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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

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KEYWORDS

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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.

* Corresponding author. Tel.: +966 505172290.
E-mail address: laljaffali@ksu.edu.sa (L. Al Juffali).

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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

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therefore an essential part of modern health care (Timmermansa 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*.

patients and from post marketing data (European Medicines Agency, 2003).

After reading the information provided, participants were asked to give a percentage probability of the likelihood of having the side effect. They were also asked to respond to five questions; about the overall likelihood of their 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. Responses to these questions were recorded on a Likert scale (1–6). Finally, patients were asked about their age, sex and educational level.

The questionnaire was organized in alternating order in a pack. The nurse of the clinic was instructed to give the next questionnaire from the pack to any patient newly prescribed Roaccutane. The nurse who distributed the questionnaire was not aware of which of the four different formats was administered to each patient.

Two dermatologists have been given the Arabic version of the questionnaire to ensure the content validity. Face validity has been assessed by three laymen their ages are within the age of the sample. A pilot study has been completed with 10 patients and reliability has been tested by re-giving the questionnaire again after 1 month, which is the follow up duration in a patient newly prescribed Roaccutane. The results were correlated using Spearman's correlation test.

2.3. Analysis of data

The main outcome measure was the estimate of the likelihood of the side effect occurring. Secondary measures were related to the Likert scale responses to the five additional questions. The main outcome measure was analyzed using independent t tests after ensuring approximately normal distributions. The Likert scale responses were analyzed using the Chi square test. The statistical analysis was performed using SPSS version 13.0.

3. Results

One hundred and forty-one patients were recruited (96 women) of mean age 23 years (range 21–25). Sixty percent of participants had a college qualification degree (Table 2). The majority of participants were recruited from the two private clinics (78%, $n = 141$). The patients recruited to each of the four groups were comparable with respect to demographic data. In general, patients had overestimated the probability of occurrence in the four groups.

3.1. Dry eyes (''very common'' versus 30%)

The mean estimate of the percentage of people who would experience dry eyes was 46% (SD31.9) in the verbal group and 41% (SD27.7) in the numerical group ($t = 0.291$; $p = 0.5$; 95%CI -11.07–19.81).

Patients in the verbal group thought that they were more likely to have the side effect then the numerical group but this difference was not statistically significant ($p = 0.1$).

There were no significant differences in the patients' rating of their satisfaction with information provided, severity of side effect, risk to health and the effect of information on decision to take the medicine (Table 3).

Eighty-five percent of patients in the verbal group who indicated that the side effect was not severe considered this information would not affect their decision to take the medicine. While 33% who rated the side effect very severe indicated that this information will affect the decision to take the medicine ($p = 0.013$). In the numerical group, all patients who rated that the side effect is not severe considered the information would not affect their decision to take the medicine ($p = 0.02$).

3.2. Loss of hair (''rare'' versus 0.01%)

The mean estimate of the likelihood of having loss of hair was 50% (SD 26.3, median = 50%) in the verbal group and 39%.

Table 2 Demographic characteristics of the patients within the groups.

Demographic characteristics		Dry eye (%)		Loss of hair (%)	
		Words ($n = 34$)	Numbers ($n = 35$)	Words ($n = 40$)	Numbers ($n = 32$)
Age	Less than 15	3		2. 5	
	16–20	24.2	31.4	30	37.5
	21–25	54.5	40	40	34.4
	26–30	18.2	22.9	22.5	28.1
	More than 30		2. 9	5	
Gender	Male	23.5	25.7	46.2	22.6
	Female	76.5	71.4	53.8	77.4
Education	None			5.1	
	Intermediate	9.1	5.7	7.7	
	High school	27.3	34.3	20.5	29
	College	60.6	57.1	59	71
	Post graduate degree	3	2. 9	7.7	
Hospital	A	5.9			3.1
	B	32.4	22.9	22.5	25
	C	47.1	54.3	60	46.9
	D	14.7	22.9	17.5	25

Table 3 Percentage of participants' responses to the Likert scale variables.

	Dry eye		x^2 test	*P* value	Loss of hair		x^2 test	*P* value
	Words (*n = 34*)	Numbers (*n = 35*)			Words (*n = 40*)	Numbers (*n = 32*)		
Satisfaction with information								
Not at all satisfied			4.52	0.2	2.5	3.1	6.99	0.03
Unsatisfied		8.8			7.5	3.1		
Slightly unsatisfied	18.2	26.5			17.5	6.3		
Slightly satisfied	18.2	17.6			20	12.5		
Satisfied	33.3	20.6			25	18.8		
Very satisfied	30.3	26.5			27.5	56.3		
Severity of side effects								
Not at all severe	11.8	5.7	3.93	0.5	7.5	18.8	3.38	0.4
Not severe	11.8	8.6			22.5	12.5		
Slightly not severe	23.5	37.1			25	28.1		
Slightly severe	26.5	28.6			22.5	25		
Severe	14.7	17.1			15	9.4		
Very severe	11.8	2.9			7.5	6.3		
Likelihood of occurrence								
Not at all likely	3	14.3	7.87	0.1	10	3.1	4.98	0.4
Not likely	15.2	25.7			15	31.1		
Slightly unlikely	15.2	17.1			22.5	28.1		
Slightly likely	18.2	20			22.5	12.5		
Likely	18.2	14.3			15	15.6		
Very likely	30.3	8.6			15	9.4		
Risk to health								
No risk at all	12.1	11.4	6.17	0.1	22.5	18.8	4.9	0.4
Not risky	18.2	286			12.5	31.3		
Slightly not risky	42.4	34.3			32.5	21.9		
Slightly risky	21.2	17.1			15	18.8		
Risky		8.6			10	6.3		
Very risky	6.1				7.5	3.1		
Effect on decision making								
Definitely will not	27.3	23.5	1.93	0.8	40	31.3	6.47	0.5
Will not	18.2	23.5			12.5	28.1		
Slightly will not	21.2	14.7			20	9.4		
Slightly will	21.2	23.5			15	25		
Will	3	8.8			5			
Definitely will	9.1	5.9			7.5	6.3		

(SD 29.5, median = 50%) in the numerical group ($t = 2.224$; $p = 0.03$; 95% CI 0.95–17.94).

