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Effect of different formats for information on side effects regarding medicine users' understanding: A randomized controlled trial

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ABSTRACT

Objective: The objective of this randomized controlled trial was to evaluate the efficacy of presenting information on the risks of side effects from a medicine, presented in different formats.
Methods: A randomized, parallel-group, single-center controlled trial was conducted among adult users of a training pharmacy. The information was categorized into the following groups: verbal descriptors + percentage range, percentage range and absolute percentage. The main outcomes were gist understanding and verbatim understanding, classified either as adequate or inadequate. The analyses were performed using ANOVA and Pearson's chi-square test.
Results: A total of 393 participants were recruited from June to October 2015. Adequate levels of gist understanding and verbatim understanding were respectively 65.6% and 53.9% for the verbal descriptors + percentage range (n = 128), 63.4% and 44.3% for percentage range (n = 131), and 62.3% and 48.5% for absolute percentage (n = 131), with no statistically significant difference between the groups (p = 0.852 and p = 0.299, respectively).
Conclusion: The understanding of the information was similar in all three formats, but the percentages of adequate understanding were low.
Practical implications: The percentage of inadequate understanding demonstrated in this study indicates that alternative formats for reporting adverse reactions need to be evaluated.

1. Introduction

The risk of side effects is a common concern among medicine users [1,2]. Understanding the risks and benefits of pharmacological treatment is fundamental for proper decision-making by patients, since information allows individuals to take more conscious and autonomous decisions and attitudes about their health [3,4].

However, reporting the risks of side effects from medicines to patients can be a major challenge. Studies have shown that there are large individual differences in the interpretation of terms that are commonly used to express the likelihood of experiencing an adverse reaction [5,6] and that understanding is influenced by the presentation of information [7,8] and by personal factors such as health literacy and numeracy [2,8].

In several countries, the risks of side effects are presented in the package inserts through verbal descriptors (e.g. very common, common, uncommon, rare and very rare) that may or may not be associated with numerical descriptors (e.g. the risk of nausea is 10%) [3,9–11]. However, studies that compared verbal and numerical formats have found better understanding with numerical formats. The responses to the numerical format were more accurate than those to the nominal format, with overestimation of the occurrence of adverse reactions with the nominal format [5]. A few studies [10,12] have evaluated a combination of verbal and numerical format versus numerical-only format. In these studies, the participants were cancer website users, predominantly female, mostly composed of people with experience of cancer and probably better motivated to find and understand the information about risk of side effects. However, the efficacy of a combined format for more commonplace medicines and about less life-threatening conditions might be different.

The objective of this randomized controlled trial was to evaluate the efficacy of presenting information on the risks of side effects from a medicine, presented in different formats, in a general population of patients attending a training pharmacy.

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Hypothesis 1 of this study was that the verbal descriptors associated with the numerical format would provide better gist understanding than the other formats. Gist understanding refers to an individual's ability to understand the essential meaning of the frequencies of adverse reactions described in the information presented. Hypothesis 2 was that the absolute percentage format would provide better verbatim understanding than the other formats. Verbatim understanding refers to subjects' ability to correctly report the frequency of occurrence of the side effects described in the information provided.

2. Methods

2.1. Design and interventions

A randomized, single-center controlled trial was conducted, in which participants were categorized into three groups (1:1:1 ratio). Group 1 (verbal descriptors + percentage range) received the information in verbal format (e.g. "common") accompanied by numerical information expressed as a percentage range (e.g. "1–10%"). Group 2 (percentage range) received the information in numerical format expressed as a percentage range (e.g. "1–10%"). Group 3 (absolute percentage) received the information in numerical format expressed as an absolute percentage (e.g. 10%).

A hypothetical scenario describing the symptoms and medical indications of a medicine for gastrointestinal problems was presented to participants, followed by information on the risks of side effects. The hypothetical scenario was as follows: "You have been feeling a stomach burn for some time and you decide to seek medical help to solve the problem. The doctor gives you the diagnosis of gastric hyperacidity (a lot of acidity in the stomach), which causes you to feel burning. So your doctor prescribes a new medicine to solve your problem. But use of this medication may cause some adverse reactions. The following are some of the side effects that may occur in people using this medicine."

