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# ASSESSMENT OF CLINICAL PRACTICES FOR CRUSHING MEDICATION IN GERIATRIC UNITS

M. FODIL[1], D. NGHIEM[2], M. COLAS[1], S. BOURRY[1], A.-S. POISSON-SALOMON[1], H. REZIGUE[1], C. TRIVALLE[1]

1. Hôpitaux universitaires Paris-Sud (AP-HP), Hôpital Paul Brousse, Villejuif, France; 2. Département de Médecine générale, Faculté de Médecine Paris-Sud, Paris, France.
Corresponding author: Christophe Trivalle, Service de Gérontologie 1, Hôpital Paul Brousse, 14 avenue Paul Vaillant-Couturier, F-94800, Villejuif, France.
E-mail: christophe.trivalle@aphp.fr

**Abstract:** *Objectives:* To assess the modification of the form of medication and evaluate staff observance of good clinical practices. *Design:* One-day assessment of clinical practices. *Setting:* 17 geriatrics units in the 3 Teaching Hospitals of Paris-Sud (APHP), France. *Participants:* Elderly in-patients with difficulties swallowing capsules and tablets. *Measurements:* Assessment of target-patient prescriptions and direct observation of nurses' medical rounds. *Results:* 155/526 in-patients (29.5%) were unable to swallow tablets or capsules: 98 (40.3%) in long-term care, 46 patients (23.8%) in the rehabilitation unit and 11 (12.2%) in the acute care unit (p = .005). In thirty-nine (27.3%) of the 143 prescriptions studied all tablets were safe to crush and all capsules were safe to open. In 104 cases, at least one medication could not be safely modified, including 26 cases (18.2%) in which none of the prescribed drugs were safe to crush or open. In 48.2% of the 110 medications that were crushed, crushing was forbidden, and presented a potential threat in 12.7% of cases or a reduced efficacy in 8.2% of cases. Crushing methods were rarely appropriate: no specific protective equipment was used (81.8%), crushing equipment was shared between patients without cleaning (95.1%), medications were spilled or lost (69.9%). The method of administration was appropriate (water, jellified water) in 25% of the cases, questionable (soup, coffee, compote, juice, cream) in 55% of the cases and unacceptable (laxative) in 21% of the cases. *Conclusion:* Management of drug prescriptions in patients with swallowing difficulties is not optimal, and may even have iatrogenic effects. In this study, 12.7% of the modifications of the drug form could have been harmful. Doctors, pharmacists and nurses need to reevaluate their practices.

**Key words:** Drugs, dysphagia, elderly, galenic form, tablet crushing.

## Introduction

As patients age, they tend to have more difficulty swallowing, either due to acute pathologies such as poor dental condition, or oral mycoses, or a chronic conditions such as neurodegenerative diseases, dementia or Parkinson's disease. In France, the estimated prevalence of dysphagia is about 30 to 40% for patients living in institutions (long-term care unit and nursing homes) (1-5).

To help these patients receive their treatment, tablets are often crushed, and capsules are opened by the nursing staff then administered by various methods (mixed with water or diverse liquids). The consequences of these practices may be harmful and be a potential iatrogenic risk for the patients as well as the nursing staff (6-8).

First, modification of the galenic form can alter the drug pharmacokinetics (9, 10) because it changes the organism absorption speed and rate. This can induce an overdose particularly with sustained release drugs because crushing this type of drug releases all of the active substance causing high concentrations, sometimes at toxic levels.

Crushing coated medications can also increase the risk of under-dosing through different mechanisms: the uncoated active substance may be degraded by the gastric juices, the active substance may be lost in powdered form, an interaction may occur with the liquid it is mixed with (i.e., enalapril may be degraded in acid liquid), the smell or taste of the unprotected active substance can prevent the patient from taking it (i.e. bisoprolol).

Substances that irritate the mucus membrane can also be released by crushing enteric coated drugs (i.e., alendronic acid/colecalciferol). Certain active substances may be altered when they are exposed to light (i.e. ranitidine or midodrine) (11). Finally, crushing medications can create a health and safety hazard for the nursing staff who crush the medications: without proper protective equipment (gloves, masks, and specific crushing systems), the risk of exposure to harmful substances increases, especially medications containing allergenic, teratogenic or carcinogenic substances (6-8).

Numerous countries have published lists of medications that should not be modified (12-15). The Medication Advisory Board for Paris Public Hospitals released its own guidelines in 2015 based on the national list of oral drugs for crushing tablets and opening capsules (16).

