Saudi Pharmaceutical Journal 27 (2019) 900–905

Contents lists available at ScienceDirect

Saudi Pharmaceutical Journal

journal homepage: www.sciencedirect.com

Original article

Health literacy among patients with poor understanding of prescription drug label instructions in Saudi Arabia

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ARTICLE INFO

Article history:
Received 6 August 2018
Accepted 8 June 2019
Available online 10 June 2019

Keywords:
Health literacy
Medication label
Label understanding
Misunderstanding
Education level

ABSTRACT

Introduction: This study conducted to assess the health literacy level among patients who have poor understanding of the medications' labels in Saudi Arabia.
Methods: This multi-center cross-sectional study was conducted on two phases. In the 1st phase, 511 patients waiting for their medications in the outpatient pharmacies of four major hospitals in Saudi Arabia were interviewed to assess their understanding ability of the labels of five of the commonly prescribed medications. Those participants who misunderstood the medications' labels were enrolled in the 2nd phase of the study to assess their health literacy level. The validate Arabic Single Item Literacy Screener (SILS) was used to assess the health literacy level.
Analysis: The sample characteristics were described by mean and percentage. Both Chi-square test and logistic regression model were used to figure out the association between health literacy with the main affecting factors.
Results: Almost 38.6% (n = 197) of the participants in phase-1 misunderstood the medications' labels. Nearly, 11.2% (n = 22) of them had low health literacy level. Participants who had low education level and low socioeconomic status were more likely to have low health literacy [adjusted odds ratio (AOR) = 2.94; 95% confidence interval (95%CI) (1.03–8.404); P-value = 0.044], [AOR = 5.28; 95%CI (1.118–24.943); P-value = 0.036], respectively.
Conclusion: Low health literacy was associated with low education level and low socioeconomic status of the patients.

1. Introduction

According to Saudi Arabia Defense & Security Report, thirteen percent of Saudi men and thirty percent of Saudi women were uneducated (Saudi Arabia Defence & Security Report, 2016). This indicates that high percent of adults in Saudi Arabia lacking the essential skills for understanding health-related information. Nearly fifty percent of adults in United States lack basic skills to understand health-related information (Baer et al., 2009). Recent studies revealed that both physicians and pharmacists have no enough opportunities to discuss the medical information to the patient about his prescribed drugs, and because of the lack of other medical information sources in Arabic language, so the patient depends on the written instruction to get the medical information about his drugs (Tarn et al., 2006; Morris et al., 1997). The prevalence of poor understanding of medication's label is 38% in Saudi Arabia (Alburikan et al., 2018). This makes patient understanding of the written instruction very important factor in the patient's health outcome. Patient's misunderstanding of the medical instruction lead to poor health outcomes, increase adverse drug effect and increase health cost (Gandhi et al., 2003; Apter et al., 2013).

Health literacy is the person's ability to process, understand, and deal with the basic health related information by the right way to make the appropriate health decisions (Services USD of H and H, 2010). Health literacy is considered one of the basics that affect patients understanding of the health related instructions (Parker, 2007). Low health literacy is associated with decrease in

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Peer review under responsibility of King Saud University.

Production and hosting by Elsevier

https://doi.org/10.1016/j.jsps.2019.06.003
1319-0164/

the patient's health status, higher mortality rate (Bostock and Steptoe, 2012; Durham and Berkman, 2011), increase rate of hospitalization (Howard et al., 2005), and in ability to control chronic diseases i.e., Asthma and heart failure (Murray et al., 2009; DeWalt et al., 2007). Patients who have low health literacy level have low ability to understand health related instructions and taking their medications appropriately (Zhang et al., 2014). Many factors play an important role in increase the ability to have low health literacy level, i.e., elderly age, some ethnic groups, and low socioeconomic status (Rowlands et al., 2015; Parker, 2007).

In Saudi Arabia, there are very low numbers of studies that assess the health literacy level among Saudi population. Therefore, the aim of this study is to assess the level of health literacy among Saudi patients who have prescription drug labels misunderstanding and to explore the main factors that affect the level of health literacy among those patients.

