Saudi Pharmaceutical Journal 30 (2022) 544–554

Contents lists available at ScienceDirect

Saudi Pharmaceutical Journal

journal homepage: www.sciencedirect.com

Original article

The impact of using pictorial aids in caregivers' understanding of patient information leaflets of pediatric pain medications: A quasi-experimental study

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ARTICLE INFO

Article history:
Received 2 December 2021
Accepted 27 February 2022
Available online 4 March 2022

Keywords:
Medications leaflets
Health literacy
Pharmaceutical pictogram
Pediatrics
Saudi Arabia

ABSTRACT

Introduction: Patient information leaflets (PILs) are one of the main sources of information for over-the-counter medications (OTCs). This study aimed to assess caregivers' understanding of instructions in PILs provided with paracetamol medications and the impact of pictograms use.
Methods: A quasi-experimental study was conducted among caregivers of children aged < 13 years recruited in pediatric outpatient clinics at University Medical City in Riyadh. The calculated sample size was 128; at least 64 participants were needed in each group (the text-only group and the text-plus pictograms group). Caregivers' health literacy was assessed using a validated Arabic version of the Newest Vital Sign scale. Participants' understanding of PILs instructions was assessed using eight questions on the route of administration, minimal hours between doses, max daily dose, shake medication before use, storage, and reporting adverse events; and was rated based on the number of questions correctly understood. Characteristics of participants were compared by Pearson X^2 and *t*-test was used to assess the significance of mean score differences between groups.
Results: A total of 130 caregivers participated in the study; almost half of them were mothers (47%, [n = 61]) and 43% (n = 56) have "a possibility of limited health literacy". The mean number of correct answers to questions assessing the understanding of PILs instructions was significantly higher among the text-plus pictograms group compared to the text-only group (5.25 ± 1.85 vs. 4.38 ± 1.27; $p < 0.001$). When results were controlled for age and gender, better health literacy was found to be associated with a better understanding of instructions (B = 0.39, 95 %CI 0.23–0.54).
Conclusion: Limited comprehension of medications instructions was observed; adding pictorial aids to PILs might enhance the comprehension. Differences in health literacy levels of caregivers should be considered when designing PILs.

1. Introduction

The sale of over-the-counter (OTC) medications from pharmacies can help individuals self-manage their symptoms. The public perceives OTCs to be safe and safer than prescription medications (Cooper, 2013). A study conducted in Saudi Arabia found that the majority of the population perceived OTC pain medications to be safe (Siddig et al., 2020). This perception may lead to unintentional misuse or abuse of these medications (Cooper, 2013). Although most OTC pain medications are considered safe when used as instructed, consumers' misuse of these medications is associated with health complications among children including allergic

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Peer review under responsibility of King Saud University.

Production and hosting by Elsevier

https://doi.org/10.1016/j.jsps.2022.02.017
1319-0164/

reactions, childhood asthma, and liver and renal damages (Arencibia and Choonara, 2012; Lowe et al., 2010). Adherence to information and instructions of medication leaflets by consumers or caregivers can help ensure safer use and prevent any potential health risks of medication misuse (Bennin and Rother, 2015). However, there is a gap in the understanding of the optimal and safe use of OTC among consumers (Hassali et al., 2012; Madlon-Kay and Mosch, 2000; Yin et al., 2010).

Patient information leaflets (PILs) are one of the main sources of information for OTC medications' use (Chan et al., 2015). Comprehension of information provided in the leaflets can affect parents' decision-making on the safe and optimal use of pain medications (Bennin and Rother, 2015). A study conducted among Saudi mothers found that only 53% of mothers can measure the accurate dose of oral liquid medications to administer them to their children (Almazrou et al., 2014). Parents may not be fully aware of indications, doses, adverse events, and drug instructions when using pain medications for their children (Bailey et al., 2009; Hassali et al., 2012; Madlon-Kay and Mosch, 2000). Previous studies have reported that the majority of parents reported reading medication leaflets, yet, the information provided was found to be less effective in informing users of the correct use (Bailey et al., 2009; Hassali et al., 2012; Madlon-Kay and Mosch, 2000). It was found between 30% and 60% of them reported difficulty in indicating the correct dosage (Bailey et al., 2009; Hassali et al., 2012; Madlon-Kay and Mosch, 2000; Wallace et al., 2012). Moreover, some found that there was misapprehension about medications' instructions and their side effects and adverse events (Hassali et al., 2012).

Comprehension of information and instructions of medication leaflets among caregivers is essential to ensure safer use and prevent any potential health risks of misuse in children (Bailey et al., 2009; Yin et al., 2008a, 2008b). The level of health literacy among caregivers is a significant factor that impacts the comprehension of medications' instructions (Eiland et al., 2008; Yin et al., 2011). Misinterpretation of written instructions can cause medication errors that can lead to serious adverse events (Chan et al., 2015; Yin et al., 2011). Previous studies reported a deficiency in parents' knowledge about the use and management of their children's OTC medications (Albsoul-Younes et al., 2011; Chan et al., 2015). Pictograms are used to enhance understanding of written instructions (Katz et al., 2006). It was found that incorporating pictograms with written instructions enhances the comprehension of medications instructions and reduces medication errors (Chan et al., 2015).

