



Pill Swallowing Gel

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Reducing the incidence of pill crushing in long-term care facilities through use of pill swallowing gels

Abstract

Pill crushing and mixing with a variety of juices, foods, or thickeners is a common practice in long-term care facilities (LTCFs) to aid medication administration to residents with swallowing difficulties. However, a large body of evidence indicates that pill crushing can decrease the efficacy of drugs and increase risk of patient side effects. Pill crushing may also expose care providers to occupational hazards associated with inhalation of pulverized medications and legal liability related to off-label use. Commercially available pill swallowing gels, formulated to break down quickly in the stomach without drug absorption, offer a well-accepted alternative to crushing and mixing for patients with mild to moderate swallowing difficulty and have been shown to reduce the incidence of pill crushing in LTCFs.



Introduction

An estimated 10–40% of adults experience difficulties swallowing pills^{1,2} and the prevalence of swallowing impairment increases with age and its associated loss of function.^{3,4} It has been estimated that nearly 70% of residents in homes for the aged exhibit some symptoms of dysphagia,⁵ with 20% reportedly skipping medication because of swallowing problems.¹

Historically, care providers have addressed this issue by crushing medication and mixing it with a variety of substances (e.g., juice, foods such as applesauce, thickeners) to ease swallowing. However, pill crushing is associated with patient and care-provider risks. An observational study of U.K. LTCFs found that 4.5% of crushed medications were specifically contraindicated for crushing by the manufacturer.⁶ Crushing of controlled-release drugs may expose patients to toxicity, erratic or delayed drug absorption, and adverse side effects.^{1,7} Though crushing of immediate-release medications remains a common practice, it has been found to significantly interfere with absorption rates, especially when crushed medications are combined with a variety of foods/juices or thickening agents commonly used as

mixing vehicles.^{8,9} Pill crushing also introduces occupational risk and potential liability to care providers.¹⁰

To address these concerns, in December 2019 the United States Pharmacopeia (USP) published a new standard (USP General Chapter <800>) on the handling of hazardous drugs in healthcare settings. The standard relies on National Institute for Occupational Safety and Health (NIOSH) definitions of hazardous drugs.¹¹ Among its occupational safety requirements, USP <800> calls for availability and proper use of appropriate personal protective equipment (PPE) when personnel cut, crush, or manipulate hazardous-drug tablets or capsules, or handle uncoated tablets during drug administration.

Commercially available pill swallowing gels (PSGs; Assure® Slide and Phazix® Level 3; ARKRAY USA, Minneapolis, Minn.), which have no known effect on drug dissolution,¹² offer a provider-accepted¹³ alternative to pill crushing and mixing. This article reviews evidence on the pharmacological effects and patient risks of pill crushing and mixing, risks and liabilities of pill crushing for care providers, and the potential patient and provider benefits of using commercially available PSGs.

Effects and consequences of pill crushing

Manufacturers of controlled-release medications use a variety of systems—dissolution, diffusion, osmotic, ion exchange resins, and more—to provide a therapeutic amount of drug over an extended time.⁷ Controlled-release medications contain a significantly greater amount of drug than do immediate-release medications. Crushing destroys the release characteristics of controlled-release medications, subjecting patients to risk of toxicity and even, in rare cases, death.⁷ Despite the well-known risk of crushing controlled-release medications and general avoidance of the practice, medication administration in LTCFs is prone to error¹⁴ and reports of erroneous pill crushing in LTCFs and hospitals have been reported to be anywhere between 0.5–10%.¹⁵

The distinction between high-risk and lower-risk pill crushing is not always well understood by LTCF staff. An observational study¹⁶ of medicine administration among 586 residents in 10 LTCFs reported alteration of at least one medicine in 46% of observed cases. Notably, 17% of medication alterations had the potential for detrimental outcomes such as increased toxicity, decreased efficacy, or unpalatability. Spillage occurred in 70% of cases where medicines were altered, potentially reducing the prescribed dose. Crushing has been found to impact dosage in varying degrees according to the device used,¹⁷ and improper cleaning of crushing devices introduces risk of cross-contamination and potential allergic reactions in patients.¹⁸

Immediate-release medications are still commonly crushed to facilitate swallowing. However, even when this practice is not contraindicated by the manufacturer, crushing may introduce a high risk of incomplete or variable dosing.¹⁹ For some medications such as warfarin

or amiodarone, crushing—even when not contraindicated—may result in clinically significant adverse outcomes for LTCF residents.^{16,20}

Mixing crushed medications with applesauce-like foods or thickeners is known to alter the dissolution rate and drug effect (i.e., bioavailability) of medications.^{8,9,21} The presence of food in the digestive tract may affect the bioavailability, and hence the safety and efficacy, of drug therapy.²¹ Fruit juice may have a significant effect on drug levels, either by magnifying drug levels (grapefruit juice) or reducing them (apple or orange juice).^{22,24}

The drug-food interactions of other foods used as vehicles for crushed medications are complex and variable. For example, dairy products such as yogurt may prevent the absorption of antibiotics, while the drug effects of other common medications such as analgesics, antihistamines, antihypertensive drugs may be affected by a wide variety of foods or the mere presence of food in the stomach.²¹ Commercially available thickeners, often used to aid swallowing without medication, have been found to impact dissolution of medication in relation to their viscosity, with even low-viscosity thickeners having a pronounced effect.⁸ Thickeners may also increase feelings of satiety and reduce thirst, potentially impacting nutrition and hydration of LTCF residents.⁸

In addition, a resident may not want or may be unable to finish eating the food into which combined crushed medications are added.²⁵ In such cases, staff would not know which medications the resident actually received because they were crushed and combined but not fully administered, putting the facility at potential risk of transgressing CMS medication-error guidance.²⁵