2. Method

2.1. Study design

A multi-center cross-sectional study by using structured interviews with the participants.

2.2. Participants

This multicenter study was done in four of the major hospitals in the capital of Saudi Arabia, Riyadh, (King Saud University medical city [KSUMC], King Fahd medical city [KFMC], Prince Sultan Medical city [PSMMC], and King Faisal Specialty Hospital and Research Center [KFSH&RC]). Almost, 511 participants were waiting for their prescriptions at the outpatient pharmacy were interviewed. The included participants were 18 year age or older. They were chosen randomly from the outpatient pharmacies of these hospitals. The participant was excluded if he/she had one or more of the following conditions: 1. Inability to read due to severely impaired vision; 2. Very weak hearing abilities, 3. Severely ill to participate, and 4. can't read and speak Arabic.

2.3. Outcomes and data collection

This study was conducted in two phases; the main objective of the first phase was assessing the participants' understanding for medication label. The objective of the second phase was assessing the level of health literacy in participants with poor understanding for the medications' label.

Participants' understanding of the prescription medication label instructions assessed by the making structured interviews with the participants. These interviews assessed the participants' understanding to the label of five of the commonly prescribed medications. The research assistant asked "How would you take this medication" and the verbatim response was reported in a separate form. The verbatim response was analyzed by two different raters who are blinded from each other and from the other participant's information. This analysis was based on a specific guideline. The participant considered misunderstanding if he/she misunderstands at least two aspects of the five medication labels. The participants' responses were given correct scores if the participants' responses contained all aspects of the labels' instructions, such as dosage, frequency, storage, and duration. Responses were given an incorrect score if they were inaccurate or if they missed one aspect of the instructions. The degree of misunderstanding was assessed. Low misunderstanding was given for participants who misunderstood only one out of the five labels. Intermediate misunderstanding was given for participants who misunderstand two or three out of the five labels. High misunderstanding was given for participants who misunderstood all or four out of the five labels.

Factors that may affect the health literacy level were collected as age, gender, socioeconomical status, use of daily medication and routine visit for family physician. Both education level and monthly income were used as indicators of the socioeconomical status of the participants. Participants who have 6th-grade education level or less considered with low education level, while those who have more than 6th-grade level considered with good education level. The participants who have monthly income less than 10,000 Saudi Riyals (SR) considered with poor socioeconomical status while those who have monthly income more than 10,000 Saudi Riyals (SR) considered with good socioeconomical status.

Health literacy of the participants was assessed by the validated Arabic Single Item Literacy Screener (SILS). This screener consists of one question which ask the participants about their need for help to read health related information. The participants answered this question based on Likert's scale which consists of five choices and the participants have to choose only one of them. The participant considered with good health literacy if his answer was "Never" or "Rarely", while considered with low health literacy if he chose "Often", "Always", or "Sometimes" (Al-Jumaili et al., 2015).

Participants visits for their physicians were divided into two groups, either one visits or more every 6 months as one group or rarely or less than one visit every 6 months as another group.

In phase 2, the participants with good understanding of the medications' label were excluded. Those participants understood all aspects of the labels or only misunderstood one aspect of the labels. Participants who misunderstood more than one aspect of the labels was considered as poor understanding and was included in the phase 2.

2.4. Analytical methods

Descriptive statistics (percentage, mean, and SD) used to describe each variable. Chi-square tests used to evaluate the association between the level of participant's health literacy with each affecting factor. Logistic regression model used to figure out the relation between the health literacy level with all significantly affecting factors.

2.5. Research ethics

The Approval of the IRB committees was taken before starting participants' interviews at the four hospitals where this study was conducted. Each participant was asked to sign a consent form before starting the interview.

3. Results

The total number of included participants in the phase 1 of the study was 511 participants; 46% of the participants (n = 235) were patients from KSUMC, 22.3% of them (n = 114) were from PSMMC, 18.2% (n = 93) from KFMC, and 13.5% (n = 69) from KFSHRC. The mean age of the participants was 38.95 years (SD = 13.25). The range of participants' age was (18–90 years). Females represent 50.7% (n = 259) of the participants. Most of the participants were Saudi (n = 489; 95.1%). (For more sample characteristics, see Table 1).

