



ELSEVIER

Contents lists available at ScienceDirect

Current Therapeutic Research

journal homepage: www.elsevier.com/locate/cuthre

Pill Properties that Cause Dysphagia and Treatment Failure

Jeremy Fields, MD^{1,2}, Jorge T. Go, MD, MSc^{1,3}, Konrad S. Schulze, MD^{1,4,*}¹ Department of Medicine, University of Iowa; Iowa City, Iowa² McFarland Clinic, Ames, Iowa³ Mercy Gastroenterology Clinics, Clive, Iowa⁴ VAMC, Iowa City, Iowa

ARTICLE INFO

Article history:

Accepted 12 August 2015

Key words:

dysphagia
medical compounds
pill swallowing

ABSTRACT

Background: Pills (tablets and capsules) are widely used to administer prescription drugs or to take supplements such as vitamins. Unfortunately, little is known about how much effort it takes Americans to swallow these various pills. More specifically, it is not known to what extent hard-to-swallow pills might affect treatment outcomes (eg, interfering with adherence to prescribed medications or causing clinical complications). It is also unclear which properties (eg, size, shape, or surface texture) Americans prefer or reject for their pills. To learn more about these issues, we interviewed a small group of individuals.

Methods: We invited individuals in waiting rooms of our tertiary health care center to participate in structured interviews about their pill-taking habits and any problems they have swallowing pills. We inquired which pill properties they believed caused swallowing problems. Participants scored capsules and pills of representative size, shape, and texture for swallowing effort and reported their personal preferences.

Results: Of 100 successive individuals, 99 participants completed the interview (65% women, mean age = 41 years, range = 23–77 years). Eighty-three percent took pills daily (mean 4 pills/d; 56% of those pills were prescribed by providers). Fifty-four percent of participants replied yes to the question, "Did you ever have to swallow a solid medication that was too difficult?" Four percent recounted serious complications: 1% pill esophagitis, 1% pill impaction, and 2% stopped treatments (antibiotic and prenatal supplement) because they could not swallow the prescribed pills. Half of all participants routinely resorted to special techniques (eg, plenty of liquids or repeated or forceful swallows). Sixty-one percent of those having difficulties cited specific pill properties: 27% blamed size (20% of problems were caused by pills that were too large whereas 7% complained about pills that were too small to sense); 12% faulted rough surface texture; others cited sharp edges, odd shapes, or bad taste/smell. Extra-large pills were widely loathed, with 4 out of 5 participants preferring to take 3 or more medium-sized pills instead of a single jumbo pill.

Conclusions: Our survey results suggest that 4 out of 5 adult Americans take several pills daily, and do so without undue effort. It also suggests that half of today's Americans encounter pills that are hard to swallow. Up to 4% of our participants gave up on treatments because they could not swallow the prescribed pills. Up to 7% categorically rejected taking pills that are hard to swallow. Specific material properties are widely blamed for making pills hard to swallow; extra-large capsules and tablets are universally feared, whereas medium-sized pills with a smooth coating are widely preferred. Our findings suggest that health care providers could minimize treatment failures and complications by prescribing and dispensing pills that are easy to swallow. Industry and regulatory bodies may facilitate this by making swallowability an essential criterion in the design and licensing of oral medications. Such policies could lessen the burden of pill taking for Americans and improve the adherence with prescribed treatments.

Published by Elsevier GmbH. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

This study was presented as a poster at Digestive Disease Week 2013, May 20, 2013, Orlando, Florida.

* Address correspondence to: Konrad Schulze, MD, University of Iowa Hospitals and Clinics, Clifton Center for Digestive Diseases, 200 Hawkins Dr, 4551 JCP, Iowa City, IA 52242.

E-mail address: konrad-schulze@uiowa.edu (K.S. Schulze).

Introduction

In a population survey conducted more than 30 years ago¹ 40% of American adults reported pills getting stuck in their throat; that

<http://dx.doi.org/10.1016/j.cuthres.2015.08.002>

0011-393X/ Published by Elsevier GmbH. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

is, pills caused the sensation of choking or of a lump in the throat (globus). Similar findings were reported in Norway,^{2,3} and recently in Germany.⁴ In our gastroenterology practice, we regularly ask patients about problems swallowing food. Many patients take that occasion to complain about having a hard time swallowing some pills. This made us wonder to what extent today's Americans experience difficulties when taking pills and how this relates to specific pill properties. We asked 100 individuals in waiting areas of our tertiary health care center whether they experienced problems when swallowing pills and which properties make pills hard to swallow.

