Study objective: The purpose of this study is to determine the prevalence of over-the-counter analgesic overuse in a sample of emergency department (ED) patients.

Methods: We conducted a survey of a convenience sample of patients presenting to an urban, academic ED. Research associates questioned patients about the use of pain or cold medications containing ibuprofen, acetaminophen, naproxen, or aspirin. Patients who reported using medications with these ingredients in the 72 hours before their visit were asked about the specific medications, daily dose, and reason for medication use. The daily dose of these 4 analgesics was determined and classified as within or above the manufacturers’ recommended over-the-counter dose range.

Results: Three hundred seven of 546 (56%) surveyed patients had reported using a medication containing one of these ingredients. Thirty-seven patients (6.2%; 95% confidence interval 4.5% to 8.6%) reported exceeding the manufacturer’s recommended daily dose at some point in the 3 days preceding their ED visit.

Conclusion: Although our study was limited by the use of a convenience sample, we found a potentially significant rate of patients who reported taking excessive doses of over-the-counter analgesics. [Ann Emerg Med. 2006;48:315-318.]
Overuse of Over-the-Counter Analgesics

Editor's Capsule Summary

What is already known on this topic
Overuse of over-the-counter pain medications has been linked to patient injury. However, how often overuse leads to injury, and the doses, dose frequency and patient characteristics predisposing to injury are not well known.

What question this study addressed
This study seeks to determine how frequently over-the-counter pain medications are overused by patients presenting to an urban emergency department (ED).

What this study adds to our knowledge
Fifty-six percent of the 546 ED patients in this study took over-the-counter analgesics in the 3 days preceding their visit. Six percent of them exceeded the manufacturer’s recommended dosing for at least one over-the-counter analgesic on at least one day.

How this might change clinical practice
This information may help clinicians in the early ED identification of those at risk for over-the-counter analgesic overuse.

reason for use of the medication (fever, cold/flu, headache, musculoskeletal pain, other pain), and the frequency of dosing and the number of pills (or teaspoons) taken each day for the 3 days leading up to the ED visit. Finally, all participants were asked, Do you believe that you can become ill from taking too much over-the-counter pain medication?

Six trained research assistants administered the surveys in private while the patient was undergoing the ED evaluation. Each researcher observed 2 surveys and administered at least 2 surveys under the observation of the primary investigator. The research assistants were given ongoing feedback during the study and were not blinded to the study purpose.

Patients were asked whether they would be willing to participate in a study of over-the-counter pain medication use. If the subject consented to participate, demographic data were collected and the patient was asked about the use of any pain or cold medication. Patients who reported taking a cold, flu, or pain medication were asked about the specific products and details of use as outlined above. Because our interviewers could not always determine whether subjects were taking potentially unsafe doses of medications, all patients who stated that they were using any product with an over-the-counter analgesic ingredient were instructed to inform their ED provider about their medication use.

Data Collection and Processing

Data were collected on case report forms and entered by a single researcher into an Excel spreadsheet (Microsoft, Redmond, WA). When an exact product name was provided, the dose of each medication in the product was determined from a database (Micromedex, Englewood, CO). If the exact product could not be determined, the lowest commonly used dose of the medication available in the formulation the patient described was entered as the dose. For example, if a patient stated he or she was taking an acetaminophen tablet but did not know the exact product name, we considered this a regular strength (325 mg) tablet. Patients who reported taking only a prescription-strength ibuprofen or naproxen product were excluded from the primary analysis.

Outcome Measures

Use was defined as taking a product containing an over-the-counter ingredient (acetaminophen, ibuprofen, naproxen, or aspirin). Although our study was designed to measure overuse of over-the-counter products, we collected information on prescription products with over-the-counter ingredients, which allowed us to identify simultaneous use of an over-the-counter and prescription product. Overuse was defined as taking a total daily dose of an over-the-counter product that exceeded the manufacturer’s recommended dose as noted in the approved package labeling: acetaminophen 4 g/day, ibuprofen 1200 mg/day, naproxen 660 mg/day, and aspirin 4 g/day.

Primary Data Analysis

We calculated the proportions and 95% confidence intervals (CIs) (using the binomial exact method) of patients overusing products containing over-the-counter analgesics. We also determined the rate of overuse by over-the-counter product, sex, and age group and determined the number of patients taking multiple products with over-the-counter ingredients. We compared the proportion of patients reporting overuse for each over-the-counter analgesic with χ² analysis. Statistics were calculated using SAS (SAS Institute, Inc., Cary, NC), and StatMate (GraphPad, San Diego, CA).

