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ARTICLE

Altering dosage forms for older adults

SUMMARY

Swallowing difficulties in older adults present challenges for medication management, particularly as polypharmacy is so common.

It is also important to review the patient's swallowing difficulties and medication management regularly. The limited availability of oral liquids and other dosage forms given by alternative routes means that crushing tablets and emptying capsules is common practice.

Altering dosage forms can have adverse clinical consequences. It is important to consider whether the medicines are still necessary.

If the medicines are essential, find out if there are alternative formulations. Check guidelines and the product information before altering dosage forms.

The legal implications of altering dosage forms can be minimised by following evidence-based practice, clearly documenting the reason for altering the medicine and obtaining written consent from the patient or their carer. Review the patient's swallowing ability and treatment regimen regularly.

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Introduction

Polypharmacy, dysphagia and age-related pathological changes in older adults present challenges for medication management. As many as one in five older patients has difficulty swallowing and may have problems taking tablets and capsules.[1,2]

The limited availability of oral liquids, patches and suppositories means that crushing tablets and emptying powder from capsules is very common, particularly in aged-care facilities and nursing homes.[3-6] Multiple medicines are often crushed together and mixed with a food or a thickening agent for administration.[3] Altering solid dosage forms is associated with a number of problems.

The stability and bioavailability of drugs can be significantly changed by the simple act of crushing a tablet, preparing an oral liquid from a tablet or capsule, or mixing a crushed tablet or capsule powder with food or other thickening agents.[7]

Manipulating solid dosage forms remains a significant source of medication error and harm to patients.[7] It may also result in non-adherence such as missed doses or discontinuation of medicines.[1,2]

Supporting patients with dysphagia

When faced with a patient who is unable to swallow solid dosage forms, consider the following:[8]

- stopping unnecessary medicines
- finding an alternative commercially available dosage form, for example liquid dosage form
- checking if another drug in the same class is available in a different dosage form
- considering extemporaneously compounded medicine – this remains off-label use but is produced using an evidence-based approach
- trialling medication lubricants
- improving swallowing function with the aid of speech pathologists.

Information on appropriate dosage-form alterations

Often medication errors and unsafe medication use occur when dosage forms are altered because of limitations in health professionals' knowledge and the lack of availability of guidelines or appropriate reference materials.[6] The Society of Hospital Pharmacists of Australia has produced the Australian Don't Rush to Crush Handbook to assist with appropriate dosage-form modification.[9] (Similar information is also available as an add-on through MIMS.) The handbook recommends five primary methods of managing a medicine that cannot be swallowed whole.[9] These include:

- dispersing a suitable tablet or capsule in water
- crushing a suitable tablet
- giving an oral liquid form
- prescribing an alternative medicine
- consulting a compounding pharmacy about the availability of other formulations.

Some examples of suitable alternatives when drugs cannot be modified are described in the Table.[9] Additionally, there have been significant developments in both transdermal drug delivery and orally disintegrating dosage forms (e.g. olanzapine wafers) which are easily administered to patients with swallowing difficulties.

Bioavailability and stability considerations

Bioavailability represents the amount of drug that reaches the systemic circulation and elicits an effect.[6] The rate and extent of drug released from the formulation may be altered by the crushing process, resulting in potential changes in the concentration–time profile.[6] Crushing solid dosage forms may also enhance dissolution and increase bioavailability. For example, if controlled-release opioids are crushed, there is a risk of dose dumping and overdose.[6] Alternatively, crushing may lower the dose because of drug loss during preparation and administration.[9-12]

Controlled-release, slow-release and extended-release products are specifically designed to deliver the drug over a prolonged period of time.[6] If a controlled-release formulation is crushed, the duration of the drug's activity is reduced and the entire quantity of the drug may be immediately released resulting in toxicity.[6] Crushing enteric-coated medicines that are acid labile will damage the coating and expose the drug to the acidic stomach environment. This may have a two-fold effect of irritating the stomach lining and causing discomfort, or inactivating the drug if it is extremely susceptible to acid degradation.[9]