A study found the current leaflets supplied with medications in Saudi Arabia needs improvement in term of content and design to enhance their comprehensibility (Al-Aqeel, 2012). Previous international studies have supported the use of pictograms to aid written medications instructions to improve its comprehensibility and readability (Badarudeen and Sabharwal, 2010; Chan et al., 2015). Scientific evidence remains limited with a lack of research investigating parental comprehension of PILs and the impact of using pictorial aids at the national and regional levels. Moreover, previous studies have extensively investigated the impact of using pictorial aids along with medication written instructions among elderly patients and illiterate parents (Badarudeen and Sabharwal, 2010; Chan et al., 2015). The impact of adding pictorial aids to PILs among the community of caregivers is still needed to be supported with evidence, especially at the national level. Therefore, this study sought to assess the parents' comprehension of the information provided on PILs for OTC paracetamol medications intended for pediatrics, and examine the impact of adding pictograms to these PILs. A secondary objective of this study is to assess the association between health literacy and the understanding of PILs instructions.

Methods.

2. Study design

This was a quasi-experimental study conducted to assess the effect of using pictograms added to text-based PILs on comprehension of paracetamol instructions among parents in comparison with the usual text-only PILs. A sample size of 128 (64 per group) was calculated; caregivers were assigned on an alternating basis to either group, text-only group (n = 64) and text-plus pictograms group (n = 64) (Fig. 1). Data were collected from a convenient sample of visitors to pediatric outpatient clinics at King Saud University Medical City (KSUMC) between the 7th of December 2020 and the 21st of December 2020. Eligibility criteria of enrollment were: being adult aged 18 years or older, providing care to at least one child aged < 13 years, speaking Arabic, and being a resident of Saudi Arabia. Prior to participants' recruitment, verbal consent was obtained from all caregivers who participated in the study; written consent was waived by the ethical committee at KSUMC. Ethical approval was obtained from the SFDA research ethics committee (013-2020) and King Saud University Medical City (E-20-5385).

3. Measurements

This study assessed caregivers' comprehension of PILs of pediatric pain medications, using paracetamol PILs. This survey consists of eight questions that were designed to assess participants' understanding of PILs' instructions about dosage, frequency, route of administration, minimal separating hours between doses, maximum daily dose, shake before use instruction, medication storing conditions, and what to do when your child develops an adverse event. Participants' responses to these questions were classified by two of the co-authors as correct or incorrect and verified by the primary author. The participants' understanding of the instructions was rated based on the number of questions answered correctly from 0 to 8; participants who answers the eight questions correctly receive the total score (8 points) as a percentage of 100%.

Sociodemographic data on participant age, gender, number of children, education level, employment status, monthly income, relationship to the child, and who provides care to the child when ill were collected. The child's age and health conditions were obtained for the child that the visit to the clinic was for.

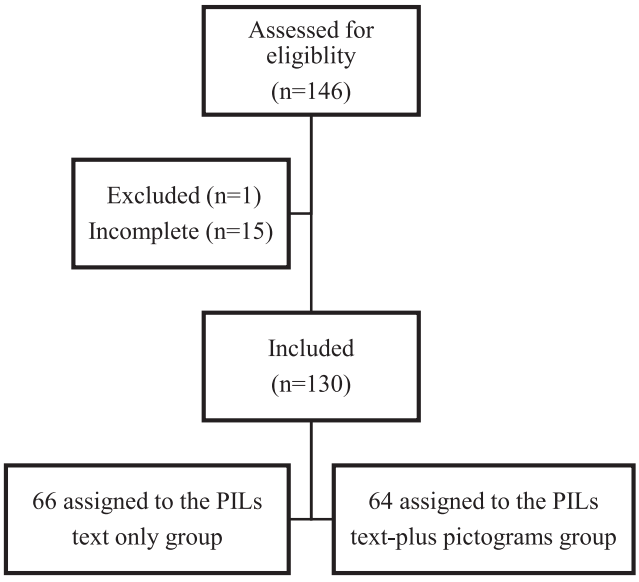


Fig. 1. Flow diagram of participants' recruitment and group allocation.

The participant's health literacy was assessed using the previously validated Arabic version of the Newest Vital Sign (NVS) scale (Fadda et al., 2016). The participants' health literacy was categorized based on the total score of answering the six questions on the NVS scale. A participant with a score of 0–1 indicates a high likelihood of limited literacy, a score of 2–3 indicates the possibility of limited literacy, and a score of 4–6 indicates adequate literacy (Fadda et al., 2016). The questionnaire items were implemented as an electronic form to be filled by the data collectors during the interview to ease the documentation, management, and storage of data.