Patients in the numerical group were more satisfied with the information provided ($p = 0.03$). The two groups showed no statistically significant differences on the remaining measures: severity of side effect, likelihood of occurrence, risk to health and the effect of information on decision to take the medicine (Table 3). Eighty-three percent of patients in the verbal group who rated the side effect not severe indicated that the information provided did not affect their decision to take the medicine. On the other hand patients who rated the side effect severe considered the information will affect the decision to take the medicine ($p = 0.03$). Ninety percent of the patients in the numerical group who rated the side effect not severe indicated that their information will not affect their decision to take the medicine ($p = 0.03$).

4. Discussion

This study confirms many other studies that have found that patients overestimate side effect occurrence when provided information in verbal format than in numerical format (Knapp et al., 2004; Berry, 2004; Berry and Knapp, 2002; Tan et al., 2005).

In fact, all types of formats presented to patients in this study were associated with overestimating the probability of side effect occurrence. However, the degree of overestimation differed between the two formats. When verbal format was presented to patients it was associated with a higher estimation than the numerical group.

For instance; patients in the "very rare" group stated that they have 50% probability of experiencing the side effect, which is 5000 times more than what happens in fact in reality. In the numerical format group, patients estimated the occurrence as 39% that is lower but yet there is an overestimation.

This finding raises an important issue about the way patients interpret the information about risks. One of the important factors that affect the interpretation is the mode of presenting risks. Verbal labels of likelihood are viewed as easy to use; their interpretation is highly variable and dependent on the specific context (Burkell, 2004 April). While numbers give precise information there are a wide number of patients who do not interpret them correctly. This can be reduced by presenting numbers as frequencies assigned with the correct

reference group (x in 100) which can help in comprehending the numbers (Edwards et al., 2002; Palling, 2003).

Patients were satisfied with the information provided nevertheless, the mode of presenting the side effect risk information did not have any effect on their satisfaction nor did it have any effect on their decision to take the medicine. Patients in the "very common" group thought they would likely experience the side effect more than patients in the numerical group.

The patients' rating of severity and risk to health did not show any trend or significance with respect to the modes of presentation.

The decision to take the medicine was affected by the perceived severity of the side effect; those who rated the side effect was very severe had a tendency to change their decision regarding taking the medicine. The health belief model supports this finding; that perceived threat motivates people to take action (Berry, 2004).

These results are in line with Knapp et al. (2004) in terms of overestimating probabilities when providing information in the verbal format. The other findings like patient satisfaction with information, the severity of the side effects and its effect on deciding whether or not to take the medication did not show the same results. An explanation for this finding could be that patients in our study are recruited from acne clinics rather than cardiac clinics which patients in the later are associated with more complicated health conditions therefore they have more experience with risks of medicine and also know more information about their medicine. Moreover, cardiac patients are taking their medicine for an average of 15.5 months that led them to base their estimation based on their experience with the medicine the whole past months rather than their perception. So when asking a patient about the likelihood of experiencing a side effect from a medicine he has been taking for more than one year he will underestimate its occurrence (Knapp, 2004). Thus they are subjected to optimistic bias. In this study we aimed to include just new patients to overcome any kind of biases that may be encountered when administering the medicine for a period of time. Also our patients are different than the Knapp et al. patients, they are younger and more educated. Another difference is the majority were females (68%; $n = 141$) in contrast to Knapp et al. where the females were less (37%; $n = 120$) recent studies suggest that females perceive risks much higher than males (Walker et al., 2003). The difference in the medicine between the Knapp et al. and this study is worth mentioning. Roaccutane the medicine studied in this study is perceived by many patients as a cosmetic owing to that acne is a cosmetic problem while in their study statins are the medicine being studied comparing the two medicines in terms of patients' controllability as no patient come and ask for a statin. A very important difference is the culture which differs in all aspects and the type of relationship between the patients and their care giver in Saudi Arabia versus UK in terms of decision making and their expectations from the decision making process might be different.

The sample of this study is representative of the Saudi population giving that the majority of the Saudi population are young (Central Department of statistics and information, 2000).

Limitations of this study, firstly Roaccutane has a very high efficacy and also a wider side effect profile. Patients with moderate to severe acne are the main candidates for this medicine they usually come to the clinic asking for this medicine and accept the risk associated with it.

Secondly, the patients have other sources of information that may affect their perception of risk. Roaccutane has a risk management program, that each physician counsels his patients about the risks and benefit of this medicine.

Another limitation, the numerical probability of occurrence provided to the loss of hair group 0.01% is very hard to estimate since when asking patients to state a percentage they will think of a number in between 1% and 100% without considering fractions as seen in our study.

In conclusion, this study has shown the impact of different formats of information about the probability of occurrence of side effects on patients' perception of risk.

There is an overall overestimating of the probability of side effect occurrences, however patients presented with the verbal format had a higher degree of overestimation than patients presented with the numerical format. This suggests using numerical equivalents of the side effect probability when communicating written information to patients.

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