This goal of the present study, performed by an interdisciplinary group of geriatricians, pharmacists, epidemiologists and nurses, was to evaluate the prevalence of this practice in daily practice, assess the actual circumstances of its practice, and evaluate staff knowledge and respect of good clinical practices.

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## Methods

### *Setting and Study Design*

This study evaluated the clinical practices performed for one day between March and June 2015, in the 17 geriatric units (acute geriatric care, rehabilitation unit, long term care and palliative care) of the three Paris-Sud (AP-HP) teaching hospitals.

### *Participants*

First, a survey was performed in each unit to assess which patients had trouble swallowing medications. These patients were considered the target population.

### *Measures*

Collected data included patients' prescriptions (drugs for the morning or afternoon rounds). The observers then assessed and noted how medications were modified and administered based on the direct observations of the nurses' rounds. The data collected for each prescription included: i) the number and type of each tablet and capsule, ii) the nurse's practices: crushing tablets, opening capsules as well as the circumstances and methods of the nurse's practices and the administration.

We then studied whether guidelines were followed by classifying every medication as "safe to crush" "safe to open" "equivalent available" or not, based on the national list of oral drugs for crushing tablets and opening capsules (16).

We could then study the number of drug forms that were modified, whether they could be replaced, or whether the practice might have been harmful.

Observations were performed by two independent observers who were not part of the unit (physician and pharmacist or nurse).

Categorical variables were compared by the Chi-square test. A p value < .05 was considered to be statistically significant.

## Results

### *Prevalence of patients with swallowing difficulties*

One hundred and fifty-five out of 526 patients hospitalized in a geriatric unit (29.5%) were unable to swallow tablets or capsules. This was more frequently observed in the long-term care unit (n= 98, 40.3%) than in rehabilitation units (n=46, 23.8%) or in an acute care units (n=11, 12.2%) (p= .005).

Units specialized in patients with neurodegenerative diseases and behavior problems had the most patients with swallowing difficulties out of all the long-term care units (p=.004) and the rehabilitation units (p=0.006) in the 3 hospitals, (Table 1).

### *Medication form modifications*

Twelve of the 155 patients with dysphagia could not be studied because they were not present in the unit on the day the observers assessed rounds. Thus, data from only 143 prescriptions (one prescription included all drugs prescribed to one patient) were collected.

**Table 1**
Number and percentage of patients with swallowing difficulties in different geriatric units

| Type of unit | Number of patients with swallowing difficulties/Total in unit | Average in per unit (%) |
|---|---|---|
| Acute care | 11/90 | 12.2% |
| Rehabilitation | 46/193 | 23.8% |
| - Specialized in Alzheimer disease | - 19/60 | - 31.7% |
| -Specialized in stroke recovery | - 13/35 | - 37% |
| - Not specialized | - 14/98 | - 14.3% |
| Long term care | 98/243 | 40.3% |
| - Specialized in Alzheimer disease | - 38/68 | - 55.9% |
| - Specialized in behavior and bedridden patients | - 15/34 | - 44.1% |
| - Not specialized | - 45/141 | - 31.9% |

*p=.005 **p=.006 ***p=.004

All the medications were safe to crush or open in 39/143 prescriptions (27.3%) in full conformity with pharmacological guidelines. In 1% of these, all drugs were orally disintegrating tablets (ODT) but were still crushed. All the other prescriptions (n= 104) included at least one medication that was not safe to modify.

A total of 110 drugs were prescribed and modified. Modification was forbidden in 53 of them (48.2%). These were mostly antipsychotic drugs (33%), cardiovascular drugs (20%), painkillers (11%) and cancer treatment (5%).

It was difficult to determine the potential harm of this practice in 30/110 medications (27.3%) because the clinical and pharmacological consequences of tampering have not yet been documented in the literature. For the remaining drugs (n = 23) the risks are well known:

- the risk of overdose with sustained release drugs: biperiden SR, levodopa/carbidopa SR, alfuzosine SR, tamsulosine SR, oxycodone SR, venlafaxine SR;
- mucosal irritation (risedronate, celectol, dutasteride, hydroxycarbamide) or unpalatable taste (donepezil, fluoxetine, mirtazapine);
- teratogenic risk for the staff: dutasteride, hydroxycarbamide, irbesartan;
- a risk of reduced efficacy when crushing gastric-resistant coated medication: divalproex sodium, valpromide, esomeprazole;
- a risk of unproven efficacy of open capsules (acetaminophen, fluconazole, gabapentin) or of crushed tablets (clozapine, pravastatin, ramipril).

This practice could have been a potential threat to patients (toxicity or overdose) for 12.7% of crushed medications

(14/110) and could have unproven or reduced efficacy for 8.2% (9/110).