3.1. Tool design

The PIL for paracetamol used in this study was obtained from one of the most common paracetamol brands used in the Saudi market. The PIL was used with no modification for the text-only group. For the text-plus-pictograms group, the adopted PIL was modified to include also pictorial aids (Appendix A).

Pictorial aids were adopted from the validated United States Pharmacopeia (USP) visual aids illustrating: route of administration, minimal hours between doses, max daily dose, shake the medication before use, storage, and reporting adverse events (USP, 2020) (Appendix B). Two additional pictograms were designed for this study: one to illustrate the minimal separating hours between doses (Fig. 2) and the second is a visual representation of needed doses based on child age using a syringe or medicine measuring cup which was added to the paracetamol dosage table in the original PIL (Fig. 3).

The designed pictograms were tested and validated during the pilot phase with 40 participants that were not included in the actual study sample; 20 participants were in the first pilot phase and 20 were in the second pilot phase. During the pilot phase, caregivers were given the newly designed pictograms on a plain page with no written instruction and were asked "If this pictogram were found in PILs, please interpret its meaning and what action do you take based on this pictogram?". Fig. 4 was used in the first pilot but < 70% of participants were able to correctly interpret the pictogram. So, the pictogram was redesigned by the research team as in Fig. 2 to increase its clarity (changes include numbering the hours in the clock, highlighting minimal separating hours, and including a clearer pictogram of a child given the medication through the mouth). The majority of participants (90%) in the second pilot phase were able to interpret correctly the meaning of the two designed pictograms. Based on findings from the pilot phase, the two pictograms along with the previously validated pictograms from the USP were implemented in the adopted PILs for the text-plus-pictograms group. Data from the pilot phase were not included in the overall analysis of this study's findings.

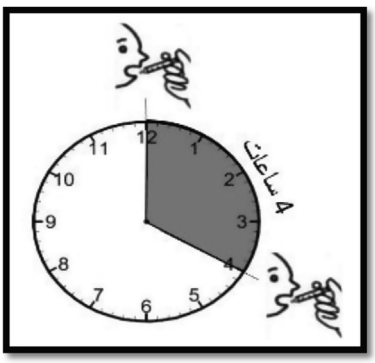


Fig. 2. Pictogram explains the minimum time between doses used in the second pilot phase.

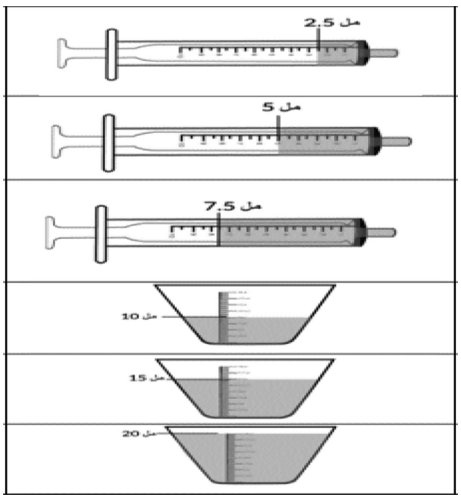


Fig. 3. Pictograms describe the needed doses.

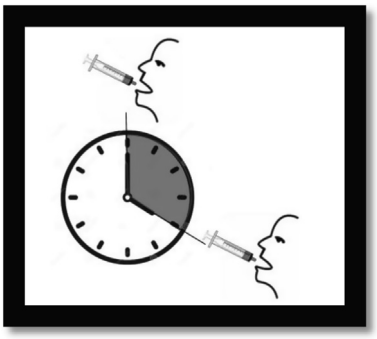


Fig. 4. Pictogram explains the minimum time between doses used in the first pilot phase.

3.2. Data collection and participants' recruitment

A clinic in the outpatient pediatric section was designated to interview participants by two trained pharmacists, instead of interviewing participants in the waiting areas to maintain the social distancing based on the KSUMC regulation for research conducted during the COVID-19 pandemic. Caregivers were approached initially in the waiting area prior to their child's appointment to invite them to participate in the study. Once the caregiver agreed to participate, a trained pharmacist lead them to the assigned clinic to interview participants. The consent for participation in the study was obtained verbally from caregivers. Each consenting participant was assigned into one of the two groups; the text-only group and the text-plus-pictograms group. Study participants were allocated on an alternating basis to either group. For equal allocation to these two groups, participants with odd sequence numbers were allocated to the text-only group, and participants with even sequence numbers were allocated to the text-plus-pictograms group (Fig. 1).

At the beginning of the interview, participants' sociodemographic characteristics were collected. Then, participants were asked to read the provided PILs. Data collectors recorded the time spent reading the PILs for each participant. Then, they asked participants eight open-ended questions that assess their comprehension of the instructions on the PILs.

3.3. Sample size calculation

A sample size of at least 128 participants was calculated to detect differences as small as 0.5 SDs at 80% power and an alpha level of 5%. As the outcome is dichotomous, a sample size of 128 participants would allow detecting differences in proportions as small as 25%. Each group recruited at least 64 participants based on the sample size calculation.