Almost 38.6% (n = 197) of the participants misunderstood the labels' instructions. Small number of those participants (n = 9; 4.6%) had low level of misunderstanding. More than half of the participants who misunderstood the labels instruction (n = 133; 67.5%) had moderate level of misunderstanding while 55 of them

Table 1
Sample Characteristics.

Characteristic	Phase-1 mean (SD)[1]/ Frequency (%)[2]	Phase-2 mean (SD)[1]/ Frequency (%)[2]
Demographic characteristics:		
Age (years):	38.95 (13.25)	43.27 (13.54)
Gender:		
Female	259 (50.7%)	73 (37.1%)
Marital status:		
Single	156 (30.5%)	49 (24.9%)
Married	355 (69.5%)	148 (75.1%)
Education level:		
0–6th grade	59 (11.6%)	36 (18.3%)
6–12th grade	198 (38.7%)	76 (38.6%)
More than 12th grade	254 (49.7%)	85 (43.1%)
Employment status:		
Employed	253 (49.5%)	102 (51.8%)
Not employed	258 (50.5%)	95 (48.2%)
Monthly income:		
Less than 10,000 SR	355 (69.5%)	120 (60.9%)
10,000 SR or more	156 (30.5%)	77 (39.1%)
Chronic diseases:		
Participants with chronic disease	300 (58.7%)	121 (61.4%)
No. of chronic diseases	1.97 (1.22)	2.15 (1.32)
Daily used medications:		
No. of daily medications	3.11 (2.45)	3.44 (2.73)

[1] For continuous data: mean (SD).
[2] For categorical data: frequency (percentage %).

Table 2
Sample Characteristics of the excluded participants in phase-2.

Characteristic	Mean (SD)/number (%)
Demographic characteristics:	
Age (years):	36.23 (12.33)
Gender:	
Female	186 (59.2%)
Nationality:	
Saudi	296 (94.3%)
Marital status:	
Single, divorced or widowed	107 (34.1%)
Married	207 (65.9%)
No. of sons:	
0–3 sons	211 (67.2%)
More than 3 sons	103 (32.8%)
Education level:	
0–6 grade	20 (6.4%)
More than 6 grade	294 (93.6%)
Employmental status:	
Employed	151 (48.1%)
Not employed	163 (51.9%)
Monthly income:	
Less than 10,000 SR	235 (74.8%)
10,000 SR or more	79 (25.2%)
Chronic diseases:	1.05 (1.25)
Daily medications:	1.93 (2.27)

[1]For continuous data: mean (SD).
[2]For categorical data: frequency (percentage %).

(27.9%) had high level of misunderstanding. The total number of responses for 511 participants was 2555 responses for the 5 labels (five responses for each participant); 984 (38.5%) of the total responses were incorrect.

In phase-2 of the study, the total number of participants who had labels' instructions misunderstanding was 197 participants. Almost half of those participants (n = 97; 49.2%) were from KSUMC and they represent 41.3% of participants who interviewed in this hospital. Forty-five participants (22.8%) were from PSMMC; 43 participants (21.8%) from KFMC; and 12 participants (6.1%) from KFSHRC; and they represent (39.4%), (46.2%), (17.3%) of the participants who were interviewed in those hospitals respectively.

The mean age of participants in phase-2 was 43.3 years (SD 13.5). The age range of the participants was between 18 and 90 years. High percent of the participants were male (n = 124; 62.9%). Most of the participants were Saudi (n = 190; 96.4%). (For more sample characteristics, see Table 1).

The total number of participants who were excluded in phase 2 is 314 participants. Those participants showed a good understanding of the medication labels. The mean age of them was 36.2 years. Most of them were females (59.2%) and Saudis (94.3%). The sample characteristics of the excluded participants in phase 2 is described in Table 2.

Almost 81.7% (n = 161) of the participants had good education level (more than 6th grade) while 18.3% (n = 36) had low education level (6th grade or less). Less than half of the participants (43.1%) had education level more than 12th grade—e.g., diploma, bachelor, or postgraduate degrees—while 38.5% had a moderate education level (6–12th-grade education level).

