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Acceptability of oral solid medicines in older adults with and without dysphagia: A nested pilot validation questionnaire based observational study

Fang Liu[a,*], Ambreen Ghaffur[a], Jackreet Bains[a], Shaheen Hamdy[b]

[a] Department of Pharmacy, pharmacology and postgraduate medicine, School of Life and Medical Sciences, University of Hertfordshire, Hatfield AL10 9AB, UK
[b] Centre for GI Sciences, Institute of Inflammation and Repair, Faculty of Medical and Human Sciences, University of Manchester, Manchester, M6 8HD, UK

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ABSTRACT

Older patients (aged 65 years and over) are the major consumers of medicines and many barriers affect their ability in taking medicines orally, especially swallowing difficulties. Moreover, the characteristics of differing medicine formulations might have an impact on their acceptability in older patients. The aims of this study were to validate a Medicines Acceptability Questionnaire (MAQ) and to assess acceptability of oral solid medicines in older ambulatory patients with and without dysphagia. One hundred and fifty six older patients attending community pharmacies were recruited and attended face to face interviews. Two questionnaires were administered during the interviews, the validated Sydney Swallow Questionnaire (SSQ) assessing oral and pharyngeal swallowing function and the newly developed MAQ evaluating patient acceptability of oral solid medicines. Seventeen (11%) participants displayed symptoms compatible with swallowing difficulties identified by the SSQ. Participants with swallowing difficulties were considered themselves more likely to have problems in swallowing tablets and capsules of large sizes (11 mm and 13 mm tablets and size #00 capsules) compared to participants without dysphagia. Dispersible/effervescent tablets and orally disintegrating tablets were considered to be the most acceptable in this cohort, followed by mini-tablets. Chewable tablets and granules were the least favoured. Consistently higher acceptability scores were seen in the dysphagic population than in the non-dysphagic population for all of the dosage forms that were easier to swallow than tablets and capsules. The development of these formulations will assist in medication taking in older patients with dysphagia and potentially their adherence to drug treatments.

1. Introduction

Patient acceptability to a pharmaceutical dosage form is critical to ensure adherence and therapeutic outcomes, especially in children and older people (Liu et al., 2014). Acceptability has previously been defined as "an overall ability of the patient and caregiver (defined as 'user') to use a medicinal product as intended (or authorised)" (Kozarewicz, 2014). The European Medicines Agency has required the assessment of patient acceptability to be an integrated part of paediatric medicinal product development (EMA, 2013; Kozarewicz, 2014). However, acceptability of medicines in older adults has been largely overlooked. Older patients (aged 65 years and over) account for 50% of the medicine prescriptions in the UK (Rajaei-Dehkordi and McPherson, 1997). The oral route remains the most preferred mode for medicine administration; however, there are barriers for older patients to take medications orally (Liu et al., 2014). Swallowing difficulties (dysphagia) are common in older people which affect their ability to take oral medicines, especially tablets and capsules (Steele et al., 1997; Strachan and Greener, 2005). Consequently, medicines are often modified such as crushing tablets or capsules opened to assist administration to older patients (Kelly and Wright, 2009; Wright, 2002). This leads to unlicensed used of medicines and can potentially cause ineffective use or toxicity of the medicine (Stegemann et al., 2012).

Characteristics of a pharmaceutical dosage form, such as the size, shape, and surface texture of a tablet, have an impact on how easily a solid oral medicine can be swallowed and pass through the pharynx and oesophagus (Channer and Virjee, 1985; Evans and Roberts, 1981; Hey et al., 1982; Overgaard et al., 2001). Previous knowledge on these effects has been demonstrated in healthy young subjects; however, this remains unclear in older people

* Corresponding author.
E-mail address: f.liu3@herts.ac.uk (F. Liu).

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especially those with existing swallowing difficulties. The type of formulation might be another factor affecting the ability and willingness of older patients to take their medicines. A number of solid oral dosage forms that are "easier to swallow" than tablets and capsules have been made available in recent years including orally disintegrating tablets (ODTs), dispersible tablets, mini-tablets and multi-particulates (granules). As most of these formulations are designed and developed for paediatric use, acceptability of some of these dosage forms in children has been reported (Cohen et al., 2005; Motte et al., 2005; Nasrin et al., 2005). For older patients who cannot swallow tablets, the availability of these formulations could be beneficial. The use of dispersible/effervescent tablets and ODTs has been demonstrated in older patients (Bayer et al., 1988; Nelson et al., 2006). Especially, ODTs have been proven to be easier to swallow than conventional tablets for patients with dysphagia (Carnaby-Mann and Crary, 2005). However, evidence in the acceptability of these solid dosage forms in older patients is still sparse. This research is a pilot study where a Medicines Acceptability Questionnaire (MAQ) was initially developed and validated before assessing the acceptability of a range of solid oral medicine dosage forms in older ambulatory patients attending community pharmacies and investigating the association between patient acceptability and the presence of swallowing difficulties.

