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Identification of different shapes, colors and sizes of standard oral dosage forms in diabetes type 2 patients—A pilot study

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ABSTRACT

The clear identification of drug products by the patients is essential for a safe and effective medication management. In order to understand the impact of shape, size and color on medication identification a study was performed in subjects with type 2 diabetes mellitus (T2D). Ten model drugs differentiated by shape, size and color were evaluated using a mixed method of medication schedule preparation by the participants followed by a semi-structured interview. Detection times were fastest for the large round tablet shape and the bi-chromatic forms. Larger size was easier to identify than the smaller sizes except for the bi-chromatic forms. The shape was the major source of errors, followed by the size and the color dimension. The results from this study suggests that color as a single dimension are perceived more effectively by subjects with T2D compared to shape and size, which requires a more demanding processing of three dimension and is dependent on the perspective.

1. Introduction

The prescription of oral drug products to patients is the most common intervention in the treatment of acute and chronic diseases. The drug products are dispensed by pharmacists to the patient for independent use at home or by caregivers in hospitals or nursing homes directly to the patients on a daily basis. The increasing prevalence of multimorbidity leads to polypharmacy and complex medication schedules (Qato et al., 2016; Charlesworth et al., 2015). Non-adherence to medication is considered to be responsible for 30%–60% of the preventable drug related hospital admissions in the USA (Howard et al., 2003; Marcum et al., 2012). Unintentional overdose has been identified as responsible for two thirds of drug related admissions and mainly concerns warfarin, insulin, oral antiplatelet drugs and oral hypoglycamic agents (Budnitz et al., 2011). A recent study further provided evidence that only every second patient of 75 years and older is able to manage polypharmacy (≥5 medications) independently at home (Sino et al., 2014). Managing drug therapy and medicinal products requires sufficient cognitive, motoric and sensory capacity to identify the drug products, reading and understanding the instructions and administering the drug as intended (Stegemann et al., 2010). Forty percent of patients 75 years and older were not able to read leaflet instructions due to poor visual performance (Moisan et al., 2002). Diabetic retinopathy, a microvascular damage caused by diabetes type 1 and type 2, is a major root cause for severe visual impairments affecting up to 50% of patients after 10 years (ACCORD Study Group, 2010).

Medication errors have been identified as a major health burden and risk for patients, which has led to the development of safety considerations for minimizing medication errors through drug product design during the drug product development by the EMA (EMA, 2015) and the FDA (FDA, 2016). One consideration in this guidance is the differentiation between different dose strengths for solid oral dosage forms by means of size, shape and color. Early work in four different patient populations (demented, depressed and normal old with an mean age of 75 years and in young volunteers with a mean age of 22 years) investigating sorting times for colors and forms showed faster identification of the color compared to the form dimension (Grewal et al., 1985). Similar results were obtained when comparing color spot detection, which was detected 5–9 times better than the luminance spot (Chaparro et al., 1993). Much less is known about the impact of shapes and sizes on human detection and recognition. The perception of shape involves different dimensions of depth, horizontal binocular disparity and

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perspective to recognize a 3D structure (Van Damme and van de Grind, 1993; Welchman et al., 2005).

The aim of this pilot study was to investigate the impact of shape, size and color on the identification of solid oral dosage forms in T2D patients receiving polypharmacy under simulated home conditions. Another aim was to collect patient responses to the different product design features in terms of their subjective perception and the objective performance.

2. Material and methods

2.1. Study design

The study received approval of the ethical committee at the Medical University of Graz (No. 28-035 ex 15/16) and was conducted at the Medical University of Graz between May 18 and June 30, 2016. The study consisted of an observational task performance by using a uniform crossover design followed by a semi-structured interview.

2.2. Study population

Twenty-two subjects with T2D provided written consent to participate to the study. Participants were included when they had T2D, lived independently, were aged 55 years or older and received polypharmacy (≥5 different medications). Additional patient data were collected from the health records and included age, sex, duration of T2D, presence of retinopathy or polyneuropathy and the number of prescribed oral medication. The participants used vision aids according to their personal mode of behavior to reflect the typical medication preparation situation. From the 22 participants, one patient was excluded due to inability to finish the tasks. The data of 21 participants were analyzed.