3.4. Data analysis

Sociodemographic characteristics were presented as frequencies and percentages for the overall sample; and the PILs text-only and the PILs text-plus-pictograms groups. Characteristics of participants in the text-plus-pictogram and text-only groups were compared by t-tests and Pearson X^2 tests as appropriate. Comparison between groups was made based on the proportion of participants who correctly responded to PILs' questions and the total mean score with standard deviation. T-test was used to assess the significance of the mean difference between the text-only and text-plus-pictograms. Health literacy was assessed based on the NVS scale score. Multiple linear regression analysis was performed to assess the association between understanding of PILs instructions (total score of questions answered correctly) and health literacy (NVS score) when controlled for age and gender. P-values < 0.05 were considered significant. Data analyses were performed using STATA software version 16 (StataCorp, College Station, Texas 77,845 USA).

4. Results

A total of 146 caregivers were approached during their waiting at pediatric outpatient clinics at KSUMC. Of those, 130 (89%) agreed to participate; 66 participants were assigned to the text-only group, and 64 to the text-plus-pictogram group (Fig. 1). Out of the total sample, 45% (n = 59) were between the age of 25–44 years with a mean age of 34 years. Almost half of the participants were female (51%, [n = 66]). About 47% of participants were mothers (n = 61), 45% were fathers (n = 59), and the remaining 8% represent others including sisters and grandmothers (n = 10). About 45% of participants had three children or more (n = 58). Caring for a sick child was mostly the responsibility of the mother as reported by 90% (n = 118) of participants. Nearly 28% of participants have a child under the age of 1 year and the majority of children do not have a chronic condition (82%, [n = 106]). Detailed demographic characteristics are presented in Table 1.

No statistically significant differences were observed in participants' characteristics between groups except for health literacy (p = 0.010) (Table 1). According to the assessment score of the NVS scale, 43% (n = 56) of the total participants have "a possibility of limited health literacy"; 57% (n = 21) among the text-only group and 43% (n = 16) among the text-plus pictograms group. While 28% (n = 37) of the total participants have "a high likelihood of limited literacy"; 61% (n = 34) among the text-only group and 39% (n = 22) among the text-plus pictograms group. Moreover, 28% (n = 37) of the total participants had "adequate literacy"; 30% (n = 11) among the text-only group, and 70% (n = 26) among text-plus pictograms group.

The mean reading time of PILs among the total participants was 1.8 min. The proportion of participants who were able to correctly answer the "How much medications does your child need?" was 69% (n = 90); 65% (n = 43) among the text-only group and 73% (n = 47) among the text-plus pictograms group. The question on "how often should you give your child this medication?" was answered correctly by 77% (n = 100) of the total; with almost no difference in proportion between groups. The highest proportion of understanding was for medication administration instruction as 97% (n = 126) of total participants was able to answer the question correctly; 98% (n = 65) among the text-only group and 95% (n = 61) among the text-plus pictograms group. The lowest understanding was for medication storage instruction as only 20% (n = 26) of total participants was able to answer the question correctly; 11% (n = 7) among the text-only group and 30% (n = 19) among text-plus pictograms group. When asked about the minimum time between doses, almost 42% (n = 54) of participants were able to answer it correctly; 29% (n = 19) among the text-only group and 55% (n = 35) among the text-plus pictograms group. The question on "how many doses per day can you give to your child" was answered correctly by 61% (n = 79) of the total participants; 56% (n = 37) among the text-only group and 66% (n = 42) among the text-plus pictograms group. The proportion of participants who were able to correctly answer "should the medication be shaken before use?" was 67% (n = 87); 61% (n = 40) among the text-only group and 73% (n = 47) among text-plus pictograms group. The differences between groups were statistically not significant except for two items; the understanding of the minimum time between doses (p = 0.003) and storage instruction (p = 0.007) (Table 2).

The mean understanding score for PILs instructions (based on the number of questions answered correctly per participant out of 8) was 5 ± 1.56 among the total participants. The mean understanding score among the text-only group (4.38 ± 1.27) was lower than the mean score among the text-plus pictogram group (5.25 ± 1.85). The mean difference between the groups was significant (-0.87, p = 0.002). When controlled for age and gender, the understanding of PILs instructions was significantly associated with health literacy among the overall cohort (Table 3). One unit increase in health literacy score was associated with a 0.39 increase in the understanding of PILs instructions (95 %CI: 0.23–0.54).

5. Discussion

The present study was conducted to assess caregivers' comprehension of the information provided on PILs of paracetamol, and examine the impact of using pictograms on the comprehension of the information of medication leaflets. Assessing parents' comprehension of the information provided on PILs of paracetamol medications is needed as medication misuse was prevalent among caregivers when treating their children with these medications (Bennin and Rother, 2015; Himmelstein et al., 2011; Senter, 2010). This study found the mean understanding score for PILs instructions was 5 ± 1.56 among the total participants. The understanding of PILs instructions was higher among the group of parents who were given text-plus pictograms PILs compared with the groups of parents who were given text-only PILs. This is might be influenced by a higher health literacy score. One unit increase in health literacy score was associated with 0.39 increase in the understanding of PILs instructions.