We also observed misusage of orodispersible (prednisolone oro, oyxcodone oro, risperidone oro, phloroglucinol oro, mirtazapine oro) and dispersible (benserazide/levodopa) tablets because crushing probably modifies their efficacy.

**Table 2**
Prescriptions evaluated and modifications of prescribed drugs

*143 prescriptions studied:*

- 39 (27.3%) prescriptions in which all drugs were safe to crush or open
- 104 (72.7%) prescriptions included at least one medication whose form should not be modified
* 30 (28.8%) prescriptions with no possible substitution
* 33 (31.4%) prescription in which at least 1 drug could have been substituted
* 41 (39.4%) prescriptions for which all drugs could have been substituted

*110 drugs prescribed and modified: modification was forbidden for 53 (48.2%)*
- Potential consequences:
* 30 (27.3%) drugs whose clinical and pharmacological consequences have not been documented in the literature.
* 14 (12.7%) drugs whose modification could have been a potential health threat.
* 9 (8.2%) drugs whose modification could have unproven or reduced efficacy.
- Possibility of substitution:
* 5 (4.5%) drugs were orally disintegrating tablets (ODT).
* 12 (10.9%) could have been substituted.
* 36 (32.7%) drugs with no equivalent substitution.

***Medication substitution***

There was no possibility of substitution for another galenic form in 30/104 (28.8%) prescriptions that included at least one medication with an unalterable form. All of the drugs could have been substituted in 39.4% (n= 41) of prescriptions. In 31.4% (n=33) of prescriptions, at least one drug could have been substituted based on official recommendations (11, 16).

Twelve of 53 medications which could not be crushed could have been replaced by a more appropriate galenic form. The instructions should have been followed for five of these drugs (orodispersible tablets). For the 36 (32.7%) remaining drugs, no equivalent substitution was available in the hospital (Table 2).

***Circumstances and methods of modifying and administering medications***

The staff never completely followed good clinical practice guidelines.

Crushing methods were rarely appropriate: no specific protective equipment was used in 117 (81.8%) of the cases (Table 3).

The medications were usually crushed using a mortar and a pestle.

In 20 cases (13.9%), the drugs were each crushed separately but in 123 cases (86.1%), they were all crushed together.

The mortar was shared and not cleaned between the drugs of two patients 136 (95.1%) of the cases. This practice induced an under-dosage due to loss of powder in 69.9% (n= 100) of cases.

Our survey showed that the method of administration was appropriate (water, jellified water) in 34 cases (23.7%), questionable (cream (n = 26), compote (n = 16), yoghourt (n = 9), juice (n = 9), coffee (n = 6), soup (n = 4) and purée (n = 4)) in 79 cases (55.3%) and unacceptable (laxative) in 30 cases (21%).

**Table 3**
Evaluation of staff practices

| **Hygiene and security** | **n= 143** |
|---|---|
| Hand washing before preparation | 87 (60.8%) |
| Use of specific protection material: | 26 (18.2%) |
| - Blouse | - 0 (0%) |
| - Gloves | - 26 (18.2%) |
| - Masks | - 0 (0%) |
| Use of specific crushing device | 0 (0%) |
| Use of a mortar | 143 (100%) |
| - Cleaning between two patients | - 7 (4.9%) |
| - Medications crushed one by one | - 20 (14%) |
| - Medications all crushed together | 123 (86.1%) |

## Discussion

Swallowing difficulties are common in geriatric units and often require changes in medication. Previous studies have shown (1-4) that the prevalence of patients receiving modified medications in geriatric units is frequent and ranges from 25 to 35%. The present study shows that this event is even more significant in long-term care units: from 12.2% in acute care, to 23.8% in recovery units and reaches 40.3% in long term care.

The long term care unit is often considered to be comparable to nursing homes, but for more severely dependent patients. An Australian study by Paradiso et al (2) showed that medications were modified in 34% of patients in nursing homes.

The need for drug modifications was also higher in units specialized in stroke recovery, neurodegenerative diseases (mostly Alzheimer's disease) and bedridden patients. This is easily explained because those units have more patients with dysphagia or behavior problems.

At least 1/3 of polypharmacy patients attending community pharmacies have dysphagia (17). Polypharmacy is more common in older patients with multiple and chronic diseases making the crushing of medication a primary concern in this group.

This study shows that drug administration practices in patients with swallowing difficulties are not optimal and may be harmful in certain cases. As many as 72.7% of the prescriptions evaluated contained at least one medication that shouldn't

have been altered and almost 28.8% contained only drugs that couldn't be substituted.

