Original Article

Liquid Medication Dosing Error amongst Parents/ Caregivers at Outpatient Clinic

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ABSTRACT

Objectives: To evaluate the effectiveness of Patient Information Leaflet (PIL) based educational intervention to improve liquid medication measuring ability of parents/ caregivers. Simultaneously, to assess parents' measuring ability by dosing instrument type, and identify the association of various factors with dosing errors. **Materials and Methods:** A multi-centric, randomized controlled interventional study conducted at 2 pediatric clinics in Gandhinagar, Gujarat. Primary caregivers who would be giving medication to the patient (1 year to 12 years) were randomized in an alternative manner into control (without education) and intervention group (education with PILs), and asked to measure a dose of 5 mL using 3 measuring devices: dosing cup, oral dropper and calibrated spoon. Measured doses were categorized as an accurate dose (<10% deviation), acceptable dose (10%-20% deviation) and inaccurate dose (>20% deviation). **Results:** Total 164 parents/caregivers were enrolled and randomized; 82 in each group. Overall, 65.8% and 79.2% measured doses were accurate in the control and intervention group, respectively ($p=0.0018$). The range of measured doses (mL) of control group was higher than that of intervention group. About the instruments, the maximum number of participants measured an inaccurate dose with the calibrated spoon (10.9%), and the range of doses of oral dropper and calibrated spoon were higher than that of the dosing cup. Additionally, the likelihood of making dosing errors was not associated with the instruments used, gender, age and education level of the participants. **Conclusion:** The education provided to the participants helped to improve their measuring ability. Participants' measuring ability was better while using the dosing cup as compared with the use of oral dropper and calibrated spoon.

Keywords: Pediatric, Oral liquid medication, Parent's dosing error, Medication error, Patient education.

INTRODUCTION

The potential for dosing errors is greater in pediatric patients than in adults.[1-2] The dependence of pediatric patients on liquid medications is a major reason for the increasing frequency of such errors. The majority of parents (>50%) make error while measuring liquid medical preparation.[3-6] The accuracy in measurement of drug volumes is dependent on the measuring device used and the health literacy and awareness in the caregivers. Studies suggest several parents make errors in measuring the drug volumes and this is dependent on the measuring device used and on health literacy.[3,7-10] With the progress in modern medicine, household spoons were regarded as a standard for measuring doses of oral liquid medication.[11-12] Caregivers often use household spoons instead of standard devices like medicinal cups, droppers, and calibrated spoons for the measurement of liquid medication.[13] The confusion amongst the parents in the identifying the difference between the volumes of different household spoons like the teaspoon, table spoon and the dosing cup has been noted in previous research.[12,14-15] This invariably results in underdosing or over-dosing leading to grave consequences of the error.[13]

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Studies have reported that two major causes of dosing errors include the misinterpreted use of dispensing cups provided with the liquid medication where either the entire cup is considered to be a unit of the measure or one cupful is considered to be the recommended dose.[14] Li *et al*.[2] found that 62% of time parents measured an inaccurate dose of acetaminophen. On similar lines, several other studies estimate that 62–80% of parents routinely administer sub-therapeutic (<10 mg/kg) doses of paracetamol solution to their children.[1,2,16-17]

Strategies for decreasing dosing errors in pediatric patients involve increasing awareness and health literacy among parents and caregivers. Several studied confirmed that the use of pictograms can be a propitious option for improving parental comprehension about dosing instructions, and they established a link between the use of pictures plus written materials and improvement in understanding of medical instructions.[18-20] Pictographic instructions for dosing liquid medications for children were recently studied as part of a randomized, controlled trial of HELPix and this randomized trial demonstrated the efficacy of the HELPix intervention in decreasing parent dosing errors and improving adherence.[9] Pharmacist's intervention through education on the selection and proper use of measuring devices fairly improved the dosing accuracy amongst the parents and caregivers irrespective of their educational backgrounds and other factors.[21-22]

The purpose of our study was to fill this gap in knowledge regarding the most effective practices for dosing liquid medications in pediatric patients. The study evaluated whether PIL can improve liquid medication measuring ability of parents/caregivers using three dosing instruments: dosing cup, oral dropper and calibrated spoon, and assessed the measuring ability of parents/caregivers with each instrument. Additionally, this study explored the association of the measuring instruments and the various demographic variables with dosing error.

