



ORIGINAL ARTICLE

Saudi young patient understanding of information about side effects Verbal versus numerical expression



L. Al Juffali *, O. Al Omran, S. Al Aqeel

Clinical Pharmacy Department, College of Pharmacy, King Saud University, Riyadh, Saudi Arabia

Received 1 November 2012; accepted 31 December 2012
Available online 20 January 2013

KEYWORDS

Risk communication;
Side effects;
Risk perception;
Saudi Arabia;
Patient information;
Package inserts

Abstract *Objective:* To determine the effect of providing different formats about side effect information (verbal versus numerical) to acne patients in Saudi Arabia that are newly prescribed Roaccutane.

Design: A prospective study assessing patients' degree of estimation about side effect information.

Participants: One hundred and forty-one acne patients newly prescribed Roaccutane.

Settings: Four dermatology clinics in Riyadh. Two in tertiary hospitals and the other two in private clinics.

Intervention: Each patient received information about two different side effects for Roaccutane. The side effect provided was supplemented with the probability of occurrence, which was written either in words or in numbers. (Dry eye "very common" or "30%"; Loss of hair "rare" or "0.01%").

Main outcome measures: Patient's estimation of side effect occurrence. Other outcomes were the likelihood of experiencing the side effect, the severity of the side effect, their perception of risk of the side effects to their general health, their satisfaction with the information provided and, whether the information provided will influence their decision to take the medicine.

Result: The mean estimate for side effect occurrence for the dry eyes was 46% in the verbal group and 41% in the numerical group ($p = 0.5$); for loss of hair it was 50% in the verbal group and 39% in the numerical group ($p = 0.03$). There are no significant differences between verbal and numerical groups regarding the remaining measures.

Conclusion: Patients overestimate the probability of occurrence of side effect. Verbal format of probability of occurrence is associated with higher estimation than the numerical format.

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* Corresponding author. Tel.: +966 505172290.

E-mail address: laljaffali@ksu.edu.sa (L. Al Juffali).

Peer review under responsibility of King Saud University.



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1. Introduction

An active role of patients in the decision-making process with regard to their treatment is becoming increasingly important, and discussing the risks and benefits of treatment options is

therefore an essential part of modern health care (Timmermans et al., 2004). Recent studies have shown that the most information required by patients is information about side effects (Dickinson and Raynor, 2003).

The information on side effects currently provided to patients in Saudi Arabia other than oral communication is limited to package insert leaflets, which mostly use words (Al -Aqeel, 2012). The European Union (EU) in 1999 developed guidelines on the readability of leaflets which indicate that the frequency of side effects could be denoted by the use of five verbal descriptions (very common, common, uncommon, rare and, very rare) each word is correlated to a numerical value (Knapp et al., 2004). After these guidelines were introduced a series of empirical studies were begun to try to find out patients' interpretation of side effect probability when presented in either the verbal descriptors or in their numerical equivalents. Berry *et al.* started these studies using hypothetical scenarios presented to people about being at the doctor and prescribed a medicine each scenario was assigned with its side effect probability either in words or number. The first study was on 268 students, they estimated the probability of a side effect occurrence that is common (1–10%) to be 45% (Berry, 2004). Berry (2004) conducted two other studies on the general population. Two hundred and thirty-two participants were given information regarding a side effect that is very common (15%) the participants were stratified based on their ages into groups (18–40, 41–60 and 60+). Patients provided with the verbal descriptor very common had overestimated the frequency to 65% in all the different age groups (Berry, 2004). The final study was on 360 of the general population, presented with either a rare side effect or a common one in either words or numerical format and again patients with the word format had overestimated the side effect (Berry and Knapp, 2002). Tan *et al.* (2005) in Singapore used a hypothetical scenario given to 95 healthcare professionals and students about the risk of side effects of an influenza vaccine. The information was presented in either a probability format (5%) or a frequency format (1 out of 20). Respondents presented with a "5% risk" were more likely to describe the risk as "uncommon" or "rare", as compared to respondents presented with a risk of "one out of twenty" (Tan *et al.*, 2005). The previous four studies done by Berry *et al.* as mentioned earlier were based on hypothetical scenarios that limited their applicability to real patients who actually read the leaflet. This led Berry *et al.* to study their hypothesis on 120 patients taking statins in different settings a cardiac rehabilitation clinic, a community pharmacy and a GP asthma clinic. The patients' in this

study have been provided with information about a common side effect constipation that occurs in 2.5%. Patients in the verbal group had overestimated the occurrence as 34% while patients given the numerical format stated the occurrence as 8% (Knapp *et al.*, 2004).

Studies in the area of risk perception in Saudi Arabia are very limited. There is a need to find out how Saudi Arabians understand and perceive different format of information and its effect on their decision-making. This study was conducted to compare the effect of providing verbal format versus numerical format when communicating written information about side effect probability to acne patients newly prescribed Roaccutane in Saudi Arabia.

2. Methods

2.1. Setting

Patients who were newly prescribed Roaccutane for the first time were recruited from the dermatological clinics of a tertiary teaching hospital (A), a Military tertiary hospital (B), private sector hospital specialized in dermatology (C), and a private sector clinic specialized in dermatology (D). The study was carried out from June 2005 to November 2005.

2.2. Source of data

A self-completed questionnaire to be completed anonymously was distributed by the nurse in the clinic to any patient newly prescribed Roaccutane. The questionnaire is based on the one developed by Knapp *et al.* (2004) the questionnaire was translated into Arabic.

It is a two page questionnaire the first page contained the purpose of the study, instructions on how to answer the questions, and a statement containing information about one side effect and the frequency of its occurrence either in words or numbers. The statement was provided to the patients in four different formats. Each patient participating in the study took just one format (Table 1).

The verbal descriptors and their numerical equivalents used in this study were based on those proposed ones by the EC very common (>10%) and very rare (<0.01%) (European Commission, 1998). The incidence rates of the side effect were taken from the European Medicines Agency EMEA which were calculated from pooled clinical trial data involving 824

Table 1 Information provided to patients.

Side effect	Verbal descriptor	Numerical equivalent
Dry eye	1 Group Roaccutane is associated with some side effects. It can cause dry eyes. This side effect is a very common side effect.	3 Group Roaccutane is associated with some side effects. It can cause dry eyes. This side effect occurs in 30% (30 in 100) of patients who take the medicine.
Loss of Hair	2 Group Roaccutane is associated with some side effects. It can cause loss of hair. It is a rare side effect.	Group 4 Roaccutane is associated with some side effects. It can cause loss of hair. This side effect occurs in 0.01% (1 in 10000) of patients who took this medicine.

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