Form modification was forbidden in about 48.2% of the drugs prescribed in this study. A study in elderly patients with dysphagia by Vallat et al (15) reported similar results with the pharmaceutical laboratory allowing form modification in 43% of cases. Form modification posed a potential health threat in 12.7% of the cases. These results are similar to the study by Paradiso et al (2) which showed a potential health threat in 17% of cases.

Although in some cases crushing tablets with a narrow therapeutic window such as for fluindione, warfarin, or levothyroxine tablets, is allowed in official recommendations (16) this is still a subject of debate. Because those medications have a narrow therapeutic window there is a risk of underdosage due to the loss of active substance, which could be followed by an increase in the prescribed dose and a potential overdose.

In many cases drugs cannot be modified because the clinical and pharmacological consequences have not yet been clarified. However, it is usually because there is a potential health threat for the patient, although none have been reported in this study (6-11).

For example, slow release medications, which cannot be crushed due to a risk of overdosage, are often prescribed to patients with neurodegenerative diseases such as Parkinson's disease, who frequently have dysphagia (8-10). Thus, better galenic forms must be developed for these patients with the help of pharmaceutical industry.

In the United Kingdom, doctors can order "special liquids" from the manufacturers which are special order medicines that are not licensed products when there is no suitable licensed alternative. Liquid forms for other medications could also be developed by the pharmaceutical industry (13) and slow release patches could be another alternative.

More than 20% of drugs whose form should not be modified could have been replaced with a direct equivalent that was more appropriate for these patients: an oral solution, an oral suspension, a sublingual treatment or a dispersible form. However, there were no direct equivalents 67.9% of the time; sometimes because it was not available in the hospital, but usually because they did not exist.

In those cases, the physician should consider other options:

- Is the drug absolutely necessary for these sometimes severely dependent patients? Can the indication of the particular drug be reevaluated, such as drugs for benign prostatic hyperplasia, statins, proton pump inhibitors…? Certain screening tools can also be used to help reduce inappropriate prescriptions (for example, Beers list, STOPP/START tool) (18, 19);

- Switch to a more suitable drug form in the same therapeutic class.

We also observed a high prevalence of inappropriate modification of medications by the nursing staff, which represented a health risk for them and the patients. No protective equipment was used 81.8% of the time and the mortar was shared between patients 95.1% of the time, which could have exposed a patient to a drug that was not prescribed.

Thus, secure crushing devices as well as protective material must be used in geriatric units.

In 76.3% of the cases inadequate food or liquid vehicles were used. Administration of medicine mixed with food or drinks is common in elderly patients, and the results in our study are similar to other reports in the literature (20).

Moreover, medications were crushed together in 86.1% of the cases, creating a risk of potential pharmacokinetic interactions (21). The study by Caussin et al (1) in 2012 reported similar results with crushing of different drugs together in 75% of the cases.

In 21% of the cases, laxatives were being used as a vehicle for delivery. This is problematic because absorption of the active substance may be reduced when it is associated with laxatives due to increased intestinal transit speed. For example, cases of seizure have been reported following an interaction between laxatives and antiepileptic drugs (22, 23).

A study by Bourdenet et al (24) showed that when national guidelines are followed, practices for drug administration in patients with swallowing disorders improve. Thus, it is important to have health professionals who manage older patients work as a team (nursing staff, pharmacists and doctors) to revise practices and implement official updated guidelines.

## Conclusion

The results of this study show that medication modifications are frequent in geriatric units. However, in many cases the methods of modification do not comply with good practices and information and staff training on crushing must be improved.

A standardized geriatric assessment by doctors and especially geriatricians should determine whether the patient has swallowing difficulties. It is especially important not to prescribe medications whose forms cannot be altered (sustained release, mucus membrane irritant, enteric-coated, film-coated, teratogenic potential) in these patients and prescribe liquid forms, or effervescent tablet equivalents. If this is not possible alternative medications should be considered and the treatment should be evaluated to make sure it is useful.

Pharmacists can help doctors, for example, by introducing notes such as "not crushable" "not to be opened" in the prescription as well as by making equivalent medications available.

A patient's swallowing capacity should be noted for nurses and the prescribing physician should be informed. For patient as well as the nurse's safety, crushing must be performed with specific devices such as secure pill crushers. Acquisition of this equipment needs to be a priority, especially in long-term care units.

More studies are needed by both physicians and the industry

to improve and develop more appropriate galenic forms for patients with swallowing disorders.

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*Ethical standard:* This study complies with French law.

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