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RESEARCH ARTICLE

Swallowing difficulties with oral drugs among polypharmacy patients attending community pharmacies

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Abstract *Background* Swallowing difficulties are common and can affect patients' ability to take solid oral dosage forms, thus compromising medication adherence. Strategies developed by patients to overcome such difficulties while taking medicines have seldom been described. *Objective* To determine prevalence and characteristics of swallowing difficulties among primary care patients attending their community pharmacies; to explore strategies developed by patients to overcome their difficulties, and health professionals' awareness of these problems. *Setting* Prospective study with a semi-structured questionnaire in random community pharmacies located in two Swiss regions. *Method* In each pharmacy, an interviewer asked 16 questions to each consecutive patient (18 years and older) with a prescription for at least 3 different solid oral forms. *Main outcome measure* Quantification of number of patients with swallowing difficulties and detailed description of difficulties. *Results* Among 122 pharmacies, 59 (48 %) accepted to join the study and 410 patients were enrolled. Thirty-seven patients (9.0 %) reported ongoing swallowing difficulties, while 55 patients (13.4 %) reported past difficulties. For the majority of patients, difficulties occurred at each single dose (83.7 %), with a single medication (59.8 %) and lasted for less than 12 months (53.8 %). Number of tablets was not the main trigger. Swallowing difficulties impaired extremely daily life in 12 % of the patients. Intentional non adherence (23 % of patients) and altering the oral dose formulation were the most common and potentially harmful strategies used by patients to overcome their swallowing difficulties. According to the patients, pharmacists and physicians rarely inquired about their swallowing difficulties. *Conclusion* We report a fairly high prevalence of swallowing difficulties in polypharmacy patients attending their community pharmacies. Pharmacists have to interview patients on their swallowing difficulties in a more systematic way, support patients in finding solutions and refer them to their physician if necessary to ensure continuity in care.

Keywords Community pharmacy · Dysphagia · History · Prevalence · Solid dosage forms · Swallowing difficulties · Switzerland

Impacts on practice

- Many polypharmacy patients attending community pharmacies in Switzerland have swallowing difficulties.
- Intentional non adherence and altering the oral dose formulation are the most common and potentially harmful strategies used by patients to overcome their swallowing difficulties.

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- Pharmacists have to interview patients about their swallowing difficulties in a more systematic way.

Introduction

Dysphagia occurs in any age group although it is more common among elderly people [1]. It has been reported to be 35 % amongst the general population over 50s [2], 12 % amongst hospitalized patients [3] and 68 % amongst nursing home patients [4]. It can severely undermine nutrition, impair quality of life, and affect patients' ability to take solid oral dosage forms, thus compromising medication adherence.

Reported prevalence of difficulties in swallowing solid oral medications varies widely between studies. It was observed in 14 % community-dwelling people over 75 years [5]. A survey conducted in community pharmacies in England and Ireland enrolled patients with suspected difficulties in swallowing medicines and found a 60.2 % prevalence of difficulties at some time; 68 % of patients opened capsules or crushed tablets, while 64 % admitted not taking their medication consequently [6]. In a recent study, 37.4 % of patients attending their GP's practices reported swallowing difficulties with medicines [7].

Although difficulties in swallowing oral forms are common and their potential clinical risks high, the literature provides little information about this issue in primary care patients, especially on outcomes and solutions found by patients to overcome their swallowing difficulties. We conducted a survey investigating difficulties in swallowing solid oral dosage forms in patients attending a community pharmacy, strategies developed by the patients to overcome the difficulties while taking medicines, and health professionals' awareness of these problems.

Aim of the study

Firstly, to determine the prevalence, characteristics and duration of swallowing difficulties (ongoing and past) among primary care patients attending their community pharmacies. Secondly, to explore impairment of daily life and coping strategies used by patients to overcome their difficulties and whether these difficulties were addressed by their pharmacist and physician.