Methods

Following approval by the Institutional Review Board we conducted structured interviews in waiting areas of University of Iowa Hospitals and Clinics. We approached the drivers (eg, relatives and friends) of patients undergoing endoscopic procedures and individuals having prescriptions filled at the outpatient pharmacy (we assume they were mostly patients who attended a specialty clinic that day). Once consent was obtained, we conducted structured interviews with participants. Our questionnaires were previously designed and tested with input from physicians, nurses, secretaries, and ancillary personnel of the tertiary health center. The first questionnaire focused on the participant's age and history of pill taking, including number of daily pills, prescribed by a provider or self, problems swallowing pills/food, and techniques used to deal with difficult pills (see Supplemental Figure 1 for a complete list of questions). Using actual samples of common medications as models (Figure), the second interview (Supplemental Figure 2) inquired about preferences for pill size, shape, and texture. Many questions addressed similar issues from different angles and viewpoints to serve as internal controls.



Figure. Examples of pills with different properties. In conjunction with Questionnaire 2 (Supplemental Figure 2), participants were shown and asked to feel commonly used pills. They were asked to place pills into score boxes labeled according to swallowing effort (1 = easy, 2 = slight, 3 = considerable, and 4 = hard/impossible). Participants were also asked to compare pills of different type (capsule vs tablet), size (large, medium, or small), shape (round or oblong), and coating/textures (firm, smooth, or crumbling) and indicate their preference of one over the other.

Participants provided estimates of their swallowing effort by placing the pill samples into score boxes (box 1 = easy, no effort and box 4 = hard or impossible to swallow).

All interviews were conducted during summer 2012 by fellows in gastroenterology-hepatology. Before this, fellows went through the structured interview with 1 of the authors. They then performed mock interviews with peers while being supervised by 1 of the authors. Fellows did not obtain a medical history from participants or inquire what their medications were for. Fellows were debriefed after completing the interviews.

Results

Population

Of a total of 100 individuals who consented all but 1 completed the structured interviews (73 were drivers—family or friends—of patients undergoing endoscopic procedures and 26 were individuals waiting to have a prescription filled). Table 1 gives demographic characteristics of the participants and their pill-taking habits. The majority took several pills daily, spending only a few seconds on individual pills and no more than 1 minute on all pills. Those following a regimen of 10 or more pills estimated that it took them about 1 minute per pill. Most participants swallowed every pill separately; a few hurried and swallowed handfuls of pills all at once.

Problems swallowing pills

Half of participants reported having problems swallowing some of their pills (Table 1), with 10% strongly expressing that those pills “should never have been made or used.” Seven percent

Table 1
Interview participant characteristics and experiences with pills.*

Variable	Result
Approached	100
Completed structured interviews	99
Age (y)	41
Range (y)	23–77
Female gender (%)	66
Taking pills on a daily basis (%)	81
No. of daily pills	4.1
Range	1–19
Taking 5 or more (%)	27
Taking 10 or more (%)	10
Taking 15 or more (%)	5
Prescribed by provider vs self (%)	56 vs 44
Sometimes experienced difficulties with pills (%)	54
Frequent ongoing pill sticking/globus sensation (%)	13
Solid food dysphagia (%)	8
Pills as bad as food (%)	5
Pills worse than food (%)	2
Clinical complications from pill swallowing† (%)	4
Measures to ensure effective swallowing (%)	
Plenty of water	55
Series of power swallows	33
Cut, break, or crush large tablets	30
Swallow in viscous medium (eg, apple sauce or chewed bread)	7
Stop hard-to-swallow medication	6
Position pill to back of tongue, turning head	2
Open capsule, swallow contents	1
Request easier preparation	1

* Participants were visitors approached in clinic waiting rooms. Sixty-six were family or friends of patients undergoing an endoscopic procedure. Thirty-four were passing through the outpatient pharmacy.

† Clinical complications included 1 report of pill esophagitis, 1 report of pill impaction leading to persistent fright of all oral medications, and 3 reports of stopped prescribed medications.

Table II
Pill properties, problems, and preferences revealed during structured interviews

Interview interest area	Result
Cause of difficulty (%)	
Pills too large or bulky	20
Difficulties with specific large capsules*	6
Difficulties with specific large tablets†	6
Small pills or pill fragments‡	7
Pills too dry, rough, sticky or hard	12
Pill of odd shape, with sharp edges	3
Pills smell/taste bad	3
Preferences regarding pill properties (%)	
Capsules vs tablets	50 vs 49
Round vs oblong (oval)	50 vs 49
Coated vs chewable	90 vs 9
Anticipated swallowing effort§	
Jumbo tablets or capsules (> 13 × 4 × 4 mm)†	3.6
Small coated tablet (low-dose aspirin)	1.2
Medium-sized tablets with smooth coating	1.3–1.6

* Antibiotic agents were a common active ingredient of very large capsules.