Fig. 1 illustrates the information formats presented to study participants. In each group, three frequencies of side effects were presented to the participants: common, uncommon and rare side effects.

2.2. Setting and procedures

Participants were recruited from a "training pharmacy" located in a university in the southern region of Brazil, from June to October 2015. This type of pharmacy in Brazil exists for the purpose of enabling internship training for pharmacy students. The users of this pharmacy will have received medical prescriptions at the university hospital to which the pharmacy is linked.

Subjects aged over 18 years with normal cognitive and communication skills were invited to participate in the study. After agreeing to participate and signing an informed consent statement, all of these individuals answered a sociodemographic questionnaire and underwent a functional health literacy test (Short Assessment of Health Literacy for Portuguese-speaking Adults-SALPHA), which had been adapted to Portuguese by Apolinário et al. [13]. Participants who showed a sufficient level of functional literacy (14 correct answers out of a total of 18 questions) were included in the study and were randomized to one of three groups.

In order to guarantee allocation concealment, the field supervisor (who was not involved in recruitment of the participants) was responsible for randomization and for organizing sealed randomized opaque envelopes, each containing the name of one of the formats evaluated. Block randomization with a block size of 15 individuals was performed through the randomization. com website and allocation concealment was maintained by the field supervisor until the analysis of the data. The interviewers and participants were blinded to the hypothesis of the study and the interviewers were also blinded to the format at the time of recruitment of participants until the envelope was opened for the interview.

After the envelope had been opened, the participant received a card containing information on the risks of side effects from the medicine. After reading the card, the participant answered a self-reporting questionnaire to evaluate his or her understanding of the information given. At the time of self-report of the outcome, the participant still had access to the card containing side effects risk information.

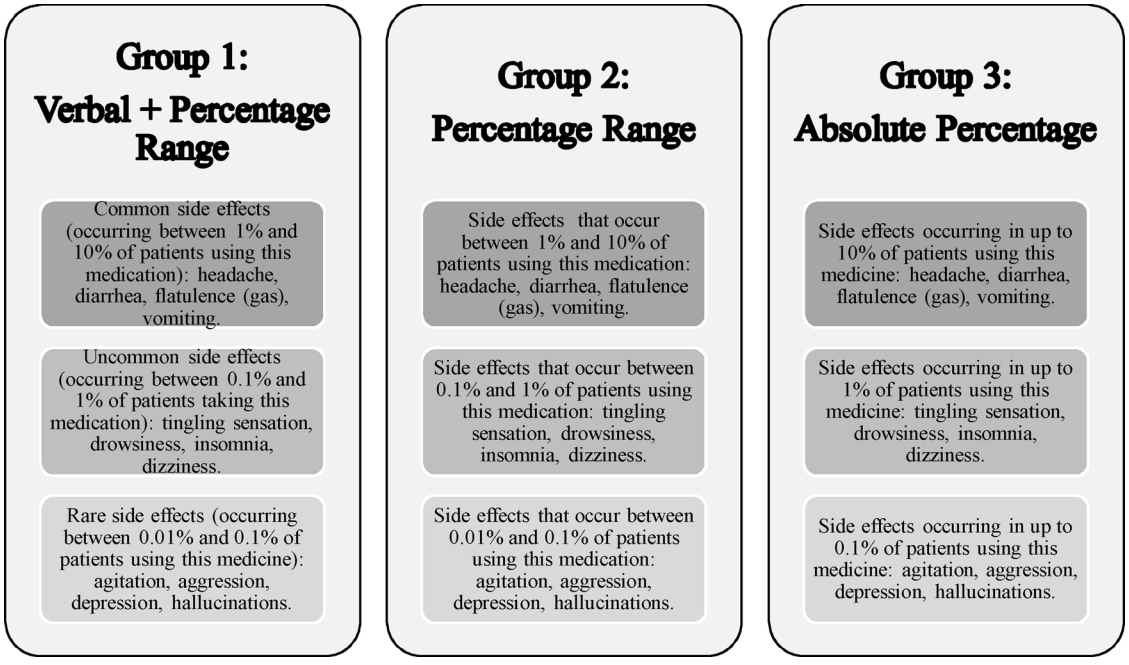

Fig. 1. Medicine side effects risk information presented to participants for understanding assessment.

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