Method

Random selection of pharmacies

This prospective study was conducted between March and May 2010 in community pharmacies in two Swiss regions: Basel area (German speaking) and Lausanne area (French speaking). The official listing of registered pharmacies in the areas was numbered. Then, a list of computer generated random numbers was used to invite pharmacies. Information on the survey was mailed to the pharmacists. One week later, the investigators called each pharmacist to ask for participation. If the pharmacist refused to participate or did not answer after three calls, the pharmacy was excluded and the next pharmacy on the random list was approached.

Development of the interview-guide

A 16-item survey was developed according to relevant dimensions [6], in interrogative and third-person format, avoiding double negations and ambiguity (see Appendix in the ESM). The dimensions were: current number of daily oral prescribed medicines, basic sociodemographic information (e.g., age, gender), swallowing difficulties (5 items; type, frequency, duration and timing of difficulties; number and name of involved medicines), patients' strategies for overcoming difficulties (4 items), impact of the difficulties on medication adherence and on daily functioning (2 items), perception of state of health (1 item), and whether patients had notified their difficulties to their physician and pharmacist (2 items).

Patient's perception of current state of health was explored with a single-item measure of health-related quality of life, i.e., with the first question of the General Health scale of the SF-36 questionnaire [8]. This item has been shown to successfully capture patient's perspective on health status and to discriminate between clinically distinct patient groups equally well as longer questionnaires [9]. Further, the SF-36 has been translated in many languages, including French and German. Answers rank from "excellent" to "poor" and were scored from 5 to 1. A high score defines a more favourable health.

Since most people falsely tip their head backwards to allow the tablet to slip towards the back of the mouth [6], we formulated a specific question to explore patient's usual technique for swallowing tablets.

The survey combined six closed-ended questions (yes/no answer; number), five open-ended questions and five Likert-scale items.

Translation of the interview-guide

The interview-guide was developed in French and tested with 3 monolingual subjects for clarity and comprehensiveness. Translation in German was done according to the "Principles of Good Practice" for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures [10]. The back translation technique was performed by two translators, one conducting the forward

translation and the other one conducting the back translation. The source language versions were compared and discrepancies lead to modifications in the target language version until both translators were satisfied with semantic and conceptual equivalence between source and target languages. The corrected target language version was tested with 3 monolingual subjects for clarity and comprehensiveness.

Observational time and inclusion criteria

In each area, the same interviewer conducted all interviews after a preliminary joint training with both interviewers to harmonize the procedure and ascertain quality in interviewing technique and coding. Each interviewer spent 4 h consecutively in each pharmacy. The pharmacist could choose one of the following time slots: from 8 a.m. to 12 a.m.; from 10 a.m. to 2 p.m.; from 1 p.m. to 5 p.m., and from 3 p.m. to 7 p.m. The pharmacist screened each consecutive eligible patient (18 years and older with a prescription for him/herself with at least 3 different solid oral medicines) and referred her/him to the interviewer who asked patients for participation. In case of acceptance, the interviewer asked the questions on the spot and filled in the obtained answers in the interview-guide. The study was approved by the Swiss Ethic Commission (canton de Vaud) for clinical research, Lausanne, Switzerland.

Calculation of sample size

Based on a prevalence of 26 % swallowing difficulties as published by Andersen et al. [11], a total of 296 patients had to be interviewed to ensure that the 95 % confidence interval spans 21–31 % swallowing difficulties [12].

Data analysis

Results are presented using descriptive statistics (i.e., percentages, medians ± interquartile range (Q25–Q75), means ± one standard deviation). The data were analyzed using independent-sample t tests and χ^2 tests. Two-sided p values below 0.05 were considered significant. All completed data sheets for every patient were entered in a Microsoft Excel spreadsheet in Lausanne and in the Statistical Package of the Social Sciences version 15.0 (SPSS, Inc, Chicago, Illinois, USA) in Basel. After control for internal validity, raw data from both centres were merged for analysis. Descriptive statistics and graphical analysis were conducted using Microsoft Excel 2007 and Stata Statistical Software™ release 12 (StataCorporation, College Station, Texas, USA).