Poor comprehensibility of PILs was found to be associated with medication errors and misuse (Gustafsson et al., 2005). Lower comprehension of PILs can be explained by their design and content readability (Raynor et al., 2007; Young et al., 2017). A study conducted in Qatar found that only 2.2% of PILs had acceptable readability (Munsour et al., 2017). Studies have found the majority of PILs need reader with at least the eleventh grade to comprehend its content, which is above the recommended level for health materials, fifth to sixth grade (Badarudeen and Sabharwal, 2010; Munsour et al., 2017). A study conducted in Saudi Arabia evaluated the leaflets supplied with medications found that the majority

Table 1
Participants sociodemographic characteristics among total participants, text only group and text-plus pictograms group.

Characteristics	Categories	Total		Text only		Text-plus pictograms		*p*-value[†]
		n	%[*]	n	%[**]	n	%[**]	
Age (years)	18–24	11	8.46	5	45.45	6	54.55	0.749
	25–34	59	45.38	31	52.54	28	47.46	
	35–44	49	37.69	26	53.06	23	46.94	
	≥ 45	11	8.46	4	36.36	7	63.64	
Gender	Male	64	49.23	32	50.00	32	50.00	0.863
	Female	66	50.77	34	51.52	32	48.48	
Number of children	One child	39	30.00	20	51.28	19	48.72	0.762
	Two children	33	25.38	15	45.45	18	54.55	
	Three or more children	58	44.62	31	53.45	27	46.55	
Education	Elementary education or below	1	0.77	1	100.0	0	00.00	0.488
	Intermediate education	2	1.54	1	50.00	1	50.00	
	Secondary education	22	16.92	12	54.55	10	45.45	
	Diploma	15	11.54	10	66.67	5	33.33	
	Bachelor	77	59.23	36	46.75	41	53.25	
	Masters	8	6.15	5	62.50	3	37.50	
	PhD	5	3.85	1	20.00	4	80.00	
Employment	Housewife	38	29.23	20	52.63	18	47.37	0.441
	Student	6	4.62	3	50.00	3	50.00	
	Work in the health sector	13	10.00	7	53.85	6	46.15	
	Work in the education sector	25	19.23	11	44.00	14	56.00	
	Work in the technology/engineering sector	14	10.77	9	64.29	5	35.71	
	Work in the business sector	8	6.15	3	37.50	5	62.50	
	Retired	4	3.08	0	00.00	4	100.0	
	Others	22	16.92	13	59.09	9	40.91	
Income	< 5,000 SR	10	7.69	6	60.00	4	40.00	0.719
	5,000 SR - < 10,000 SR	33	25.38	19	57.58	14	42.42	
	10,000 SR – 15,000 SR	26	20.00	14	53.85	12	46.15	
	≥ 15,000 SR	29	22.31	13	44.83	16	55.17	
	I prefer not to disclose	32	24.62	14	43.75	18	56.25	
Health literacy	High likelihood of limited literacy	37	28.46	21	56.76	16	43.24	0.010
	Possibility of limited literacy	56	43.08	34	60.71	22	39.29	
	Adequate literacy	37	28.46	11	29.73	26	70.27	
Relationship to the child	Mother	61	46.92	33	54.10	28	45.9	0.672
	Father	59	45.38	29	49.15	30	50.85	
	Other	10	7.69	4	40.00	6	60.00	
Caring for a sick child	Mother	118	90.77	61	51.69	57	48.31	0.550
	Father	1	0.77	0	00.00	1	100.0	
	Other	11	8.46	5	45.45	6	54.55	
Child age	Less than a year	36	27.69	21	58.33	15	41.67	0.739
	Between 1 and 3	26	20.00	12	46.15	14	53.85	
	Between 4 and 5	25	19.23	13	52.00	12	48.00	
	Between 5 and 10	32	24.62	16	50.00	16	50.00	
	Between 10 and 12	11	8.46	4	36.36	7	63.64	
Child health condition	No chronic conditions	106	81.54	52	49.06	54	50.94	0.412
	Morbidity with chronic conditions	24	18.46	14	58.33	10	41.67	

[*] Percentage by the column.
[**] Percentage by the row.
[†] *p*-value < 0.05 is statistically significant.

Table 2
Participants correctly understanding PILs instructions among total participants, text only group, and text-plus pictograms group.