MATERIALS AND METHODS

Study Design

A multi centric, randomized controlled interventional study was carried out over a period of 6 months, from September 2019 to March 2020: 1-month pre data collection for obtaining necessary permissions and approvals, 4 months for the data collection, and 1 month after data collection for data analysis.

Ethical Approval

The study was approved on 1st October, 2019 by the K. B. Institute Ethics Committee (protocol number: KBIEC/2019/133), K. B. Institute of Pharmaceutical Education and Research, Gandhinagar, Gujarat.

Study Participants and Setting

The participants enrolled were parents or caregivers presenting with their children at Shaishav Children Hospital, Sector 21, Gandhinagar, Gujarat- 382021, India and Rudraksh Children Hospital and Vaccination Centre, Sector 24, Gandhinagar, Gujarat- 382024, India.

Sample Size

The expected error rate (p) was estimated to be 11.3%.[8] 164 participants were enrolled in the study of which 154 was the original calculated sample size according to the below mentioned formula. 10 participants were added over the calculated sample size to compensate for the biases in the study. Inclusion of 164 participants was consistent with the recruitment feasibility by an intent to assess this percentage error rate with a precision (d) of 0.05 at a statistical probability (α) threshold of 5%.

$$\text{Sample Size} = \frac{z_a^2 \cdot p(1-p)}{d^2}$$

Eligibility Criteria

Inclusion criteria were: primary caregivers of the patient or first blood relative of the age >18 (who would be giving the medication to the patient), and caregivers of patients from the age of 1 year to 12 years.

Exclusion criteria included: caregivers who were not involved in the dosing of the drug to the patient; caregivers who had a prominent physical disability (which might have affected the dose measurement and produced obvious errors); caregivers who had already previously participated in this type of study, and parents/caregiver of the child who was too ill to participate.

Patient Information Leaflets (Liquid Medication Dosing)

Four PILs were prepared in English and vernacular language (Gujarati), covering instructions about proper use of measuring cup, oral dropper and calibrated spoon as well as handling of liquid medications and their dosing. A total of 14 pictograms, which had 90.57% average score on semiotic evaluation, were used in the PILs. According to the Baker Able Leaflet Design (BALD) method the score of our PILs was found to be 31 out of 32, and

Ensuring Quality Information for Patient (EQIP) tool score was 75.95%. Readability level of the PILs text was standard (Flesch Readability Ease score was 65.7 and Flesch-Kincaid Grade level was 7.2).

Data Collection Procedure and Dosing Accuracy

Participants were invited for participation in the study based on the eligibility criteria. Prior to enrollment in the study, the eligible participants were explained about the details of the study with the help of participant information sheet (PIS), and informed consent was also obtained from the participants who agreed to voluntary participation. Following this, the participant's demographics were recorded, and then participants were requested to select the most commonly used device at home for measuring 5mL liquid medications from the various liquid dosing devices (teaspoon, tablespoon, calibrated spoon, oral dropper, dosing cup and oral syringe) presented before them.

Subsequently, the participants enrolled were assigned to the control and the intervention group randomly in an alternative manner maintaining the ratio of 1:1 (randomisation). The participants in the intervention group were given education with the prepared PILs prior to measurement of the dose, while the participants in the control group were not provided with prior education. Then, the participants in both the groups were requested to measure three doses of 5 mL of the given Paracetamol Pediatric Oral Suspension IP 250 mg (CALPOL 250 mg Suspension, GlaxoSmithKline Pharmaceuticals Limited) using three different dosing instruments: Dosing cup (GlaxoSmithKline Pharmaceuticals Limited, 10 mL); Oral dropper (Buddsbuddy™, 5 mL) and Calibrated spoon (Babyhug™, 5 mL). The measured doses of the participants were compared against a BOROSIL graduated measuring glass cylinder (10 mL: 0.2 mL). All the measuring instruments and the glass cylinder were pre-calibrated with the help of P'fact Autoclavable Variable Volume Micropipette (100 μL -1000 μL).