† Calcium and potassium were common ingredients of jumbo tablets.

‡ Small pills or pill fragments included preparations of thiazide diuretics, thyroid supplement, birth control pills, beta-blocking agents, and histamine 2 blockers.

§ 1 = easy to swallow to 4 = hard/impossible to swallow

categorically refused to ever take hard-to-swallow pills. Four percent recounted serious complications: 1% pill esophagitis, 1% pill impaction, and 2% stopped treatments (an antibiotic and a prenatal supplement) because they could not swallow the prescribed pills.

Responsible pill properties

Many participants (37%) faulted specific pill properties (Figure) for problems taking pills (Table II), with size the most common complaint. Jumbo tablets and capsules were widely loathed, and 4 out of 5 participants would rather take the requisite amount of drug in several medium-sized preparations. Tiny tablets and split pills were disliked for being hard to sense, gritty, and prone to stick to gums. Six female participants voiced frustrations with tablets sized 4 mm or less, whereas 2 tall men objected even to tablets 4 to 5 mm in size. All participants expressed that medium-sized pills with smooth coatings were easy to swallow and gave oval caplets of ~6 mm length a near perfect swallow score, and gave extra-large tablets with a rough surface a failing score. Participants split evenly regarding type and shape of pills they preferred: half preferred capsules to tablets of the same size, praising their smoothness and easy gliding. The other half rejected capsules for being sticky and dissolving too easily. Given their choice of shape, half of the participants opted for oval, and the other half opted for round tablets of the same size. Only 9% opted for the chewable preparation of low-dose aspirin. All others preferred the coated variety of low-dose aspirin.

Discussion

Pills (ie, tablets and capsules) are widely used for the oral delivery of drugs (therapeutic agents and supplements of vitamins or minerals) but little is known about efforts or problems Americans might have taking these pills. Pills are specifically prepared as stable vehicles for drugs that upon swallowing release precise amounts of active ingredients in the intestine.⁴ Their design and manufacture is not specifically geared at making pills easy to swallow. No industrial guidelines exist that ensure the swallowability of pills, and regulatory bodies do not ensure that pills require no undue swallowing effort. Little is known about material

properties that might affect the oropharyngeal transit and swallowability of pills. Pill dysphagia is not reported as a side effect of taking drugs.^{4,5}

Our survey results suggest that 4 out of 5 Americans take pills on a daily basis and that about half have encountered pills that are hard to swallow. Half of our participants regularly make extra efforts when swallowing difficult pills and 4 out of 5 preferred to take several medium-sized pills over 1 jumbo pill. Four participants experienced serious complications, including pill esophagitis, pill impaction, or failure to complete treatments because of pills that were hard to swallow.

One may question how representative our findings are for the American public at large. The scope of our study is limited by the small number of participants, and by selecting participants among visitors to our tertiary health care center. Individuals who accompany patients to endoscopic procedures and especially individuals waiting to have medications filled might very well take more pills and experience more problems swallowing than a typical American. On the other hand we did not specifically select populations likely to experience pill dysphagia such as the very young or very old, patients taking many medications or with multiple comorbidities, or patients with cerebrovascular disease.^{6–8} We have virtually no information on the health status of our participants and for that reason alone we cannot claim that our findings are representative of the American public at large or specific population groups. The shortcomings of our study should not distract from 2 important findings: far too many Americans experience problems swallowing some pills and most of these problems might be prevented by the use of easy-to-swallow pills. Both of these findings are in line with the results of large American and Norwegian surveys performed years ago and a German survey conducted around the same time as ours.^{1–5,9–11} Like the recent German work,⁴ our study revealed serious problems and complications caused by hard-to-swallow pills that should not be ignored, even if they occur much less commonly than reported here. Similar to the German study,⁴ our participants admitted to opening, breaking, or crushing pills without checking with a health care provider. Such tampering could be harmful by interfering with the pharmacodynamic parameters and safety profiles of preparations that are specifically formulated for controlled release of active ingredients.⁴