RESULTS

We interviewed 546 patients during the study period. Of these, 307 (56.2%) patients reported taking a medication containing an over-the-counter analgesic. The mean age of patients was 38 years (SD 17 years), and 42.8% were men. During the study period, the mean age of all adult patients evaluated in the ED was 41 years, with an SD of 17 years, and 44.0% were men. Of the 307 patients reporting use of medications with over-the-counter analgesic ingredients, 163 (53%) patients reported taking acetaminophen, 106 patients reported taking ibuprofen (34%), 53 (17%) patients reported using aspirin, and 24 (7.8%) patients reported using naproxen (patients may report use of more than 1 medication). Patients stated the following reasons for using the medication (patients may report more than 1 reason): musculoskeletal pain (n=108), headache (n=85), cold symptoms (n=26), fever (n=9), and other (n=143).

Overall, 34 of 546 patients (6.2%; 95% CI 4.5% to 8.6%) reported exceeding the manufacturer’s maximum recommended dose of each medication in the product.
daily dose for at least 1 medication for at least 1 day during the 3 days before ED evaluation (Table 1). One patient reported exceeding the recommended dose for ibuprofen and acetaminophen on the day of ED visit, and 2 patients reported exceeding the recommended dose for ibuprofen and acetaminophen each day for all 3 days leading up to the ED visit. The highest daily dose of over-the-counter ibuprofen reported was 6,000 mg. The highest daily dose reported for acetaminophen was 8,000 mg, and the highest reported daily naproxen dose was 1,320 mg.

Users of ibuprofen and naproxen reported exceeding the manufacturer’s recommended over-the-counter dose more often than users of acetaminophen or aspirin ($\chi^2=24.8$, $df=3$, $P<.001$). Three patients taking ibuprofen reported exceeding the maximum recommended prescription dose of 2400 mg/day. An additional 3 of 23 patients using prescription-strength ibuprofen reported taking more than 2400 mg/day. The rate of reported overuse was similar for men (7.2%; 95% CI 4.5% to 11.0%) and women (6.3%; 3.7% to 9.9%). The rates of reported overuse for patients (with 95% CI) by age group were 18 to 29 years 9% (4.8% to 7.6%), 30 to 39 years 10.0% (5.1% to 17.2%), 40 to 49 years 9.2% (4.5% to 16.3%), 50 to 59 years 2% (0% to 7.8%), and older than 59 years 2.3% (0.3% to 8.0%).

In addition to exceeding the manufacturer’s recommended dose, reports of simultaneous use of 2 or more products containing over-the-counter analgesics were also common (Table 2). Most patients reported taking acetaminophen and a nonsteroidal antiinflammatory drug, but several patients reported taking 2 nonsteroidal antiinflammatory drugs concurrently. Three patients reported taking 2 or more products containing acetaminophen. All were taking an acetaminophen product and a nonprescription, multi-ingredient preparation. None of these patients reported exceeding the maximum recommended dose of acetaminophen.

More than 85% of patients agreed with the statement that you could become ill from taking too much pain medication (95% CI 82% to 89%). This proportion did not differ by sex, whether the patient was taking a medication, or whether the patient was taking an excessive dose of over-the-counter analgesic medication.

### Table 1. Proportion of patients who reported taking a pain reliever containing an over-the-counter ingredient in excess of the manufacturer’s recommended daily dose for that medication.

<table>
<thead>
<tr>
<th>Daily Medication Dose</th>
<th>Proportion of Patients*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen (&gt;4 g)</td>
<td>9/160 (5.6%)</td>
<td>2.6%–10.4%</td>
</tr>
<tr>
<td>Ibuprofen (&gt;1,200 mg)</td>
<td>23/106 (21.7%)</td>
<td>14.3%–30.7%</td>
</tr>
<tr>
<td>Naproxen (&gt;660 mg)</td>
<td>5/24 (20.8%)</td>
<td>7.1%–42.2%</td>
</tr>
<tr>
<td>Aspirin (&gt;4,000 mg)</td>
<td>0/53 (0%)</td>
<td>0%–6.7%</td>
</tr>
</tbody>
</table>

*Total exceeds 34 because some patients were overusing more than 1 medication.