Measuring ability was analyzed as both a categorical (dosing error rates) and a continuous (measured dose) variable. Measured doses were categorized as an accurate dose (< 10% deviation), an acceptable dose (10%-20% deviation) and an inaccurate dose (>20% deviation). We also used criteria of error (>10% deviation), and no error (<10% deviation).

Statistical Analysis

Data were analyzed by Graphpad prism version 5 (GraphPad Software Inc., La Jolla California USA) and MS office excels worksheet (MicroSoft, California USA). A two tailed p value of <0.05 was considered to be statistically significant.

Descriptive statistic was used to present demographic details of study population. Chi square tests were conducted to compare the dosing error rate and control-intervention group. Moreover, the continuous data (measured doses) of each group were not normally distributed (Skewness, control vs. intervention: -1.4391 vs 0.2154; Kurtosis, control vs. intervention: 6.0123 vs. 4.6084), so non parametric test i.e., Mann-Whitney U test was used for the comparison of the measured doses in control and intervention group for each instrument. As our continuous data (measured doses) were not normally distributed, a range of measured doses was used for the interpretation of the difference in measured doses instead of the mean measured dose values.

Furthermore, we used dosing error rates as well as measured doses of the control group to assess the measuring ability of parents/caregivers with each instrument. Here, data of the intervention group was excluded because the participants of intervention group were educated before measurement process, so if data of intervention group had been included, then it would have created a bias. Adjusted Odds Ratio was performed on control group data to assess the association of participant's demographic factors and dosing instruments with dosing error.

RESULTS

Between 4th November, 2019 – 8th February, 2020, 733 parents/caregivers at the clinics were assessed for eligibility. One hundred and seventy two of the 733 were found to be eligible, of which 164 parents/caregivers were enrolled in the study and randomized; 82 in the control group (without education) and 82 in the intervention group (with PIL based education) [Figure 1]. Of the 164 participants studied, the majority of the participants were female (74.3%, n = 122), and the number of males and females were almost equally distributed in both the groups. About 60% (control, 47; intervention, 51) of participants were in the age group of 31-50, while only few (5.4%, n = 09) participants were older than 50 years. In addition, most of the participants were mothers (n = 118) who were evenly distributed in both the groups, and 36 (control, 16; intervention, 20) were fathers. Furthermore, 110 participants had an education level of at least up to basic graduation, of which 49 (44.5%) were in the control group and 61 (55.4%) in the intervention group; no participant was without any formal education. Participants often described the use of dosing cup

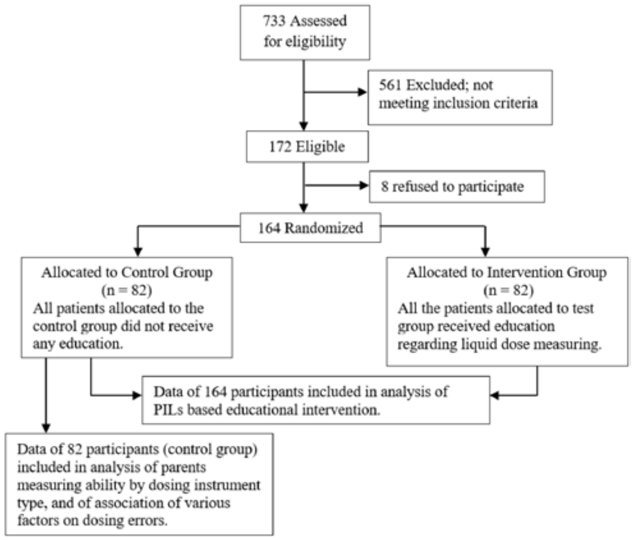

Figure 1: Recruitment and enrollment of study participants.

(72.5%, *n* = 119) and tablespoon (12.1%, *n* = 20) at home. Detailed descriptive data are outlined in Table 1.

Effect of Educational Intervention on Measuring Ability (Dosing Error Rates and Measured Doses) of Parents/Caregivers

Eighty-two participants in each group measured doses with the three dosing instruments, so a total of 246 doses were measured in each group. Our study found that overall, 65.8% (*n* = 162) and 79.2% (*n* = 195) measured doses were accurate in the control group and intervention group respectively, while the number of inaccurate dosing (> 20% deviation) was less in the intervention group compared to the control group (intervention vs. control: 9 (3.6%) vs. 23 (9.3%)). Overall, the difference of dosing error rates was statistically significant at the *p* value of 0.0018 [Table 2].