Mixing formulations with foods and thickeners

Crushed tablets and capsule contents are commonly mixed with food to assist with both drug administration and adherence. In studies of various health facilities, 23–96% of patients were given at least one medicine daily mixed into their food or beverage to mask the unpleasant taste.[3,5,10] Common foods and beverages used included fruit juices, apple sauce, milk, jams, custards, yoghurt, honey, pudding and in one case sprinkled on a patient's toast.[5,6,9,13]

Dissolution, which is required before a drug can be absorbed, has been investigated when solid dosage forms were crushed in orange juice, honey, jam, yoghurt and a commercial powder thickener.[11,12] Although yoghurt is often used as a vehicle for mixing and administering crushed tablets, this is controversial as it may affect drug dissolution.[12] The adhesive properties of honey and jam may not significantly affect dissolution, but they can be sticky in the mouth and their high sugar content can cause dental problems and affect a patient's glycaemic control.[12]

Potential complexation of the drug with the food or an alteration of the pH environment (which can affect drug stability) may also alter a drug's therapeutic effect.[6] Accurate dosing is also difficult to achieve if patients do not finish their food.[12] Additionally, adding medicines to food and drink may discourage patients from eating.[14]

Table **Examples of drugs unsuitable for dosage-form modification and suitable alternatives**[9]

Drug	Suitable alternative
Enteric-coated drugs	
Proton pump inhibitors	Oral granules or dispersible form
Sulfasalazine EN tablets 500 mg	Sulfasalazine tablets 500 mg (plain)
Slow-release/controlled-release drugs	
Metformin 500 mg/1000 mg extended-release tablet	Metformin 500 mg tablet (plain)
Ferrous sulfate 325 mg modified-release tablet	Ferrous sulfate 150 mg/5 mL liquid
Paracetamol 665 mg controlled-release film-coated tablets	Paracetamol 500 mg tablets (plain or dispersible form)
Gliclazide 30 mg/60 mg modified-release tablet	Gliclazide 80 mg tablet (plain)
Dabigatran 75 mg/110 mg/150 mg capsule	No alternative formulation available – consider other anticoagulants

Reference 9 provides a comprehensive list for prescribers to refer to.

Legal implications

Health professionals who modify formulations have both legal and clinical implications to consider (Box). Administration of any medicine that has been altered from the licensed (original) dosage form by any health professional is considered off-label use and has liability consequences.[9] As modification produces neither an approved or labelled product, administration, particularly if mixed with food or a thickening agent could be seen as unlawful practice.[7] In some cases dosage-form modification may be occurring without the knowledge or authorisation of the prescriber.[2]

Potential liability may be minimised by:[9]

- clearly documenting the reason for altering the medicine
- following evidence-based, safe and effective practice
- obtaining written consent from the consumer or legal guardian where possible
- regularly reviewing the swallowing ability of patients and discussing medication management needs.

Conclusion

Older adults make up 20% of the population, but take 50% of all prescribed medicines. Consequently, the bioavailability, stability, safety, clinical and legal impacts of drug administration and alteration require careful consideration.

The following recommendations may be used as a guide if patients are having swallowing difficulties:

- consider appropriate alternative medicines and formulations
- use guidelines, references or product information before authorising medicines to be crushed
- evaluate the patient's ability to swallow dosage forms regularly. <

Conflicts of interest: none declared

Box Clinical and legal implications of altering solid dosage forms[7,9]

Clinical implications (examples)

Increased toxicity (crushing extended-release products results in dose dumping)

Medication errors

Reduced efficacy (crushing enteric-coated tablets may result in the drug being destroyed by stomach acid)

Instability of the drug (pharmacokinetic changes)

Unpalatability (resulting in non-adherence)

Potential risk to healthcare workers (exposure to cytotoxic drugs)

Unintended aspiration (patient with dysphagia aspirating a medicine)

Incorrect dosage administration (loss of drug during crushing process)

Legal and professional implications (examples)

Off-label drug use (opening a capsule or crushing a tablet before administration)

Lack of consent for administration (patient may be unaware of medication provided in food)

Cross contamination (one crushing device being used for multiple patients' medicines, placing patients at risk of adverse effects such as allergic reactions)

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