Items	Total		Text only		Text-plus pictograms		*p*-value[†]
Based on the leaflet instructions:	n	%	n	%	n	%	
How much medication does your child need?	90	69.23	43	65.15	47	73.44	0.306
How often should you give your child this medication?	100	76.92	51	77.27	49	76.56	0.923
How will you administer the medication to your child?	126	96.92	65	98.48	61	95.31	0.295
What is the minimum time between doses of medication that you can give to your child?	54	41.54	19	28.79	35	54.96	0.003
How many doses per day can you give to your child?	79	60.77	37	56.06	42	65.63	0.264
Should the medication be shaken before use?	87	66.92	40	60.61	47	73.44	0.120
Where should you store the medication?	26	20.00	7	10.61	19	29.69	0.007
Assume your child suffers from side effects from the medication, who should you call to report side effects?	63	48.46	27	40.91	36	56.25	0.080

[†] *p*-value < 0.05 is statistically significant.

needs improvement to enhance its comprehensibility as an information source for patients (Al-Aqeel, 2012). This study found that the mean understanding score for PILs instructions was 5 out of 8 (62.5%), which is considered to be low compared with the values (>70%) reported in other studies (Mansoor and Dowse, 2003; Sletvold et al., 2020).

Table 3
The association between understanding of PILs instructions and health literacy when controlled for age and gender among total participants, text only group and text-plus pictograms group.

Characteristics	Total			Text only			Text-plus pictograms		
	B	95% CI		B	95% CI		B	95% CI	
Age (years)	−0.03	−0.07	0.01	−0.07*	−0.12	−0.01	−0.01	−0.07	0.05
Gender	−0.24	−0.81	0.32	−0.46	−1.12	0.19	0.13	−0.81	1.07
Total score of NVS	0.39*	0.23	0.54	0.15	−0.06	0.36	0.50*	0.27	0.74

* p-value < 0.05 is statistically significant.

The health literacy of caregivers contributes to the understanding of medication instructions. It was found that some caregivers were unable to make informed decisions from the provided information in the PILs (Bennin and Rother, 2015). This is mostly attributable to the limited provision of information and low health literacy (Calamusa et al., 2012). The study finding showed that higher comprehensibility of PILs instructions was associated with higher health literacy scores (B = 0.39, 95% CI: 0.23–0.54). Pictograms were found to be helpful in conveying important information and precautions to patients with a lower level of health literacy and reading ability (Yin et al., 2008a, 2008b). They aid low-literate caregivers who cannot comprehend the provided information on PILs when using self-administering medications (Chan et al., 2015). The role of caregivers' health literacy should be also considered when designing medication leaflets to best meet the needs of all parents, and reduce the impact of health disparities.

The use of pictograms on PILs is one of the strategies used to improve the comprehension of medication instructions provided to patients (Dowse and Ehlers, 2005; Katz et al., 2006). This study examined the impact of using pictograms to improve the comprehension of the information on PIL among parents. It was found that the mean comprehension of PILs instructions among the text-plus pictogram group (5.25 ± 1.85) was higher than the mean among the text-only group (4.38 ± 1.27). The finding showed a significant difference between the two groups on PILs instructions comprehension (p = 0.002). These findings were consistent with the findings of previous studies that found using pictorial aids enhances comprehension of medication instructions and improves adherence to these instructions among caregivers (Tork, 2013; Yin et al., 2011; Yin et al., 2008a, 2008b).

Pictograms are used to help in illustrating how often to administer medication and other cautionary statements (Chan et al., 2015). A study conducted among Saudi mothers, found that only 53% of mothers can measure the accurate dose of medications to their children and the authors suggested the use of pictograms to improve mothers' dosing abilities and, thus, reduce dosing errors (Almazrou et al., 2014). Findings of our study showed that more than half (55%) of participants given instruction plus pictogram shown in Fig. 2 were able to identify the required minimum time between doses compared with only 29% of those given text-only instruction (p < 0.01). It has been found that caregivers struggle to understand how often to administer medication (especially OTC's) to their children (Lokker et al., 2009). This may lead to administering these medications too or less often than needed, which may increase the risk of dosing errors and diminish their maximum therapeutic value. Using a pictogram as in Fig. 2 to supplement written instructions helps patients or caregivers understand the required time between doses.

Pictograms were found to improve the comprehension of the information of PILs among parents. However, PILs is needed to become attractive to read and informative source for instructions with the medications as consumers are reluctant to read them. The mean reading time of PILs among participants of this study was less than 2 min (1.8 min). It was noticed that some participants were reluctant to fully read the PILs, instead they quickly skim through them. This might be due to that caregivers believe that paracetamol medications are very well known that they do not need to read more about them (Bennin and Rother, 2015). Moreover, they might be familiar with the PIL since some of them have other children than the one they are bringing to the clinic. In addition, the PILs' content layout and presentation can also have an impact. The unattractive presentation of content, design, and layout format such as small fonts affect the level usability of PILs among caregivers. Assessing the needs of caregivers and consumers should be considered when designing PILs to increase the usability and readability of provided information in these leaflets.