The ranges of measured doses (mL) of the control group with each instrument (Instrument, minimum measured dose – maximum measured dose (range): dosing cup, 3 – 6.6 (3.6); oral dropper, 1.2 – 6.4 (5.2); calibrated spoon, 2.4 – 6.8 (4.4)) were higher than that of the intervention group (dosing cup, 3.2 – 6.0 (2.8); oral dropper, 3.8 – 7.4 (3.6); calibrated spoon, 4.4 – 6.4 (2.0)) [Figure 2A,B]. Additionally, the comparison of measured doses of the control and intervention group showed a significant difference in calibrated spoon (*P* = 0.0369). [Table 3]

Measuring Ability (Dosing Error Rates and Measured Doses) of Parents/Caregivers with Each Instrument

Dosing error rates using dosing cup and oral dropper were almost the same, 68.3% and 65.85 of measured doses were accurate respectively; while this percentage decreased to 63.4 (*n* = 52) for calibrated spoon. In contrast, the number of inaccurate dosing was the highest using calibrated spoon (calibrated spoon, 10.9% (*n* = 9); dosing cup, 8.5% (*n* = 7); oral dropper, 8.5% (*n* = 7)). [Table 4]

The range of measured doses was the highest in the oral dropper, which was 5.2 ml (minimum measured dose, 1.2; maximum measured dose, 6.4) followed by the calibrated spoon with 4.4 mL (minimum measured dose, 2.4; maximum measured dose, 6.8). [Table 4]

Table 1: Socio-Demographic Characteristics of The Study Population.

	Total No. (%)	Control, No. (%)	Intervention, No. (%)
Gender			
Male	42 (25.6)	20 (47.6)	22 (52.4)
Female	122 (74.3)	62 (50.8)	60 (49.2)
Age (year) Mean (SD)		34.20 (9.17)	32.62 (6.81)
20 – 30	57 (34.7)	28 (49.1)	29 (50.9)
31 – 50	98 (59.7)	47 (47.9)	51 (52.0)
>50	09 (5.4)	07 (77.7)	02 (22.2)
Education			
No formal education	0 (0.0)	0 (0.0)	0 (0.0)
Primary	10 (6.0)	7 (70.0)	3 (30.0)
Secondary	30 (18.3)	17 (56.6)	13 (43.3)
Higher Secondary	14 (8.5)	9 (64.3)	5 (35.7)
Graduate	110 (67.0)	49 (44.5)	61 (55.4)
Relation			
Mother	118 (72.0)	59 (50.0)	59 (50.0)
Father	36 (22.0)	16 (44.4)	20 (55.5)
Other	10 (6.0)	7 (70.0)	3 (30.0)
Instrument chosen			
Teaspoon	10 (6.0)	3 (30.0)	7 (70.0)
Tablespoon	20 (12.1)	12 (60.0)	8 (40.0)
Oral syringe	5 (3.0)	2 (40.0)	3 (60.0)
Dosing cup	119 (72.5)	58 (48.7)	61 (51.3)
Oral dropper	9 (5.4)	6 (66.7)	3 (33.3)
Calibrated spoon	1 (0.006)	1 (100.0)	0 (0.0)

Association of Various Factors on Dosing Error

In adjusted analysis, the likelihood of making dosing errors was not associated with the instrument, gender, age and education level. In other words, the association of various factors on dosing error was not found [Table 5].

Table 2: Effect of Educational Intervention on Measuring Ability: Dosing Error Rates.

