooner than directed on the label and this was significantly higher than those who did not drink heavily (32%; $p = 0.001$). Similarly, 37% of heavy drinkers took more pills at a single time than directed on the label, which was significantly higher than those who did not drink heavily (28%; $p < 0.001$). In addition, two-thirds (65%) of heavy drinkers reported consuming alcohol the same day that they were taking an OTC. This was almost 40% higher than in those who did not drink heavily (27%; $p < 0.001$). Heavy drinkers were also more likely to be not too or not at all concerned about potential side effects from OTC medications (57% vs 49%; $p < 0.001$).

Table 5. Ways of and reasons for taking more than the recommended dosage of OTC pain reliever*. Values expressed as number (%).

The next dose sooner than directed on the label	1198 (34)
More pills than the label recommended at a single time	1024 (29)
More than the number of doses/day as directed on the label	676 (19)
Believed it would bring relief more quickly	1051 (67)
Had severe symptoms	1047 (67)
Did not get better taking the recommended dose	888 (57)
Had taken the prescription version of the medication previously	382 (24)
Doctor or nurse told me to	298 (19)

* From the National Consumers League survey.

Patterns of use in arthritis patients. Respondents who reported suffering regular arthritis pain were primarily women (61%). Nearly 9 in 10 of these (85%) used OTC pain relievers, 29% reporting daily OTC use and 21% using such agents several times weekly. Interestingly, arthritis sufferers were not more concerned about potential side effects associated with OTC than non-arthritis sufferers (data not shown). However, 43% believed they would avoid serious risk of side effects as long as they took the recommended dosage of OTC medications, and 30% believed OTC were safer than prescription. Only 39% reported discussing with their physician the interactions of OTC with their prescription medication(s).

DISCUSSION

The unique findings from these surveys highlight the striking prevalence of OTC analgesic use, particularly NSAID, among the American public. Extrapolating these rates of use to the general population suggests that 36 million Americans are using OTC pain medications daily, with roughly 23 million using NSAID. Further, one-fourth of users exceeded the recommended dose of OTC medication, and the belief that OTC are safer than prescription doses was common. More disturbing is that about half of the interviewees either were unaware of the potential toxicity of these agents or were unconcerned. These findings strongly underscore the need for educational interventions directed to the general public as well as physicians.

Studies in diverse populations worldwide have also shown a high frequency of OTC NSAID use, misperceptions regarding their toxicity, and underreporting of use¹³⁻²⁴. Kaufman and colleagues reported on a telephone survey of 2590 adults including both prescription and OTC agents¹³. Similarly to our study, they found 81% had used at least one medication in the preceding week, and 23%, 17%, and 17% had used acetaminophen, ibuprofen, or aspirin, respectively, in the last week. Data from the Nurses Health Study²¹ showed that 42% of women age 51 years or older used NSAID at least weekly. In a study of 2433 patients attending an outpatient physical therapy unit²², 79% reported either OTC or prescription antiinflammatory drug or aspirin use during the week prior to the survey. While this high frequency of use is not surprising given the clinical setting, 49% had at least one risk factor for GI toxicity and 13% reported 2 or more factors. In a small survey of 213 patients from an emergency department²³, 67% had taken NSAID during the weeks prior to their visit, and misperceptions regarding toxicity were related to age, sex, and education status. A lack of knowledge was shown in a survey of adults more than age 60 years attending a blood pressure clinic, where the participants demonstrated little knowledge of potential drug interactions and recognition of interactions of these medications with both antihypertensive medications and alcohol²⁴. The survey results reported here also parallel

observations that patients take more than the recommended dose of prescription NSAID including COX-2 agents²⁵. Collectively, these studies support the findings of our report showing the high rates of OTC NSAID use and lack of understanding of the toxicity of these drugs among a wide spectrum of the population. Our results extend these observations on the reasons for use and misinformation on GI toxicity.

As with any survey, the findings must be interpreted cautiously. While both surveys attempted to assess a diverse and adequate sample of the American public, the relatively small sample size of exclusive OTC users in the Roper survey potentially limits its applicability. Survey results are also plagued by potential for misunderstanding of the question, and an inability to formulate additional questions based on response. Further, since these 2 surveys did not use the same questions, comparisons between them are difficult. For example, differences in concern about side effects were striking between the 2 surveys. It would have been interesting to compare issues of knowledge regarding side effects over time to assess for any trends in the awareness of potential complications from NSAID, as this could explain some differences, but since the same questions were not used, reliable comparisons cannot be made. Nevertheless, the large sample size coupled with the demographics of the survey population suggest these results can be generalized to the general public.

Taken together, these results suggest that users may underestimate the potential for adverse side effects of OTC analgesics. This inference is based not only on the fact that people reported that these drugs were safe in the Roper survey, but also on the fact that many people in both surveys appeared not to be concerned about side effects. This lack of concern is supported by responses that these drugs were commonly taken in higher than recommended doses, the frequent reporting of combined use of these agents with other drugs or alcohol, and the lack of frequency with which discussions with medical professionals about use of these agents were undertaken. Nevertheless, when given scenarios regarding potential toxicities, the majority of the respondents then expressed concern supporting a role for educational interventions.

In summary, our study suggests that OTC analgesic NSAID are widely used, are frequently taken inappropriately and potentially dangerously, and are generally believed to be safe. Educational intervention directed toward both patients and physicians appears warranted. The campaign recently launched by the Food and Drug Administration to address these educational issues supports the urgent need for such initiatives.

ACKNOWLEDGMENT

The Roper Survey was performed for the American Gastroenterological Association as part of an educational effort entitled Risk Education to Decrease Ulcer Complications and Their Effects from NSAIDS

(REDUCE). The authors thank Linda Golodner of the National Consumers League for providing the results of their survey, and Ashutosh Tamhane, MD, for assistance with the statistical analyses.

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