Results

Among the 122 approached pharmacies, 59 (48.4 %) accepted to join the study. Reasons evoked by pharmacists for refusal were: too few eligible patients or patients speaking another language than the local one (23.8 %), lack of time or interest (19.0 %), lack of space (14.3 %), did not want to bother their patients (11.1 %) or disturb the staff workflow (11.1 %), no reason given (20.6 %). Among 505 recruited patients, 410 (81.2 %) were enrolled (Table 1); inclusion rates were well balanced between both study sites. Lack of time (54.7 %) and interest (27.4 %) as well as language issues (13.7 %) were the most frequent reasons evoked by patients to refuse participation. All included patients answered all questions (no missing data).

A total of 37 patients (9.0 % of all patients) reported ongoing difficulties in swallowing oral drugs, while 55 patients (13.4 %) reported past swallowing difficulties at some time during a personal history of drug intake (Table 1). There was no statistical difference between the study sites (ongoing/past difficulties: 13/23 patients in Basel vs. 24/32 patients in Lausanne; $p = 0.66$). Patients' and treatments' characteristics are described in Table 2. There was no difference in gender ($p = 0.1$), age ($p = 0.6$), daily number of solid oral drugs ($p = 0.8$) or current state of health ($p = 0.1$) between patients with ongoing and those with past difficulties. Most patients described their health as good (44 %) or fair (34 %).

Ongoing or past swallowing difficulties were triggered by a single medicine in 55 (59.8 %) patients, by some medicines in 28 (30.4 %) and by all medicines in 9 (9.8 %) patients. The difficulties occurred at each single dose for the majority of patients (83.7 %). The large size and sticky coating of drugs were perceived as the main causes of swallowing difficulties (Fig. 1), far beyond bad taste of drugs, and patients' mouth or pharyngeal disabilities. Shape was never mentioned as a trigger of swallowing difficulties. Of the 104 drugs mentioned by patients, 41 were analgesics; paracetamol (acetaminophen) was the most frequently quoted (n = 19). In 53.3 % of patients, the difficulties lasted for less than 12 months (Fig. 2). Past difficulties were depicted as shorter than ongoing difficulties (<6 months for 32 patients with past vs. 10 with ongoing difficulties; $p = 0.001$).

The most frequently techniques used by patients to overcome swallowing difficulties were to drink more water, split or crash the tablet or mix it with food (Fig. 3). They either crushed their tablet manually, with a knife, a spoon or even with a garlic press, with a mortar, a pill crusher or pill splitter. Nineteen patients (21 %) also tried other forms as effervescent or chewable tablets, syrup, drops, powder or granule. These forms were perceived as easier to swallow but the major perceived drawback was

Table 1 Characteristics of enrolment in the two study centers Basel (German speaking) and Lausanne (French speaking)

Number of	TOTAL	Basel	Lausanne
Contacted pharmacies	122	61	61
Enrolled pharmacies	59 (48.4 %)	30 (49.2 %)	29 (47.5 %)
Eligible patients	659	374	285
Recruited patients[a]	505 (76.6 %)	230 (61.5 %)	275 (96.5 %)
Enrolled patients[b]	410 (81.2 %)	188 (81.7 %)	222 (80.7 %)
Patients with ongoing swallowing difficulties	37 (9.0 %)	13 (6.9 %)	24 (10.8 %)
Patients with past swallowing difficulties	55 (13.4 %)	23 (12.2 %)	32 (14.4 %)

[a] Recruited patients were eligible patients the interviewer was able to approach. The 154 eligible but not recruited patients left the pharmacy before the interviewer was free to start the next interview

[b] Enrolled patients were patients who accepted to participate

Table 2 Patients' and treatments' characteristics of the enrolled patients (n = 410)