2. Materials and methods

2.1. Study population and setting

The study was approved by the Ethics Committee of University of Hertfordshire (LMS/SF/UH/00081) and was conducted at community pharmacies in the South East England area in the UK during October to November 2014. A convenient sample of pharmacies were recruited to participate in the study. The pharmacist in charge in each pharmacy was informed the purpose of the study and approached consecutive patients attending the pharmacy during week-day (Monday–Friday) opening hours who were eligible for the study. The eligibility criteria include patients aged 65 years or over and prescribed at least one oral medicine. No financial incentive was received by the pharmacies for participating in the study.

Given the stated aims, the primary endpoint of the study was the proportion of primary care older patients having swallowing difficulties. Based on the literature, prevalence of swallowing difficulties in community dwelling older adults was estimated as 11% (Holland et al., 2011). Approximately 150 participants would need to be enrolled to ensure a desired precision of at least 5%.

2.2. Administration of the Sydney Swallow Questionnaire (SSQ)

The SSQ is a validated questinnarie and composed of 17 questions assessing oral and pharyngeal swallowing function with responses entered onto a 101 mm visual analog scale except for question 12 (Dwivedi et al., 2010; Wallace et al., 2000). The SSQ was administered to the participants during an interview which took place in the private consultation room in the pharmacy. The participant placed a mark on the horizontal line of the visual analog scale. The first millimeter of the line was disregarded and a score of 0–100 was calculated by measuring the distance from the center of the mark to the first millimeter of the line for each question. A mark placed within the first millimeter of the line was scored as zero. Question 12 contains 6 categorical responses each representing a score of 0, 20, 40, 60, 80 or 100. The maximum possible total score for the SSQ was 1700, with higher score indicating greater severity of swallowing dysfunction. Analogous to the description of Holland et al. (2011), a score greater than 200 was considered indicating symptomatic dysphagia.

2.3. Pilot of the Medicines Acceptability Questionnaire (MAQ)

The MAQ comprised 15 questions evaluating patient acceptability of oral solid medicines. The questions were developed around three major topics. The first topic (3 items) covers general health status of the participant, number of oral medicines currently taking and any difficulties in taking solid oral medicines. The health status of the participant was measured using a 5-point Likert scale. Excellence in general health was ranked as a score of 1 and a score of 5 represented the health perception being poor. The second topic (5 items) evaluates participants' perception on the size and shape of tablets and capsules in relation to difficulties in swallowing. The participants were shown a printed diagram of tablets of varying sizes and shapes (Appendix). Samples of 9 mm tablets (the middle size of all sizes presented) of each shape were taped onto the diagram to provide visual representatives of the size and shape. Participants were also shown samples of hard gelatin capsules (HGC) of different sizes ($4^{\#}$, $3^{\#}$, $2^{\#}$, $1^{\#}$, $0^{\#}$ and $00^{\#}$). They were then asked from what size they will start to have difficulty to swallow the tablets and capsules.

The third topic (7 items) assesses participants' acceptability of other alternative solid medicine dosage forms to tablets and capsules, including mini-tablets, granules in a sachet, dispersible/effervescent tablets, orally disintegrating tablets (ODTs) and chewable tablets. These dosage forms are referred to as "alternative solid oral dosage forms" throughout this article. The participants were shown samples of all formulation types and were given an explanation of how the formulation should be administered. Mini-tablets were shown to participants as mini-tablets filled in HGCs. Granules were presented as sprinkles onto food. Dispersible tablets were presented as a drink with a minimum amount of 60 ml (or half a glass) water required to dissolve the tablet. ODTs were described as melting/dissolving on the tongue and chewable tablets were explained as needing to be chewed before swallowing. They then provided their opinion on the formulation including past experience in using the formulation, giving a score of 0–10 indicating their acceptance with 10 being the most acceptable. Open-ended questions were also used to obtain opinions of the participants on good and bad points of each formulation. The open-ended questions were analysed by reporting the percentages of participants stating the same comments on a formulation.

The content/face validity of the MAQ was assessed by two experts in the field acting as respondents. Cronbach's alpha test was conducted to evaluate the level of reliability and internal consistency using the Statistical Package of the Social Sciences (SPSS) version 22.0 (IBM Corp., Armonk, NY, USA). Cronbach's alpha scores of 0.7 or above were deemed as acceptable according to Nunnally and Bernstein (Nunnally and Bernstein, 1994). The MAQ was administered to the participants during the interview together with the SSQ. The interviews were conducted by two of the authors (AG and JB). Three pilot interviews were conducted in the presence of both interviewers to reach a consensus on how to conduct the interview and the subsequent interviews were conducted by one interviewer per participant.

2.4. Data analysis

Data analysis was performed using the Statistical Package of the Social Sciences (SPSS) version 22.0 (IBM Corp., Armonk, NY, USA). The results are reported as mean ± standard deviation (SD). Spearman's nonparametric correlation was used to identify the presence of significant correlations between total SSQ score and