Instruments	Group	Dosing error category[a], No. (%)			*p* value[b]
		Accurate dose	Acceptable dose	Inaccurate dose	
Dosing cup, *n*=164	Control (*n* = 82)	56 (68.3)	19 (23.2)	7 (8.5)	0.0869†
	Intervention (*n* = 82)	67 (81.7)	13 (15.8)	2 (2.4)	
Oral dropper, *n*=164	Control (*n* = 82)	54 (65.8)	21 (25.6)	7 (8.5)	0.1559†
	Intervention (*n* = 82)	65 (79.3)	13 (15.8)	4 (4.8)	
Calibrated. spoon, *n*=164	Control (*n* = 82)	52 (63.4)	21 (25.6)	9 (10.9)	0.0941†
	Intervention (*n* = 82)	63 (76.8)	16 (19.5)	3 (3.6)	
Total, *n*=492	Control (n = 246)	162 (65.8)	61 (24.7)	23 (9.3)	0.0018*
	Intervention (n = 246)	195 (79.2)	42 (17.0)	9 (3.6)	

[a] accurate dose indicates within 10% of the recommended dose (5 mL); acceptable dose, 10% to 20% deviation from recommended dose; inaccurate dose, more than 20% deviation from recommended dose
[b] from chi square analysis.
* indicate significant p value, † indicate non-significant *p* value.

Table 3: Effect of Educational Intervention on Measuring Ability: Measured Doses.

Instruments	Control Measured dose, mL			Intervention Measured dose, mL			*p* value[a]
	Mean (SD)	Median	Range	Mean (SD)	Median	Range	
Dosing cup	5.01 (0.59)	5.0	3 – 6.6 (3.6)	4.96 (0.44)	5.0	3.2 – 6 (2.8)	0.9509†
Oral dropper	4.93 (0.78)	5.0	1.2 – 6.4 (5.2)	5.09 (0.48)	5.0	3.8 – 7.4 (3.6)	0.3967†
Calibrated spoon	5.30 (0.62)	5.4	2.4 – 6.8 (4.4)	5.23 (0.36)	5.2	4.4 – 6.4 (2.0)	0.0369*

[a] Mann Whitney U test was used for the comparison of measured doses of control and intervention groups.
* indicate significant p value, † indicate non-significant p value.

Table 4: Measuring Ability by Dosing Instrument Type.

Instruments	Measured dose, mL		Dosing error category[a], No. (%)			*p* value[b]
	Mean (SD)	Range	Accurate dose	Acceptable dose	Inaccurate dose	
Dosing cup, *n* = 82	5.01 (0.59)	3 – 6.6 (3.6)	56 (68.3)	19 (23.2)	7 (8.5)	
Oral dropper, *n* = 82	4.93 (0.78)	1.2 – 6.4 (5.2)	54 (65.8)	21 (25.6)	7 (8.5)	0.9600†
Calibrated spoon, *n* = 82	5.30 (0.62)	2.4 – 6.8 (4.4)	52 (63.4)	21 (25.6)	9 (10.9)	

[a] accurate dose indicates within 10% of the recommended dose (5 mL); acceptable dose, 10% to 20% deviation from recommended dose; inaccurate dose, more than 20% deviation from recommended dose.
[b] from chi square analysis.
*indicate significant *p* value, †indicate non-significant *p* value.

DISCUSSION

Effect of Educational Intervention on Measuring Ability (Dosing Error Rates and Measured Doses) of Parents/Caregivers

This study reveals that PIL based educational intervention can be helpful in improving the accuracy of dosing, as the number of accurate measured doses were significantly higher in the intervention group as compared to that in the control group. The observation of this study are similar with the data of previous studies about the use of pictograms and medical direction.[9,18-20,23-24]

Peacock *et al.*[23] (2010) found that pharmacist's advice about the use of dosing instrument decrease the incidences of dosing error; errors in nystatin and digoxin elixir measurement were made by 88.0% and 24.8% of patients before pharmacist's education respectively and by 85.6% and 4.0% of patient after pharmacist's

Table 5: Association of Various Factors on Dosing Error[a].

Factors (measured doses, no.)	Error[b], no.	No Error[c], no.	AOR[d]	95% CI	*p* value[e]
Instruments[f]					
Dosing cup (82)	26	56	0.8048	0.42-1.54	0.5101
Oral dropper (82)	28	54	0.8988	0.47-1.70	0.7439
Calibrated spoon (82)	30	52	1.00	Reference	NA
Gender[g]					
Male (60)	21	39	1.051	0.57-1.93	0.8726
Female (186)	63	123	1.00	Reference	NA
Age[h]					
20-30 (84)	24	60	0.80	0.28-2.22	0.6687
31-50 (141)	53	88	1.205	0.45-3.176	0.7064
>50 (21)	7	14	1.00	Reference	NA
Education level[i]					
Primary (21)	7	14	1.00	Reference	NA
SSC (51)	22	29	1.517	0.52-4.39	0.4407
HSC (27)	6	21	0.5714	0.15-2.06	0.3902
Graduate (147)	49	98	1.00	0.37-2.63	1.00

