Patient knowledge and use of acetaminophen in over-the-counter medications

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Abstract

Objectives: To evaluate patient knowledge of over-the-counter (OTC) products containing acetaminophen and to determine patients' accuracy in dosing adult, child, and infant formulations.

Design: Cross-sectional study.

Setting: Six community pharmacies in Tucson, AZ, between February and May 2011.

Participants: 88 adults aged 19 to 89 years.

Intervention: Investigator-administered, semistructured interviews.

Main outcome measures: Patient knowledge of and ability to safely use OTC products containing acetaminophen, including understanding risks, identifying products, and dosing different formulations.

Results: Although most (86%) participants heard of acetaminophen, only 68% understood at least one of its uses and only 9% knew the abbreviation APAP. Virtually all knew that consuming too much acetaminophen in 1 day could be harmful, but only 17% and 35% knew that overdoses could result in death or liver damage, respectively. On average, participants correctly identified 80% (range 27–100%) of products with and without acetaminophen from a lineup of 11 OTC products. Although 38% (n = 84) of participants correctly measured both the child and infant doses of acetaminophen, doses ranged from one-half to twice the amount of the labeled child dose and one-third of the labeled infant dose. Findings from the regression analysis suggested that on average, women and those with college degrees had higher overall scores, while participants' age or parent status were nonsignificant predictors.

Conclusion: Many patients remain confused about using acetaminophen safely, signaling the need for greater patient education to prevent unintentional harm. The results further specify common misunderstandings to address during patient contact, which also includes replacing "APAP" with "acetaminophen" on any prescription bottle labels or patient-directed information.

Keywords: Acetaminophen, nonprescription drugs, safety, administration, dosage, packaging.

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Acetaminophen is the most commonly used medication among U.S. adults and is consumed by approximately 19% of the population each week.[1] It can be used in both adult and pediatric populations and can be an effective analgesic and antipyretic to relieve symptoms associated with injury, viral and bacterial infections, and headaches.[2,3] Although considered safe when taken as recommended, liver toxicity can occur with doses greater than 4 g or when used in patients with preexisting liver dysfunction.[1,4]

Acetaminophen toxicity is the most common cause of acute liver failure in the United States and is the most common reason for calls made to poison control centers.[2, 5] It has been estimated that overdose with acetaminophen leads to more than 56,000 emergency department visits, more than 2,600 hospitalizations, and approximately 400 deaths from acute liver failure every year.[2]

Acetaminophen is found in more than 600 over-the-counter (OTC) and prescription products.[6] It is the single active agent in products such as Tylenol (McNeil-PPC) and Triaminic (Novartis OTC) and in combination with other agents in products such as Nyquil Cold and Flu (Procter & Gamble), Excedrin (Novartis OTC), and Theraflu (Novartis OTC). Acetaminophen is available in multiple dosage forms, including oral pills and liquids, suppositories, and even intravenous formulations in some hospitals. Because of its presence in so many different products, patients may not recognize which products contain acetaminophen. An estimated 15% of acute liver failure cases result from patients who unknowingly consumed multiple acetaminophen-containing preparations simultaneously and more than 100 deaths annually are caused by unintentional overdose.[2,3]

Measuring devices included with medications may be difficult for patients to understand, or patients may be unable to recognize the appropriate mark on the device to which they should measure.[7,8] A 1997 study by Simon et al.[8] asked caregivers to determine and measure a dose of acetaminophen for their child. They found that only 30% of participants were able to both calculate and measure a correct dose. In the years following that research, the Food and Drug Administration (FDA) issued several recommendations for labeling of OTC pain relievers. In 2006, FDA proposed adding a new warning for liver damage and making the active ingredient more prominent on the packaging.[9] These changes were finalized in 2009 with some additional requirements.[10] The new regulations require the liver warning to be present on the immediate container and the outer carton labeling. In addition, a warning appears stating that patients should not use acetaminophen with warfarin and that they should ask a physician or pharmacist if they are unsure whether a medication contains acetaminophen. Examining the effect of these changes on patient knowledge of acetaminophen safety, dosing, and identification is important.

In May 2011, manufacturers of OTC acetaminophen products announced that they will no longer produce concentrated infant drops and only will produce children's liquid acetaminophen in a standardized concentration of 160 mg/5 mL.[11] On behalf of the manufacturers, the Consumer Healthcare Products Association reported that the changes were aimed at reducing dosing errors.[12] In addition, syringes with dose restrictors will be included with products for infant use and measuring cups will continue to be included for dosing of older children.

Better identification of gaps in patient knowledge regarding the presence of acetaminophen in OTC medications is needed. This will facilitate development of interventions to increase patient safety, prevent overdoses, and guide patients in obtaining appropriate care following an overdose.

At a Glance

Synopsis: Acetaminophen safety has been under close scrutiny in recent years by the Food and Drug Administration and has received attention from the mainstream media. Acetaminophen overdoses in children have resulted in the removal of higher-concentration infant formulations from the market in order to standardize the concentration of available over-the-counter (OTC) liquid products containing acetaminophen. However, limiting acetaminophen concentration alone cannot adequately mitigate risks of acetaminophen toxicity and overdose without additional intervention. This study indicates that many patients remain confused about using acetaminophen safely, signaling the need for greater patient education to prevent unintentional harm.

Analysis: *Patients need to be aware of ingredients listed in OTC and prescription products to avoid duplication of acetaminophen therapy. Health care providers will be able to use these results to better understand their patients and provide optimal directions for medication use and safety information. Disseminating information about how to better educate patients can assist in avoiding accidental acetaminophen overdoses.*

Objectives

The purpose of this study was to evaluate patients' knowledge about OTC acetaminophen-containing products and to determine patients' accuracy in dosing adult, child, and infant formulations (i.e., before manufacturers' voluntary concentration standardization of child and infant formulations).