The employment status varied between the participants; more than half of the participants (n = 102; 51.8%) were employed or had their own private businesses while (n = 95; 48.2%) were unemployed. The total number of participants with good monthly income (10,000 Saudi Riyal (SR) or more) was 77 participants (39.1%); and 120 participants (60.9%) had low monthly income (less than 10,000 SR).

Almost (61.4%) of participants had chronic diseases with an average of 2.15 (SD 1.32) chronic diseases. The average daily used medications was 3.44 medications daily (SD 2.73). Participants who had poly-pharmacy (4 medications or more) represent 38.4%.

The SILS revealed that 22 participants (11.2%) had low health literacy while 175 (88.8%) had good health literacy. The mean age of participant with low health literacy was 43.05 years (SD 16.69). Female participants represent 54.5% of the participants with low health literacy. Exactly, half of those participants (50%) had low education level. The socioeconomic status of those participants was very low; 90.9% of them had low monthly income while 77.3% of them were unemployed. More than half of them (59.1%) had chronic diseases. (For more characteristics of participants with low health literacy see Table 3).

The use of chi-square test revealed that there is a significant association between the level of health literacy with the education level (P-value < 0.001), monthly income (P-value = 0.002), number of chronic diseases (P-value = 0.014), and the number of daily used medications (P-value = 0.047). Age, gender, nationality, the routine visits of participants to their family physician, and the use of polypharmacy were not significantly associated with the participants' health literacy level (the P values > 0.05). To figure out the association between health literacy level and the previously mentioned factors, logistic regression model was used. Logistic regression model showed that the health literacy significantly associated with the socio-economic status of the participants - both education level (P-value = 0.044) and monthly income (P-value = 0.036) - while not significantly associated with the number of chronic diseases (P-value = 0.380) and the number of the daily used medications (P-value = 0.727) (Table 4).

Participants who have 6th grade education level or less have higher probability to have low health literacy than those participants who have more than 6th grade education level [adjusted odds ratio (AOR) = 2.94; 95% confidence interval (95% CI) (1.03–8.404); P-value = 0.044]. Participants who have low monthly income were five times more likely to have low health literacy

Table 3
Sample Characteristics of participants with low health literacy.

Characteristic	Mean (SD)[1]/Frequency (%)[2]
Demographic characteristics:	
Age (years):	43.05 (16.69)
Gender:	
Female	12 (54.5%)
Marital status:	
Single	10 (45.5%)
Married	12 (54.5%)
Education level:	
0–6th grade	12 (54.5%)
6–12th grade	7 (31.8%)
More than 12th grade	3 (13.7%)
Employment status:	
Employed	5 (22.7%)
Not employed	17 (77.3%)
Monthly income:	
Less than 10,000 SR	20 (90.9%)
10,000 SR or more	2 (9.1%)
Family's physician visits:	
One or more every 6 months	13 (59.1%)
Rarely or once every 6–12 months	9 (40.9%)
Chronic diseases:	
Participants with chronic disease	13 (59.1%)
No. of chronic diseases	3.46 (1.61)
Daily used medications:	
No. of daily medications	4.8 (3.23)

[1] For continuous data: mean (SD).
[2] For categorical data: frequency (percentage %).

level than the participants with good monthly income [AOR = 5.28; 95% CI (1.118–24.943); P-value = 0.036] (Table 4).

4. Discussion

Over the past few years, many studies assessed the patient understanding of the instructions of their medications. One study conducted in the United States revealed that the level of misunderstanding among patients in 3 primary clinics was 46.3% of the participants. Patients with low literacy were less able to understand the labels instructions (Parker, 2007).

This study showed that 38.6% (n = 197) of the participants misunderstood more than one aspect of the medication labels' instructions of 5 of the commonly used medications. Most of them misunderstood 2 or 3 labels while one-third of the participants misunderstood at least 4 of the labels.