[a] No error was used as the base outcome
[b] Error indicate >10% deviation of the recommended dose (5mL)
[c] No error indicates within 10% of the recommended dose (5 mL)
[d] adjusted odds ratio, adjusting for instruments, gender, age, education level and knowledge score
[e] from chi square analysis
[f] the calibrated spoon was used as reference
[g] female was used as reference
[h] the age group >50 was used as reference
[i] primary education was used as reference

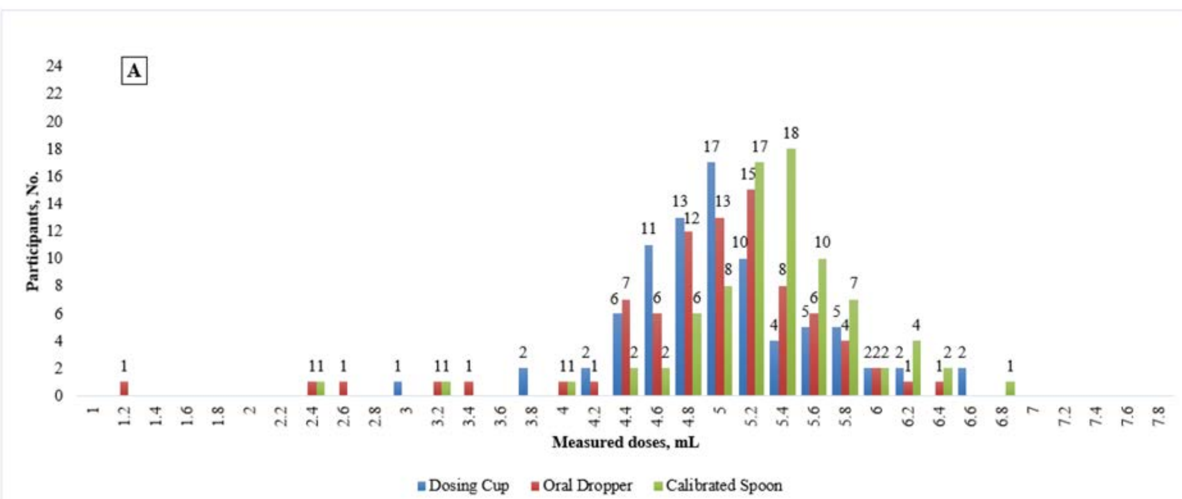

Figure 2 (A): Measured doses of CONTROL group participants with each instrument (*n*=246)

education respectively. Yin and Dreyer *et al.*[24] published that 41.1% made dosing error, advance counselling and instruction provision in the ED were reported by 33.1% and 19.2% respectively. Two other studies conducted by Yin and Benard *et al.*[9] and Yin and Mendelsohn *et al.*[20] used absolute risk reduction [ARR] to compare intervention group and control group. Yin and Mendelsohn *et al.*[20] stated that "text-plus-pictogram recipient (intervention) were less likely to make an error compared to text only recipient (43.9% vs 59.0%, $p = 0.01$; ARR, 15.2% [95% CI, 3.8 – 26.0]), and only 0.6% large dosing error were reported in intervention group compared to 5.6% in text-only group (ARR, 4.9% [0.9 – 10.0])". Only 5.4% of intervention (pictogram-based) caregivers gave inaccurate doses (>20% deviation), as against 47.8% of control caregivers (standard medication counselling) in the study conducted by Yin and Benard *et al.*[9] while in our study 3.6% and 9.3% measured doses were inaccurate