Legal and occupational risks of crushing

The law requires that medicines are given to the right person, at the right time, in the correct form, using the correct dose, via the correct route.²⁶ Off-label crushing or opening of medication, and/or mixing medication with food or beverages prior to administration, has legal implications.^{4,6} If pill crushing has not been authorized by a manufacturer, the liability for any resulting patient injury rests with the administering care provider.²⁷ For these reasons, providers are advised to avoid pill crushing as a general practice, consult with the prescriber and the pharmacist before altering dose forms, and keep accurate records of such discussions and subsequent actions.⁴

Use of refrigerated substances, such as applesauce, as swallowing vehicles must also comply with each facility's infection control policy. To prevent contamination,

such policies may include restrictions for dispensing of refrigerated foods, including no use of open containers on med carts and strict time limits for their nonrefrigerated use. By contrast, PSGs can safely remain at room temperature (e.g., on a cart) for 60 days with a normal disinfectant wipe-down of the container.²⁸ As a side benefit, a teaspoon of Assure® Slide and Phazix® Level 3 contains approximately half the sugar of applesauce (0.55g/1 tsp vs 1.06g/1 tsp, respectively).²⁸

Pill crushing may introduce health risks to care providers as well as patients. Inadvertent inhalation of airborne powder from crushed medications, particularly antineoplastic drugs, is a recognized occupational hazard for care providers.²⁹

Pill swallowing gels

PSGs, the first purpose-designed medicine lubricants, have been in clinical use since 2016. As of publication, the only commercially available PSG in the United States is Assure® Slide and Phazix® Level 3 (ARKRAY USA, Minneapolis, Minn.), available in International Dysphagia Diet Standardization Initiative (IDDSI)³⁰ levels 3 (moderately thick) and 4 (extremely thick). These gels, designed to breakdown quickly in the stomach, have no known effect on drug dissolution rates¹² and can be used in place of food, juice, or thickeners as mixing vehicles or to facilitate swallowing of whole pills.¹⁵ The Society of Hospital Pharmacists of Australia (SHPA) has recommended PSGs as a front-line tool to aid medication administration in patients with mild to moderate swallowing difficulty³¹:

‘First consider if the person can swallow the tablet or capsule whole with the aid of an oral medication lubricant. A medication lubricant is a gel that is thick and easy to swallow and moistens the mouth and throat. The whole tablet or unopened capsule is placed in a spoonful of the gel and swallowed. This may not be suitable for people with more severe swallowing difficulties.’

Research cited in the SHPA *Don't Rush to Crush Handbook* concluded that more evidence is required to determine whether PSGs will safely transport medicines without risk of aspiration before these lubricants can be recommended in patients with dysphagia.³¹ Consultation with a speech pathologist is generally recommended for patients at risk of aspiration due to dysphagia.¹⁵

PSGs are made from all-natural ingredients and are flavored to promote resident acceptance and to potentially mask the unpleasant taste and smell of medications. By facilitating pill swallowing for LTCF residents, PSGs have been shown to reduce the incidence of pill crushing in an Australian LTCF by 38% (Table 1).

Table 1. Reduction of incidence of pill crushing in an Australian long-term care facility following adoption of pill swallowing gels.*

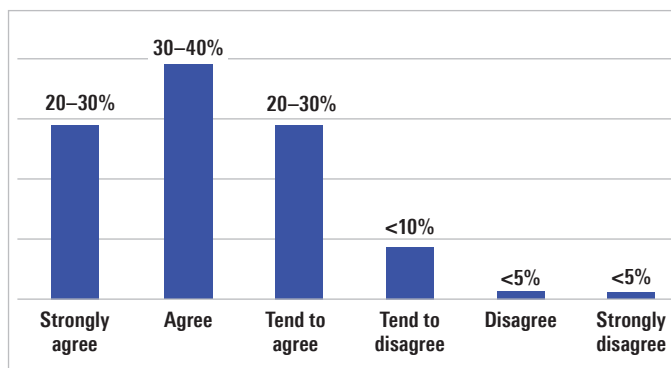
	No. of medications to be crushed	No. of medications able to be administered using pill swallowing gels	Reduction in crushing of medications (%)
Total facility	332	126	38.0%
AM	206	83	40.3%
PM	118	35	29.7%
Night duty	8	6	75.0%

* Landsdowne Aged Care facility, Cabramatta NSW, Australia. Quality improvement project to reduce incidence of medication crushing. Measurements were taken over 1 full week commencing July 8, 2019.²⁸

PSGs have also been recommended as a consideration to help prevent whole pills from becoming stuck in the throat, a risk factor for oesophagitis.¹⁵

PSGs have been well accepted by care providers. In a survey²⁸ of 355 healthcare workers in Australian LTCFs, 48% (170/355) of the respondents had used PSGs. Of those who had never used PSGs, nearly one-third (58/185) had heard about these products. Most respondents that had used PSGs believed them to be an effective method to facilitate pill swallowing (Fig. 1). Easier medication administration (48%), reduction in the need to crush pills (34%), and better medication compliance (33%) were reported as the main benefits of using PSGs.

Fig. 1. Long-term care facility care provider responses to the statement that pill swallowing gel “is an effective method to facilitate pill-swallowing in residents” (n=170).²⁸



Conclusion

Many residents of long-term care facilities (LTCFs) experience difficulties in swallowing that can challenge the proper administration of medications. Crushing of medications and/or using food or thickeners as vehicles for medications may significantly alter drug bioavailability, put patients at risk, and present care providers with occupational and legal hazards. Pill swallowing gels are safe, effective, and do not impact drug bioavailability. PSGs are well-accepted by care providers as a tool to aid with the administration of medications to LTCF residents who experience mild to moderate difficulties in swallowing.



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