Among those participants who misunderstood the medication labels, the level of low health literacy was (11.2%). These findings is contiguous with the low level of health literacy in other countries as Germany (12.3%) (Jordan and Hoebel, 2015); United States (14%) (Kutner et al., 2006); Austria (18.2%), Greece (13.9%), Poland (10.2%), and Ireland (10.3%) (Sørensen et al., 2015). In Australia, it is reported that the low health literacy among adults is higher (60%) (Practitioners RC of G, 2014). In a community study conducted in China, a higher prevalence of low health literacy was reported (84%) (Wu et al., 2017).

Bad health literacy significantly associated with the socioeconomic status of the participants. Both education level and monthly income were used as indicators of the socioeconomic status. The prevalence of low health literacy among participants with low education level was higher than that in the participants who have good education level (30.6% vs. 6.8%). Participants with low education level nearly 3 times more likely to have low health literacy than those with good education level.

It is expected that participants who have good education level can read the health related information and have the ability to understand the medical instructions by themselves without the need of help from the others. Also, they have the ability to find useful information from different resources as journals, books, the web sites, and even by the use of their smart phones. Furthermore, they have a good health-related awareness. In contrast, participants with low education level have multiple difficulties in reading health related information and finding useful information from trusted and well-known resources. In addition, their ability to use the modern technology to find health related information is limited. Thus, they usually need the help of their family members or the others in processing health related information.

Participants who have low monthly income are 5 times more likely to have low health literacy than those with high monthly income. The prevalence of low health literacy among participants with low monthly income was (16.7%) while the prevalence for those with high monthly income was (2.6%) (Table 5).

Participants with low economic status loss the opportunities to get enough resources for health-related information. Furthermore, their ability to get high quality healthcare is limited. Thus they usually have low health-related awareness and need the others help to process health related information.

Similar findings were published in Germany (Jordan and Hoebel, 2015) and China (Wu et al., 2017). In a comparative study conducted in the Europe countries (Austria Bulgaria, Germany, Greece, Ireland, Netherlands, Poland, and Spain), they found that the financial deprivation is the main predictor of low health literacy, followed by low education level (Sørensen et al., 2015). In Australia, they found that low health literacy is associated with

Table 4
Odds Ratio for low health literacy.

Variable	OR (95% CI)	P-value	AOR (95% CI)	P-value
Education level:				
More than 6th grade	1.00		1.00	
6th grade or less	5.98 (2.35–15.38)	<0.001	2.94 (1.03–8.404)	0.044
Monthly income:				
10,000 SR or more	1.00		1.00	
Less than 10,000 SR	7.52 (1.70–33.33)	0.002	5.28 (1.118–24.943)	0.036
No. of chronic diseases:	–	0.014	1.19 (0.808–1.752)	0.380
No. of daily used medications:	–	0.047	1.04 (0.835–1.296)	0.727
Age:	–	0.933	–	–
Gender:	–	0.072	–	–
Nationality:	–	0.137	–	–
Polypharmacy:	–	0.164	–	–
Family's Physician visits:	–	0.822	–	–
Adherence:	–	0.895	–	–

OR: odds ratio; 95% CI: 95% confidence interval.

Table 5
Prevalence of low health literacy in Participants' Characteristics.

Variable	Prevalence %	P value
Education level:		0.044
More than 6th grade	30.6%	
6th grade or less	6.8%	
Monthly income:		0.036
10,000 SR or more	2.6%	
Less than 10,000 SR	16.7%	
Gender		0.072
Female	16.4%	
Male	8.1%	
Chronic disease		0.812
No	11.8%	
Yes	10.7%	
Use of daily medications		0.625
No	9.7%	
Yes	12.0%	
Physician visits:		0.649
Rarely or less than once every 6 months	10.6%	
One or more every 6 months	11.6%	
Adherence:		0.895
Adherent	10.6%	
Non-adherent	11.3%	
Poly-pharmacy:		0.164
Yes	16.7%	
No	9.4%	

bad employment status and low education level (Jayasinghe et al., 2016).