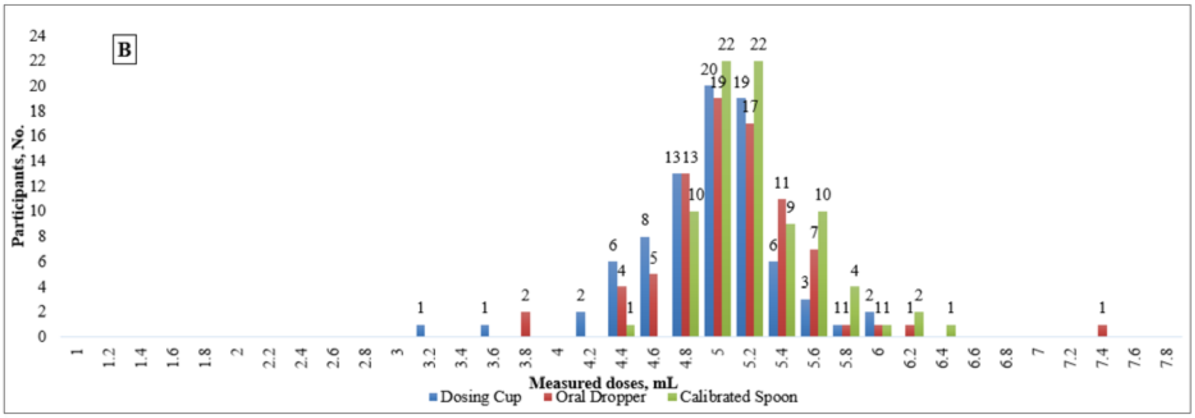

Figure 2 (B): Measured doses of INTERVENTION group participants with each instrument (*n*=246)

(>20% deviation) in the intervention and control group, respectively.

To our knowledge, very few studies have used the range of measured doses to compare the control group and the intervention group. In this study, the measured doses of control group participants were spread over a larger range than that of intervention group participants, it means the measured doses of intervention group were closer to the recommended doses (5 mL) compared to that of control group. A similar trend was seen in the study performed by Yin and Mendelsohn *et al.*[20] (range of doses: 0.1 – 10.4 mL in control group vs. 0.2 – 4.0 mL in intervention group). Allied to this, PIL based intervention showed significant improvement in the measurement of doses by calibrated spoon because majority of study participants were not familiar with the use of calibrated spoon.

Measuring Ability (Dosing Error Rates and Measured Doses) of Parents/Caregivers with Each Instrument:

Regarding the dosing error rates of dosing cup, 68.3% (*n* = 56) measured an accurate dose in our study, while this percentage was declined to about 53% and 14.6% in the study conducted by Ryu and Lee,[8] and Sobhani *et al.*[21] respectively. The percentage of participants who measured an acceptable dose using dosing cup was 23.2% (*n* = 19) in this study which was similar to the result reported by Ryu and Lee,[8] however, this proportion was only 16.67% in one Indian study published by Joshi and Bavdekar.[25] Inaccurate dose using dosing cup was measured by 8.5% (*n* = 7) participants in the present study, this percentage was considerably different in comparison with other 2 Indian studies (Ravikiran and Shivarajashankara,[26] in Karnataka (India), 23.8%; Joshi and Bavdekar,[25] 2.22%). Moving over to the dosing error rates of oral dropper, which was almost the same as dosing cup. The study by Ravikiran and Shivarajashankara,[26] showed that the 41.1% participants had made a dosing error of >20% of deviation using dropper, as opposed to only 8.5% in our study. Furthermore, in this study, we found the highest rates (10.9%) of inaccurate dosing with calibrated spoon. This percentage is almost similar to Yin and Mendelsohn *et al.*[3] study and Ryu and Lee,[8] study, in which a dose error greater than 20% for dosing spoon was 14.0% and 10.0%, respectively. Error (>10% deviation) with calibrated spoon was seen to be slightly higher than with a cup, in contrast to previous findings, in which more error was associated with a cup.[3,21,27]

With respect to the ranges of measured doses for each instrument, the range of doses using cup was 3 – 6.6 mL, while the previous studies found 4 – 6.2 mL,[25] and 4.6 – 6.4 mL.[8] On the contrary, the range was very broad (2.5 – 17.0 mL) in the study conducted by Yin and Mendelsohn *et al.*[3] The range of doses was the highest using oral dropper (1.2 – 6.4 mL); the most common practical issue encountered with dropper during the study was air bubble in the dosing measure. The same issue was observed by Almazrou and Alsanly *et al.*[28] in their study. About calibrated spoon, the range was 2.4 – 6.8 mL which is slightly different to the past studies: 3.76 – 6.61 mL,[29] and 3.7 – 5.6 mL.[8] Again, Yin and Mendelsohn *et al.*[3] reported the highest range using calibrated spoon (2.9 – 11.2 mL). The range of doses in calibrated spoon was higher than that in dosing cup, which may have resulted from difficulty in seeing the calibration marking while measuring, and participants experienced inconvenience while using the calibrated spoon.