Physical properties of pills remain a common source of frustration. Jumbo pills are known to require multiple swallows to clear the esophagus and are prone to causing pill dysphagia.^{4,12} At least one-third of participants blamed wrong size, shape, or texture for making pills difficult to swallow. Extra-large, bulky capsules and tablets were loathed by virtually every participant. Most participants expressed a preference for taking several medium-sized pills over a single bulky pill. It is noteworthy that many participants loathed pills that are too small. Small pills are difficult to sense, leading to uncertainty about their clearance from the oropharynx. This also might explain the aversion of many participants to chewable tablets: little fragments can stick to gums or in mouth recesses. These findings suggest it would be ideal if all oral medicinal preparations were of medium size, meaning a pill length of between 6 and 13 mm. This range is similar to the dimensions of capsules and tablets that caused least difficulties in a German family practice population.⁴ Further studies may help to determine the optimal upper and lower limits of pill size for a typical American. Eventually, it might help to know how gender, age, body size, and specific medical conditions affect a patient's ability to swallow pills.

The width and height of pills, their shape, and their surface texture are additional parameters that affect swallowing. Capsules 18 mm in length were readily acceptable to German patients who had problems with round tablets > 8 mm diameter, and oblong or oval tablets > 13 mm.⁴ Our participants wished for a firm and

smooth coating for pills to glide easily without sticking or disintegrating, but disagreed whether capsules or tablets better fit that bill. They were evenly divided regarding the ideal shape of tablets, with as many preferring round, flat tablets as oblong or oval ones. Oblong tablets clear the esophagus quicker than round ones,¹² but how pill shape affects the oropharyngeal passage and clearance has not been studied in detail. Pills presumably follow the same general trajectory as food and drink from the dorsum of the tongue through the left or right piriform sinus and into the esophageal inlet. Yet pills are profoundly different from a malleable bolus of food that readily adapts its shape to the structures through which it passes. Pills may collide with and be deflected by pharyngeal structures, and therefore be in need of repeated course corrections. It is conceivable that short, oval or round pills readily bounce off or roll over obstacles, whereas long or oblong pills would be likely to get stuck. This might explain the preference for round, oval, or even odd pill shapes that many of our participants and German patients⁴ expressed.

It would be good to take measures to reduce the burden of pill taking for Americans at large, and presumably even more so for patients with swallowing problems (whether from cerebrovascular accidents, oropharyngeal operations, or other disease processes). Rapidly disintegrating compounds have been developed for this explicit purpose, and have been shown to outperform solid pills in patients with dysphagia.⁵ Carnaby-Mann et al⁵ pioneered the objective assessment of pill swallowing by measuring patient acceptance, swallow effort, and effectiveness of oropharyngeal clearance. Similar studies might help to design and market additional preparations that require minimal swallowing effort. Imaging studies might provide a better understanding of the dynamic interactions of pills with oropharyngeal structures.^{13–17} Ultimately, it might be possible to design a drug-delivery vehicle that outperforms currently available capsules and tablets for the swift and effortless oral delivery of medications. Regulatory bodies like the Food and Drug Administration should be called upon to provide guidelines for the manufacture and prescription of pills that are easy to swallow. It might also help if regulatory bodies reported on hard-to-swallow preparations and advised on which preparations can safely be cut down in size or taken apart. Health care providers, including pharmacists, ideally should regularly ask patients about their preferences, and preferentially prescribe and dispense medicinal formulations requiring minimal swallowing effort. Health care providers often choose to prescribe large pills in an effort to keep the total number of pills in a regimen to a minimum. Unfortunately this strategy seems to more often increase rather than decrease the pill burden to patients and contribute to decreased satisfaction because patients believe their health care providers are ignoring preferences or underrating swallowing problems, especially when it comes to unwieldy pills.

Acknowledgments

Dr. Jeremy Fields spearheaded the project. Dr. Peter Kaboli, Iowa City VAMC, offered critical advice on structured interviews. Dr. Lisa Mascardo and Brenda Carmody, UIHC pharmacy, advised on pharmaceutical preparations and drug dispensing; they authorized interviews in the waiting area of the outpatient pharmacy. Dr. Jorge Go performed the data entry and processing. Dr. Schulze mentored Drs. Field and Go throughout the study and authored the text for publication. Administrative support was provided by Jessica Vales-tin, research assistant in Motility and Neurogastroenterology Core of the Clifton Center for Digestive Diseases (Dr. Satish Rao, director).

Drs. Fields, Go and Schulze had full data access. Gastroenterology fellow trainees performing interviews included Drs. Abu-Rajab M, Akhauri B, Bangsund P, Eliason E, Fallon E, Fields J, Go J, Haslem B, Huerta-Alardin A and Platt A. Parts of this work were presented by Dr. Jeremy Fields as a poster at Digestive Week 2013. Publication assistance was provided by Carole Kern. There was no funding support for this research.