The prevalence of low health literacy was higher in participant's who didn't suffer from chronic diseases (11.8%) than those who had at least one chronic disease, but the logistic regression model revealed that the level of health literacy is not affected by the number of chronic diseases which the participants have (P = 0.380). In a similar way, there was no significant association between health literacy level and the number of daily used medications by the participants (P = 0.727), even though, the prevalence of low health literacy among participants who use daily medications was higher than those who didn't use daily medications (12.0% vs. 9.7%). These findings were confirmed by assessing the association between the level of health literacy with the use of poly-pharmacy (use of 4 medications or more). Although, the prevalence of low health literacy among participants who were taking poly-pharmacy is nearly twice the prevalence in participants not taking poly-pharmacy (16.7% vs. 9.4%) but there was no significant association between the health literacy level with the use of poly-pharmacy (Table 5).

It is expected that participants who routinely visit their family physician have good health literacy than those who rarely or never visit their family physician at all. This study found that there was no significant difference in the prevalence of low health literacy between participants who visit their family physician one time or more every 6 months (11.6%) and those who visit their family physician rarely or less than one time every 6 months (10.6%) (P = 0.649).

In contrast to the findings in the United States and the European countries, neither age nor gender have effect on the level of health literacy of participants (P = 0.933, 0.072) respectively. However, the prevalence of low health literacy among female participants was two times higher than the prevalence among male participants (16.4% vs. 8.1%). In the United States and the European countries, they found that low health literacy is associated with old age and male gender (Parker, 2007; Kutner et al., 2006; Sørensen et al., 2015). The Chinese population showed that age and gender are not predictors of the low health literacy level (Wu et al., 2017). Race was not assessed in our study because there are no definitely determined races among the population in Saudi Arabia.

There is a very low number of studies that assessed the health literacy level among patients who poorly understand their medication instructions in Saudi Arabia. Most of the conducted studies assessed the effect of patients' age on the level of understanding of the medication label. Thus, a high number of these studies examine elderly patients (Morrell et al., 1989; Morrell et al., 1990). This study included participants from age 18 to 90 years with an average age of 39 years in phase-1 and 43 years in phase-2.

This study has several limitations, the first limitation that the result of this study is limited to the population of Riyadh city only. Furthermore, this study excluded participants who can't speak Arabic. In addition, the health literacy assessment was limited to those participants who have poor understanding of the medications' labels. Therefore, the results of this study can't be generalized to all population of Saudi Arabia. Second limitation, almost 95% of the participants in this study were Saudi, only less than 5% were non-Saudi. However, according to the formal governmental statistics published in 2016, one-third of the population in Saudi Arabia are non-Saudi (General Authority of Statistics, 2016). Non-Saudis represents 42.7% of the population in Riyadh where this study was conducted (General Authority of Statistics, 2016). The difference between the prevalence of non-Saudis in this study with the prevalence of non-Saudis among Riyadh populations can be justified by the hospitals' regulations were this study was conducted which provide healthcare services for Saudi patients who live in Riyadh. To generalize the results, additional studies are needed which include participants from different regions in Saudi Arabia, furthermore, private hospitals should be included where high percent of non-Saudi receive their healthcare services. Third limitation, the sample size, which was included in this study, is not enough to detect the factors that affect the prevalence of low health literacy among patients who poorly understand the medications' labels. Larger number is needed to clearly detect these factors because the prevalence of the low health literacy among those participants is low (n = 22 participants). Fourth limitation, health literacy level was assessed by the SILS tools, which consist of single question about the need of the participants for the help of the other to process health related information. However, this SILS tool is validated as the Arabic tools to assess the health literacy level (Al-Jumaili et al., 2015), it is a subjective tool, depends on the participants answer, which may affected by the Hawthorne effect, which made an alteration of the participants' behavior due to their awareness of being observed (McCarney et al., 2007; Fox et al., 2008). Fifth limitation, this study was conducted to assess the health literacy level among participants with poor understanding of the medications' labels, and not designed to assess the association between health literacy level and medication error or medication safety.

5. Conclusion

Low education level and financial deprivation are the main predictors of low health literacy among patients with poor understanding of the medication label instructions in Saudi Arabia. Additional efforts should be applied to enhance the level of understanding of the medication labels among patients with low health literacy, especially those with low education level and/or have poor socioeconomic status.

Declaration of Competing Interest

None.

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