2.3. Model drug product design

The study medication (SM) samples consisted of 10 model oral drug products, which were composed of 5 designs with different shapes and colors. Each of the 5 design concepts was presented as a small and a large version whereby the size dimensions were comparable between the design concepts. The design concepts of the SM generated from existing, marketed drug products and included round, oblong, diamond and a capsule shapes (Fig. 1). For the evaluation of the color, the oblong form was presented in white and yellow color and the capsules shared either yellow (large capsule-oblong form) or blue (large – small capsule). The round, oblong and diamond shaped design concepts were prepared by 3D printing (Colorcon, Idstein, Germany), the capsule shaped design concepts were generated from hard capsules (Capsugel, Bornem, Belgium).

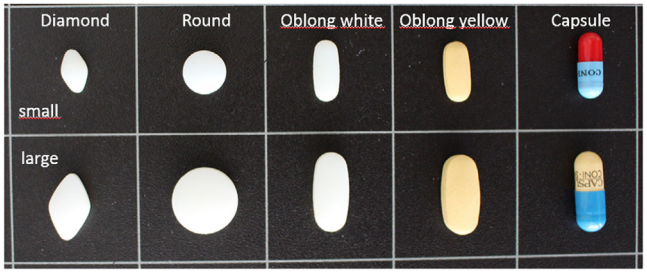

Fig. 1. Model oral drug products investigated in the study.

2.4. Observational task performance

The objective of the task was to evaluate the identification and selection of the different drug product designs under polypharmacy conditions. Seven units of each drug product design were collected in a white bowl (70 units in total). All participants were used to medication schedules and prepared a medication schedule composed of all model drug products to familiarize with the SM. Each patient had to prepare four different medication schedules, whereby each medication schedule focused on two specific design features (1. color – large size, 2. color – small size, 3. shape – color and 4. shape – size). The products were named according to their specific design features (e.g. small round, large round etc.). In each medication schedule 7 items of the SM had to be identified and filled into a dosing aid with four compartments in accordance with the medication schedules into morning, noon, evening and night doses. The participants performed the task in a quiet room sitting in front of a white table with good lightening. The bowl with the SM was placed on the right side and the medication schedules on the left side and the dosing aid in front of them.

Before starting the four medication schedules, the SM and the task was explained to the participants and a generic medication schedule was filled which included all 10 different drug product designs. After assuring that the participants understood the task, each patient filled the four medication schedules in randomly allocated sequence such that each schedule occurs only once within each sequence and once within each period (1-2-3-4; 2-3-4-1; 3-4-1-2 or 4-1-2-3). Participants were videotaped during the task performance until the end of the semi-structured interview. The task performance was analyzed by determining the time required to determine the relevant item (identification time, in seconds) and by the number of incorrect item selections (errors). The time was measured from the moment when the participant directed attention to the bowl and started searching for the item until the item was touched with the hand. The time required to take hold of the item and transfer it to the dosing aid was not measured. Participants were neither interrupted nor corrected during their preparation of the four medication schedules. The verbal feedback of the participants during the task performance was recorded but not commented.

2.5. Narratives and semi-structured interview

During the task performance the verbal and narrative feedback of the participants was collected and analyzed in the context of the task. After performing the medication schedule tasks, participants were interviewed in a semi-structured manner with open ended questions to collect direct feedback on the experience and their subjective perception. The second part of the semi-structured interview was the collection of feedback on the own medication and personally important issues and strategies related to preparation and management at home. During the interview, the participants were not interrupted and the interviewer only asked clarifying questions in order to obtain additional details or further pursue a participant's narrative descriptions.

2.6. Statistical evaluation

For statistical analysis, SPSS Version 24 (IBM Corp, Armonk, NY, USA) was used. All outcome parameters are summarized descriptively. Continuous variables are presented as mean ± standard deviation (SD) or median (med), minimum (min) and maximum (max), categorical data as frequencies and percentages.

The mean identification time per item in a schedule (in total 7 drugs) was calculated in order to evaluate the impact of the four different medication schedules and the four periods on