	All patients (n = 410)	Patients with ongoing swallowing difficulties (n = 37; 9.0 %)	Patients with past swallowing difficulties (n = 55; 13.4 %)	Patients without swallowing difficulties (n = 318; 77.6 %)
Women	252 (61.5 %)	24 (64.9 %)	40 (72.7 %)	188 (59.1 %)
Age in years:				
mean ± SD	66.5 ± 14.8	65.3 ± 17.3	61.5 ± 16.4	67.5 ± 14.0
Median (Q25, Q75; range)	68.0 (57, 78; 19–96)	69 (52, 76.5; 21–95)	63 (51, 77; 19–89)	69.0 (58, 78; 20–96)
Daily number of solid oral drugs:				
mean ± SD	5.9 ± 3.5	5.7 ± 2.5	5.5 ± 3.8	6.0 ± 3.5
median (Q25, Q75; range)	5 (3, 7; 1–28)	5 (3.75, 7.25; 1–20)	4 (3, 7; 1–20)	5 (3, 7; 1–28)
Current state of health:				
mean	3.4	3.8	3.5	3.4
(SD; range)	(0.94; 1–5)	(0.64; 3–5)	(0.86; 2–5)	(0.93; 1–5)

Answers to current state of health rank from "excellent" = 5 to "poor" = 1. A high score defines a more favourable health

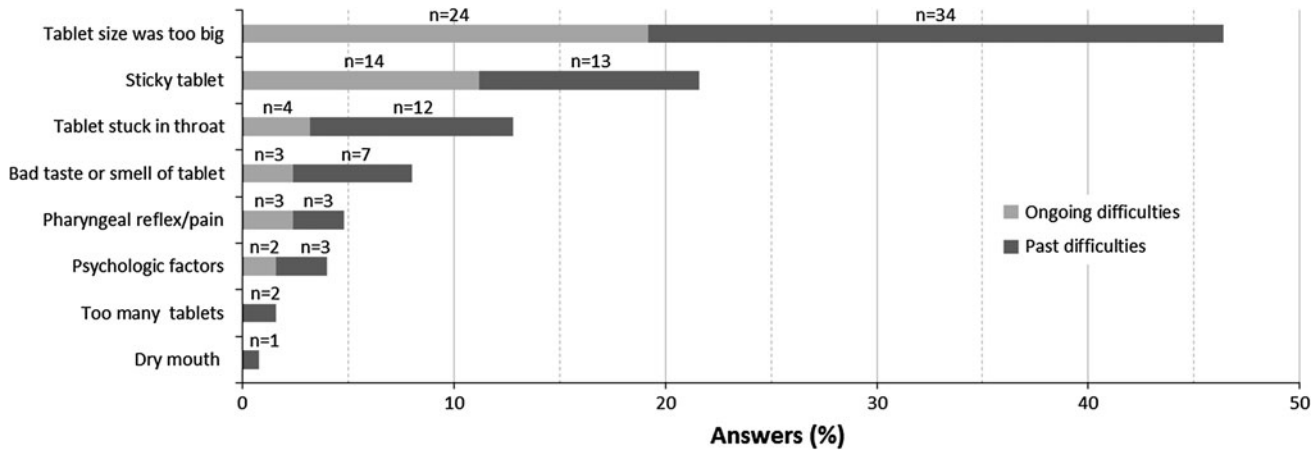

Fig. 1 Causes of swallowing difficulties; n = 125 answers from n = 92 patients (multiple answers were possible)

their bad taste. One-third (32 %) of patients with swallowing difficulties tilt their head backwards to swallow their tablets although this shrank their throat instead of opening it up.

Ongoing and past difficulties impaired quality of daily life in 47.3 % of the patients. Difficulties were even rated as "extreme" by 12.1 % of the patients (6 men, 5 women), independently of the type of difficulties (ongoing or past).