The use of pictograms helps in conveying medication instructions and precautions, and assists those who may be confused by written instructions (Chan et al., 2015). Still, this study found that the comprehension of studied instructions items was ranged between 95% and 30% among the text-plus pictograms group, which is considered low compared with values reported in previous research (Mansoor and Dowse, 2003; Sletvold et al., 2020). Verbal reinforcement of instructions might increase the impact of using pictograms. Studies have found that combining verbal consultation with PILs aided with pictograms increases comprehension of instructions (Hu et al., 2013; Raynor et al., 2007). Therefore, healthcare providers have a key role in helping caregivers become informed and empowered in using medications safely and effectively for their children. Educating caregivers on the safe use of paracetamol is a collective effort for all healthcare providers as caregivers refer to healthcare providers as their main source of medication use information (Grime et al., 2007; Sletvold et al., 2020).

5.1. Limitations

There was no substantial evidence to claim a temporal relationship among factors given the study design. The use of the PILs of paracetamol, one of the most commonly used OTC medications, was making some participants answer some questions based on their previous experience using this medication to their children. Moreover, the PILs assessed in this study used the original PILs available in the market without changing the design with the same font size, color, and content except adding pictograms, which make it not attractive to be read and make some participants be reluctant to fully read the PILs. Future research should consider controlling for these factors when designing the study.

The success of adopting standardized pictograms not only depends on the comprehension but also the cultural differences in the interpretations of pictograms, which was not assessed in this study. Future research should test the cultural differences in the interpretations of pictograms in the Saudi community. Moreover, further studies are needed to confirm this association and assess other impacts of pictorial aids on improving caregivers' recall,

readability, and adherence to instructions and in addition to assessing its impact of preventing dosing errors.

6. Conclusions

The study findings highlight the importance of assessing caregivers' understanding of paracetamol PILs written instructions when designing these materials to improve their content and design. The different health literacy levels of caregivers should be considered when designing and writing PILs as health literacy was found to be significantly associated with the understanding of medication instructions. The use of pictograms promotes better understating of PILs' instructions when parents administer medications to their children. The instructions provided in PILs incorporating pictograms are better understood by caregivers than text-only PILs instructions. Still, caregivers' comprehension of PILs needs more improvement using different strategies such as combining verbal consultation with PILs aided with pictograms. The pictograms' appropriateness and cultural appropriateness should be considered to be assessed along with comprehension in future research.

Funding

The author (OA) received a fund from the Researcher Supporting Project number (RSP-2021/77), King Saud University, Riyadh, Saudi Arabia, to support the publication of this article.

Disclaimer

Conclusions reached in this study are based on the scientific interpretations of the authors and do not necessarily represent the opinion of their institutes.

Authors contribution

Aljoharah Algabbani: conceptualization, assessment tool design, supervised data collection, data analysis, and writing. Khalid Alzahrani: data collection and data cleaning. Sarah Sayed: assessment tool design, data collection, and data cleaning. Meshael Alrasheed: data collection. Deema Sorani: supervised data collection. Omar Almohammed: supervised the study. Amani S. Alqahtani: supervised the study. All authors reviewed the results and approved the final version of the manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