Conflicts of Interest

The authors have indicated that they have no conflicts of interest regarding the content of this article.

Appendix

Supplementary data

Supplementary data associated with this article can be at <http://dx.doi.org/10.1016/j.curtheres.2015.08.002>.

References

- Harris Interactive Survey online study between May 27 and June 4, 2003. <http://www.harrisinteractive.com/>. Schwarz Pharma, Inc., based in Milwaukee, WI. Accessed November 13, 2014.
- Strachan I, Greener M. Medication-related swallowing difficulties may be more common than we realize. *Pharmacy in Practice*. 2005;15(10):411–414.
- Andersen O, Zweidorff OK, Hjelde T, Rodland EA. Problems when swallowing tablets. A questionnaire study from general practice. *Tidsskr Nor Laegeforen (abstract of Norwegian text)*. 1995 Mar 20;115(8):947–949 PMID: 7709385.
- Schiele JT, Quinzler R, Klimm HD, Pruszydo MG, Haefeli WE. Difficulties swallowing solid oral dosage forms in a general practice population: prevalence, causes, and relationship to dosage forms. *Eur J Clin Pharmacol*. 2013 Apr;69(4):937–948.
- Carnaby-Mann G, Crary M. Pill swallowing by adults with dysphagia. *Arch Otolaryngol Head Neck Surg*. 2005 Nov;131(11):970–975.
- Strachan I. Medicines and older people: a nurses' guide to administration. *Br J Community Nurs*. 2001 Jun;6(6):296–301. PMID: 11873205. <http://dx.doi.org/10.12968/bjcn.2001.6.6.7075>.
- Vakil NB, Traxler B, Levine D. Dysphagia in patients with erosive esophagitis: prevalence, severity, and response to proton pump inhibitor treatment. *Clin Gastroenterol Hepatol*. 2004 Aug;2(8):665–668. PMID: 15290658. [http://dx.doi.org/10.1016/S1542-3565\(04\)00289-7](http://dx.doi.org/10.1016/S1542-3565(04)00289-7).
- Kawamura O, Easterling C, Aslam M, Rittmann T, Hofmann C, Shaker R. Laryngo-upper esophageal sphincter contractile reflex in humans deteriorates with age. *Gastroenterology*. 2004 Jul;127(1):57–64. PMID: 15236172. <http://dx.doi.org/10.1053/j.gastro.2004.03.065>.
- Preston M, Morris H. Dysphagia, the impact on dispensing doctors. *Dispensing Doctor J*. 2005;21(3):11–15.
- Bending A. Hiding medicines or hiding problems? *Nursing and Residential Care*. 2001 Sep;3(9):439–441.
- Ferguson DD, DeVault KR. Dysphagia. *Curr Treat Options Gastroenterol*. 2004 Aug;7(4):251–258 PMID: 15238199.
- Hey H, Jørgensen F, Sørensen K, Hasselbalch H, Wamberg T. Oesophageal transit of six commonly used tablets and capsules. *Br Med J (Clin Res Ed)*. 1982 Dec 11;285(6356):1717–1719. PMID: 6816343. PMID: PMC1500648.
- Williams RB, Pal A, Brasseur JG, Cook IJ. Space-time pressure structure of pharyngo-esophageal segment during swallowing. *Am J Physiol Gastrointest Liver Physiol*. 2001 Nov;281(5):G1290–G1300. PMID: 11668038.
- Nicosia MA, Robbins JA. The fluid mechanics of bolus ejection from the oral cavity. *J Biomech*. 2001 Dec;34(12):1537–1544. PMID: 11716855. [http://dx.doi.org/10.1016/S0021-9290\(01\)00147-6](http://dx.doi.org/10.1016/S0021-9290(01)00147-6).
- Dantas RO, Kern MK, Massey BT, Dodds WJ, Kahrilas PJ, Brasseur JG, Cook IJ, Lang IM. Effect of swallowed bolus variables on oral and pharyngeal phases of swallowing. *Am J Physiol*. 1990 May;258(5 Pt 1):G675–G681. PMID: 2333995.
- Dantas RO, Dodds WJ, Massey BT, Kern MK. The effect of high- vs low-density barium preparations on the quantitative features of swallowing. *AJR Am J Roentgenol*. 1989 Dec;153(6):1191–1195.
- Cook IJ, Dodds WJ, Dantas RO, Massey B, Kern MK, Lang IM, Brasseur JG, Hogan WJ. Opening mechanisms of the human upper esophageal sphincter. *Am J Physiol*. 1989 Nov;257(5 Pt 1):G748–G759.