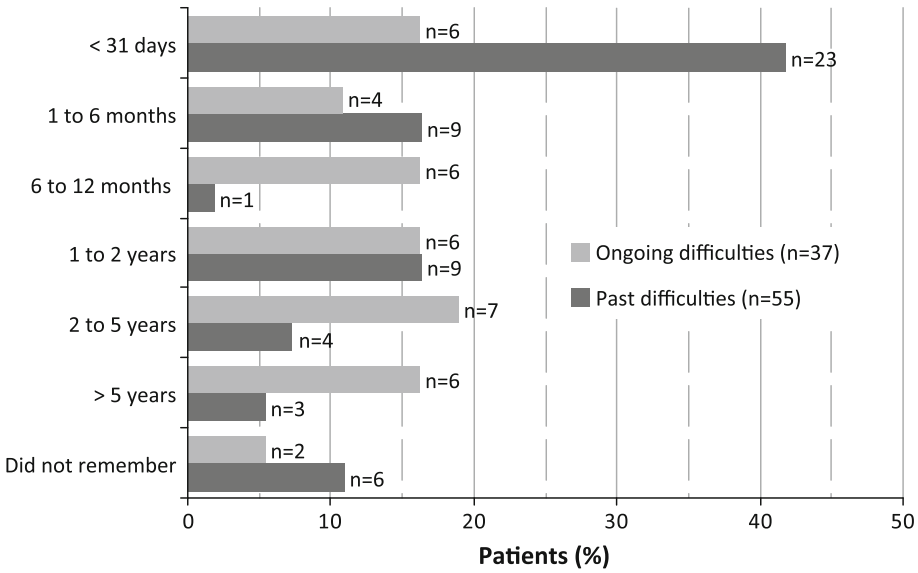

Fig. 2 Duration of swallowing difficulties (n = 92 patients)

There was no statistical difference in gender, age, quality of life or daily number of solid oral drugs between patients perceiving extreme impairment versus all others. Swallowing difficulties resulted in self-reported omission of drug intake (intentional non adherence) in 22.8 % of patients. Among them, 5 patients (5.4 %) stopped their medication and 5 further patients asked their physician for a substitute drug. A total of 34 patients (37 %) addressed their swallowing difficulties either with their physician (n = 24) or pharmacist (n = 4), or both (n = 6). Two patients only mentioned that their physician inquired about their swallowing difficulties but no patient mentioned the pharmacist.

Discussion

This study showed that 9 % of the patients visiting their community pharmacy for a prescription reported ongoing swallowing difficulties, while 13.4 % recalled past swallowing difficulties. Sociodemographic characteristics were similar in both groups. Our prevalence is in the lower range of reported prevalence of swallowing difficulties for ambulatory patients in the literature, which varies between 11 and 37 % [3, 11, 13, 14]. Interestingly, our study provides specific information on adult polypharmacy patients visiting community pharmacies, which is an under-investigated setting. It also describes patients' perceived consequences of such difficulties and ways they managed them.

In about one in eight patients (12.1 %), swallowing difficulties impaired extremely patients' daily life, and in about one out of four patients, they compromised adherence. However, in most cases, the problem went unnoticed, since 63 % of the patients did not inform their physician or pharmacist, which is in line with prior reports [14, 15]. In essence, almost half of swallowing difficulties in the study population was overcome within 6 months, and most

Fig. 3 Patients' applied techniques to cope with swallowing difficulties; n = 111 answers from n = 92 patients (multiple answers were possible)

patients managed their swallowing difficulties by drinking more water to assist swallowing and by developing strategies to overcome the difficulties on their own. Altering the solid dose formulation by splitting or crushing the drug was the most used technique. However, such practice carries many risks, especially with modified release dosage forms, enteric coated tablets or layered tablets [16]. The pharmacist must inquire and inform about correct ways of swallowing tablets in order to protect patients from potentially harmful and preventable effect of crushing or altering non-chewable or non-crushable tablets or capsules (i.e., toxicity, modified efficacy, unpalatability, potential hazards). In the event of such a harm, the person who crushed or advised the crushing of the tablet will be liable, but not the manufacturer, since altering the formulation represents an off-label use [17].