Accuracy of calibrated spoons was proven to be higher in comparison to the dosing cups in the previous studies.[29-30] However, majority of our study participants were not aware about the usage of calibrated spoons, but they were comfortable with using dosing cup. Although calibrated spoons have higher precision in dosing measurement, more error rates and higher range of doses was seen during the study. Hence, the dosing accuracy is dependent upon handling and usage of the measuring instrument rather than the type of the instrument.

Association of Various Factors on Dosing Error

Surprisingly, there was no impact of participant's gender age, education level and dosing instruments on the overall risk of making errors.

Compared with other studies of liquid medication dosing; Yin and Mendelsohn *et al*.[3] found that cup were associated with increased odds of making a dosing error (>20% deviation) as compared with the oral syringe (cup with printed marking: AOR= 26.7; 95%CI=16.8-42.4; regular cup: AOR= 11.0; 95% CI= 7.2-16.8), similar results were reported by Yin and Parker[18] which showed cup were associated with increased odds of making a dosing error as compared with the oral syringe (cup: AOR=3.3; 95% CI= 2.7-4.0). In the study conducted by Almazrou *et al*.[28] it was noted that participants >46 year of age were associated with underdosing using syringe (AOR=3.37; 95%CI= 1.35-8.38). Similar to our study; Almazrou and Alsahly *et al*.[28] reported that there was no association of educational level of mother with under or over dosing using any dosing instruments.

Limitation

The subjects/participants were asked to measure the liquid medication dosage form in the presence of investigator, which might have affected the measuring ability. The participants in our study measured paracetamol suspension only, although we have extrapolated our results to other liquid medications. In our study, the majority of participants were with at least a graduate level of education. Therefore, the present study cannot be generalized to the average population. The dosing measurement was performed as a hypothetical scenario which does not reflect on the participant's ability to measure the dose of the drug at home. Complete blinding was not possible in the study as the investigator had to know the assignment of the participant in each group, to provide them with educational intervention on dose measurement. Instructions given by the physician before the participation in the study were also counted as educational intervention and were a reason for the limited differences seen between the control and the intervention groups for each instrument.

CONCLUSION

We found that the PIL based education provided to the participants about dosing devices and their usage helps to improve the measuring ability of the participants. The study threw light on the matter that dosing cups were the most commonly used devices at home for measuring liquid medications, and participants' measuring ability was better while using dosing cups when compared with oral dropper and calibrated spoon. The type of instrument and demographic factors were not associated with the participant's accuracy of dose measurement.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

BALD: Baker Able Leaflet Design; **EQIP:** Ensuring Quality of Information for Patients; **PIS:** Participant Information Sheet; **PIL:** Patient Information Leaflet.

SUMMARY

The study was a multi-centric, randomized controlled interventional study conducted at 2 pediatric clinics in Gandhinagar, Gujarat. Primary caregivers who would be giving medication to the patient (1 year to 12 years) were randomized in an alternative manner into control (without education) and intervention group (education with PILs), and asked to measure a dose using 3 measuring devices: dosing cup, oral dropper and calibrated spoon. Measured doses were categorized as an accurate dose (<10% deviation), acceptable dose (10%-20% deviation) and inaccurate dose (>20% deviation). Overall, 65.8% and 79.2% measured doses were accurate in the control and intervention group, respectively (p=0.0018). The range of measured doses (mL) of control group was higher than that of intervention group. About the instruments, the maximum number of participants measured an inaccurate dose with the calibrated spoon (10.9%), and the range of doses of oral dropper and calibrated spoon were higher than that of the dosing cup. Additionally, the likelihood of making dosing errors was not associated with the instruments used, gender, age and education level of the participants. The education provided to the

participants helped to improve their measuring ability. Participants' measuring ability was better while using the dosing cup as compared with the use of oral dropper and calibrated spoon.

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