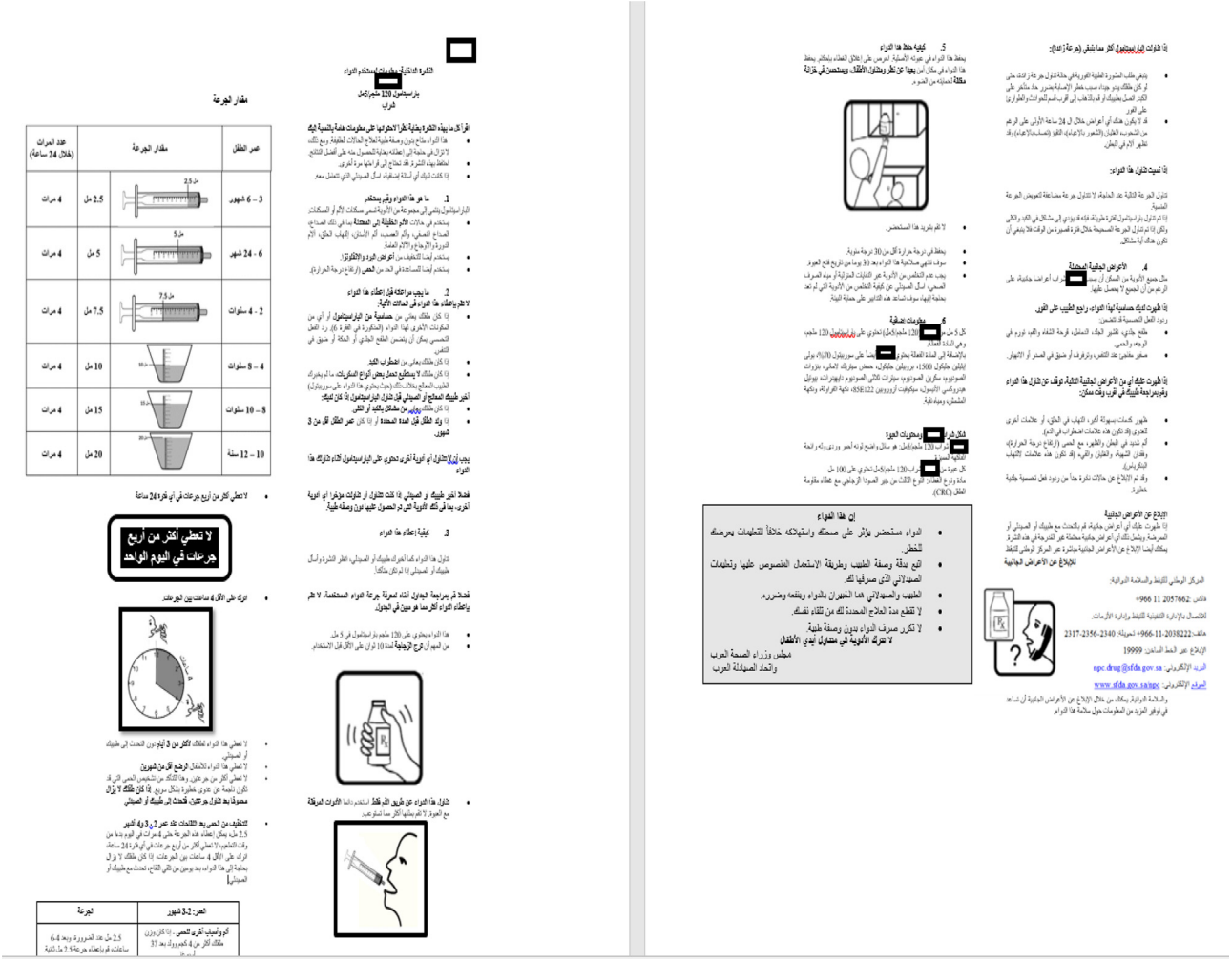
Acknowledgments

The authors would like to extend their appreciation to King Saud University for funding this work through the Researcher Supporting Project (RSP-2021/77), King Saud University, Riyadh, Saudi Arabia. We also would like to thank Abdulrahman Almarshad for his role in project management, coordination, and Radwan Hafiz for his role in mentoring the research project process.

Ethics approval and consent to participate

Prior to each interview, the researcher explained the study and ethics, and verbal informed consent was obtained from each participant. Ethical approval was obtained from the SFDA research ethics committee (013_2020) and King Saud University Medical City (KSUMC) (E-20-5385).

Appendix A



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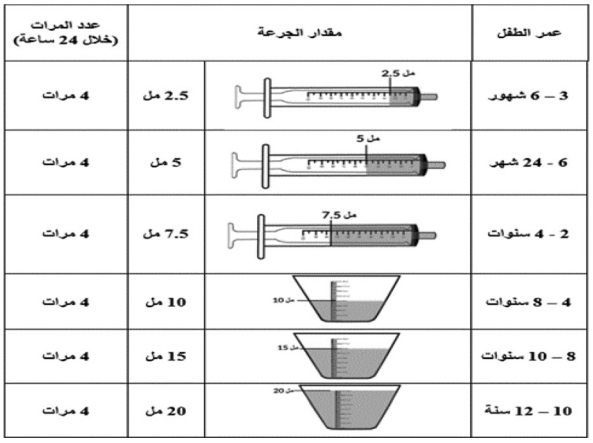
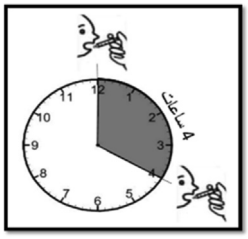
Appendix B

Pictorial aid along with written instructions in Arabic	Meaning in English
	Table of doses and frequency determination based on the child age
	
تناول هذا الدواء عن طريق الفم فقط. استخدم دائما الاداة المرفقة مع العبوة	The medication should be given through mouth using the provided tool
	
اترك على الأقل 4 ساعات بين الجرعات	The minimum time between doses is 4 h
	
لا تعطي أكثر من أربع جرعات في أي فترة 24 ساعة	The maximum number doses that can be given in 24 h is four doses
	لا تعطي أكثر من أربع جرعات خلال 24 ساعة
	
من المهم أن ترج الزجاجة لمدة 10 ثوان على الأقل قبل الاستخدام.	The medication should be shaken for 10 s before use
	
يحفظ هذا الدواء في مكان آمن بعيداً عن نظر ومتناول الأطفال، ويستحسن في خزانة مغلقة لحمايته من الضوء.	The medication should be kept in a safe storage out of the sight and reach of children, and it is recommended in a closed cabinet to protect it from light

(*continued*)

Pictorial aid along with written instructions in Arabic	Meaning in English
إذا ظهرت عليك أي أعراض جانبية، قم بالتحدث مع طبيبك أو الصيدلي أو الممرضة.	 If any side effect appeared, callo your doctor, pharmacist or nurse 

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