Our results show that the number of tablets was not the main trigger. Much more, specific pharmaceutical characteristics of the drug formulations mattered, i.e., large size, sticky coating, unpalatability. This is in concordance with findings of a similar survey where size and surface were the two most frequent reasons for swallowing difficulties [7]. However, in our study, the shape was never mentioned and a psychological reason like aversion to drugs was 4 times less reported (Marquis 5.4 % vs. Schiele 21.1 %).

Paracetamol was the most cited drug, similarly with results from others [13]. Besides the big size and the rugged coating of many paracetamol formulations, we suppose that the frequent prescription of paracetamol contributed to this finding. Nevertheless, as paracetamol is often used, pharmacists must inquire about its related swallowing difficulties to avoid any unnecessary escalation in the use of stronger analgesics.

One-third of patients with swallowing difficulties mentioned tilting their head backwards to swallow their tablets, which comes naturally since it seems to facilitate the sliding down of a tablet into the throat. However, this technique narrows the oesophagus and opens the trachea, and facilitates aspiration. The exact opposite, i.e., the chin-tuck technique (sitting upright, keeping the chin down [18]), is widely recommended by speech and language therapists as a method to improve swallowing since it increases swallowing pressure. This recommendation particularly applies to dosage forms with a density <1, which float on liquids. In this case, pharmacists should deliver this simple advice to their patients.

In our study, almost twice as many women as men experienced swallowing problems, which was also observed in other studies [11]. Indeed 55.9 % of women reported "*present or past swallowing difficulties with tablets and capsules*" among 1,132 patients in 11 general practices in Germany [7]. A gender difference in the perception of such a disability can be postulated. Indeed, such gender differences have already been observed with the perception of pains or discomfort, for example in case of gastrointestinal symptoms [19] or headache [20]. A physiological explanation can further be speculated. Anatomical differences with regard to the oral cavity and pharynx/larynx may contribute to the higher prevalence in women.

This study is subject to some limitations. First, we selected an adult primary care population with a prescription for at least 3 daily solid oral forms, in order to enhance the probability of positive findings. However, the results showed that swallowing difficulties did not correlate with the number of prescribed tablets. Second, the results rely on patients reporting and are subject to recollection bias. Ongoing difficulties were clearly distinguished from past difficulties, knowing that recalling past events might not be as accurate as current events, and might be subject to bias. Finally, there was no follow-up to verify patient self-report, e.g., by means of direct observed therapy.

Conclusion

This study reports a fairly high prevalence of swallowing difficulties in polypharmacy patients visiting their community pharmacy. It highlights the need for a better communication between patients and health professionals for addressing such issues. Indeed swallowing difficulties are largely underestimated by health professionals. Not all patients with swallowing problems are affected enough to seek medical care, omission or interruption of drug intake, and altering the oral form are common and potential harmful strategies.

Since patients do not necessarily disclose their problem to physicians or pharmacists, pharmacists involved in medicine management should prospectively inquire about swallowing difficulties with a single question e.g., "Have you ever encountered or do you encounter difficulties in swallowing medicines?". This question allows the pharmacist to initiate a counselling interview in concordance with the latest Good Pharmacy Practice Guidelines which states that "*Pharmacists should provide advice to ensure that the patient receives and understands sufficient written and oral information to derive maximum benefit for the treatment*" [21]. Moreover, active listening allows the professional to ascertain the clinical impact of the difficulties. Recommending the chin-tuck technique could represent the first step intervention for preventing difficulties in patients with oral formulations. Further studies should explore pharmacist's activities in screening and preventing swallowing difficulties.

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