### LIMITATIONS

There are several threats to the internal and external validity of our study. The precision of our estimated rate of overuse is sensitive to selection bias from nonconsecutive patient recruiting. Although our research associates were present during the busiest times in the ED, patients presenting during these hours may systematically differ from the ED population as a whole. We also excluded critically ill, intoxicated, and non-English speaking patients. Internal validity could also be altered by information bias. Face-to-face surveys are subject to interviewer bias, recall bias, and self-reporting; it is possible patients systematically over- or underreported their medication use during the interview. Misclassification could also occur if patients were exceeding the over-the-counter dose on advice of a health care provider. Finally, we were also not able to identify specific products for some patients. In these cases, we assigned the lowest commonly used strength, which could lead to an underestimation of dosing.

Our study findings may not be generalizable to other populations, because we surveyed patients at only 1 site, and our ED population may differ from that of other settings. We did also not collect data on comorbid conditions or alcohol use, 2 factors that may alter physician recommendations about over-the-counter analgesic dose.

### DISCUSSION

A large proportion of the subjects in this study reported using medications that contained over-the-counter analgesics. Although the majority of patients reported doses within the recommended range, we detected a group of patients who reported overusing over-the-counter analgesics. Although our study design may limit the precision and generalizability of our estimated prevalence of misuse, our study suggests that overuse is occurring at a clinically significant rate in our ED population.

Nonsteroidal antiinflammatory drugs and acetaminophen are safe when used appropriately. The primary adverse effects of nonsteroidal antiinflammatory drugs are peptic ulcer and gastritis. If the manufacturer’s maximum recommended dose of ibuprofen (1200 mg/day or less) is used, the risk for upper gastrointestinal tract bleeding is increased only 1.1 times compared to that of patients not treated with nonsteroidal antiinflammatory drugs. If the dose exceeds 1800 mg/day, however, the risk increases 4-fold. A similar increase in risk has also been shown for naproxen. These risks can be detected within 1 week of starting therapy. Concomitant use of nonsteroidal antiinflammatory drugs and aspirin also increases the risk of gastrointestinal tract bleeding. The major toxic effect of acetaminophen is hepatic injury. Although most deaths occur after intentional overdose, toxicity may occur during self-medication for pain. In retrospective reports, the dosage of acetaminophen associated with liver injury ranges from less than the recommended maximum dosage of 4 g/day to more than 30 g/day. We detected several patients who were taking doses of over-the-counter analgesics that may increase the risk of adverse...
Overuse of Over-the-Counter Analgesics

Kennon Heard, MD; Dyanne Severs, RN, BSN; Sheryl Wadley, RN, BSN; Keene KK; Alicia H, Gessery, MD; Serena L, DeCarolis, PharmD; Jahnigen Career Scholars Award from the American Geriatric Society and the Harford Foundation.

Table 2. Number of respondents who reported taking more than 1 product containing an over-the-counter medication as an ingredient (546 respondents).

<table>
<thead>
<tr>
<th>Day of Use</th>
<th>APAP+IBU</th>
<th>APAP+ASA</th>
<th>APAP+NAP</th>
<th>IBU+ASA</th>
<th>IBU+NAP</th>
<th>NAP+ASA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Today</td>
<td>11</td>
<td>8</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Yesterday</td>
<td>21</td>
<td>12</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2 Days ago</td>
<td>20</td>
<td>11</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3 Days ago</td>
<td>17</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

APAP, Acetaminophen; ASA, aspirin; IBU, ibuprofen; NAP, naproxen.

As noted in our limitations, it is possible that overusers may have been advised by a health care provider to take more than the over-the-counter dose of nonsteroidal antiinflammatory drugs or use a nonsteroidal antiinflammatory drug and aspirin. Although this advice is usually a reasonable practice, we believe a health care provider should consider the risk and benefits of these treatments case by case because these practices increase the risk of adverse effects. We are aware of no circumstances in which the recommended dose of acetaminophen exceeds 4 g/day.

Most patients were aware that overuse of over-the-counter analgesics may cause illness. The similar rate of awareness between overusers (86%) and nonoverusers (85%) suggests that, although patients are aware that excessive dosing may be dangerous, they either disregard this risk or do not believe that the dose they are using is excessive. Cham et al6 found many patients were aware of the possible complications related to over-the-counter analgesic use, but they did not determine whether patients understood that these effects are dose related. Future studies will need to determine whether overuse occurs because patients disregard the risks of overuse or whether patients do not know the appropriate doses, because each of these problems will require a different intervention to change behavior.

In summary, we found that a clinically significant proportion of patients presenting to our ED were overusing over-the-counter analgesics. This overuse included doses that have been associated with an increased risk of complications in other studies. Patients who overused over-the-counter analgesics usually recognized overuse could lead to complications. This overuse may contribute to the adverse effects reported from these medications.

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Reprints not available from the authors.

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REFERENCES