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Tablet Splitting: To split or not to split

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Tablet Splitting: “To Split or Not To Split”

Tablet splitting can save patients money, especially when considering sole-source brand name products. Yet, the practice of tablet splitting can be problematic as a result of failed therapeutic outcomes due to over or under dosing. Also, the stability of a medication might be altered or there may be other unknown reasons not to split a tablet. The following checklist and guide may help you determine which patients are able to split their own tablets and which tablets might safely be split.5

A. Patient Considerations:
   a. Physical ability:
      i. Does the patient or patient’s caregiver have the skill, dexterity, strength, and visual ability to split a tablet?
         ☐ No, splitting should not be considered
         ☐ Yes, go to the next question
   b. Cognitive ability:
      i. Does the patient or patient’s caregiver have the mental ability to select the correct medication and split a tablet?
         ☐ No, splitting should not be considered
         ☐ Yes, go to the next question

B. Product Considerations (Drug, Potency, and Dosage Form):
   a. Is the active ingredient a narrow therapeutic index product (digoxin, levothyroxine, others)?
      ☐ Yes, splitting should not be considered
      ☐ No, go to the next question
   b. Is the tablet a controlled- or modified-release product?
      ☐ Yes, go to the next question
      1. Is the tablet scored?
         ☐ No, splitting should not be considered
         ☐ Yes, go to the next question
      ☐ No, go to the next question
   c. Does the tablet contain more than one active ingredient?
      ☐ Yes, splitting should not be considered
      ☐ No, go to the next question
   d. Does the tablet easily break into pieces with minimal handling (friability)?
      ☐ Yes, splitting should not be considered
      ☐ No, go to the next question
   e. Is the tablet enteric-coated, sublingual, or buccal or does it have a poor taste, is it teratogenic if handled, or can it cause mouth irritation?
      (See Detail-Document # 241204 “Medications That Should Not be Crushed” for a helpful list of these medications).
      ☐ Yes, splitting should not be considered
      ☐ No, splitting is possible.
Background

Tablet splitting has been a popular, cost-saving practice among many patients for years. Patients have been able to trim prescription costs by splitting a tablet in halves or quarters. This is achievable because the prices of some drugs are similar despite the strength of the tablet. Now, some HMOs and insurance companies are utilizing tablet splitting as a cost-saving strategy. They are implementing policies that often require patients to split tablets of some commonly used medications.1,2 A December 2000 class-action lawsuit in the California court system contends that Kaiser Permanente has required its health plan members to split tablets regardless of the patients’ ability to accurately split tablets and the products’ suitability for splitting. The lawsuit states that Kaiser’s tablet-splitting policy is a violation of the California Business and Professions Code and the state’s Consumer Legal Remedies Act.3 National pharmacy and medical societies have expressed several concerns over this controversial issue. Primary concerns have ranged from the patient’s ability to accurately split the tablet, the content uniformity of the split tablet, and the possibility of a prescription error if “1/2 tablet” is misinterpreted as “1-2 tablets.”4-7

Views of Professional Organizations

The American Pharmacists Association and the American Medical Association are both formally against mandatory tablet splitting.5 The American Pharmacists Association (APhA) acknowledges the widespread practice of tablet splitting, and has developed a set of guidelines to evaluate the appropriateness of tablet splitting based on individual patient and product characteristics. The APhA suggests tablets that are uncoated and scored, for example, are often the easiest to split. Tablets that are round, coated, small, or unscored may be difficult to split accurately. The patient or caregiver must also be physically able to divide the tablet as directed.5-7 The American Society of Consultant Pharmacists opposes policies that deny payment for lower strengths of tablet dosage forms, or policies that mandate tablet splitting by patients.4 The Department of Veterans Affairs (VA) has also investigated this issue. Although the VA did not find specific studies indicating tablet splitting was detrimental to patients, the VA does not currently recommend mandatory tablet splitting.8

Studies

Rosenberg et al evaluated the weight-variability of twenty-two prescriptions containing 560 pharmacist-dispensed split tablet halves. The United States Pharmacopeia (USP) tablet uniformity standards require tablets to contain between 85% and 115% of the labeled dosage, allowing a 6% relative standard deviation in overall drug content. Of the twenty-two prescriptions tested, only seven (31.8%) met USP tablet uniformity standards.9

In another study, Teng et al evaluated the accuracy of tablet splitting by a trained individual. In this study, tablets found to be commonly divided were split by hand alone and by a single-edged razor blade. The trained individual split tablets of three products by hand, and tablets of eleven products with a single-edged razor blade. The three hand-split tablet groups and eight of the eleven groups split with a single-edged razor blade failed to meet USP tablet uniformity standards.10

Polli, et al examined the issue of tablet splitting within the Veterans Affairs (VA) Maryland Healthcare System. In 2001, this regional VA system promoted tablet splitting of products including atorvastatin, citalopram, lovastatin, paroxetine, sertraline, sildenafil, and simvastatin. Patients, however, could opt out of the program if they had difficulty splitting the tablets. The study examined the accuracy of twelve commonly split tablets. A trained pharmacy student split 30 tablets of each product
using a splitter device provided by the VA, and the tablet halves were then assessed for weight uniformity. Eight of the twelve products (67%) tested passed the USP-based uniformity testing, while four failed.\textsuperscript{11}

A separate retrospective study by Gee, et al evaluated the effects of splitting HMG-CoA reductase inhibitors. A total of 2,019 patients were enrolled and evaluated on parameters such as clinical effects, patient satisfaction, compliance, and cost issues. The cost avoidance over a one-year period for splitting atorvastatin, lovastatin, and simvastatin was estimated to be $138,108, an average of $68.40 per patient per year. Of the 454 patients who filled out the satisfaction questionnaires, 46% believed it was easier to take medications they did not have to split. However, 74% believed the tablet splitter was not too bothersome or time-consuming. Another 7% believed they had missed more doses during a month of tablet splitting. Of the 512 patients evaluated for laboratory considerations, there was no difference in total cholesterol and triglyceride values before or after tablet splitting while four failed.\textsuperscript{11}

**Conclusion**

Mandatory tablet splitting remains a controversial policy. Because of the variability in dose that may occur with tablet splitting, this practice should probably be avoided when accuracy of the dose is crucial. Enteric-coated and certain controlled-release tablets are not intended for splitting. It might be prudent to contact the tablet manufacturer before recommending tablet splitting, when in doubt. The stability of the medication might be altered or there may be other unknown reasons not to split a tablet. The patient’s individual ability to accurately split the tablet and the medication itself should continue to be key concerns.

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