

Reliability and Concurrent Validity of a Clinical Syringe with 5mm-Nozzle in the Quantification of Topical Methyl Salicylate

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Abstract:

The Finger Tip Unit (FTU) is a subjective description without metric value for quantifying dosage for topical medications but recently Finger Tip Unit Metric Length (FTUML) was being advocated for. However, a modified clinical syringe tube is being speculated to be more appropriate than FTUML but its reliability and validity is yet to be ascertained, hence the need for this study. The objectives of this study were to determine the Inter-rater Reliability and Concurrent Validity of the modified syringe. Fifty apparently healthy participants were recruited using sample of convenience. The major instruments were 5mm diameter nozzle syringe, methyl salicylate cream and tape ruler. The principal investigator filled the syringe tube (nozzle modified to 5mm opening) with methyl salicylate cream and ensured no vacuum or air was trapped within it. The cream was ejected through the nozzle and applied on the participant's index finger from distal skin-crease to the tip (Finger Tip Unit Metric Length [FTUML]). The volume (ml) ejected from the syringe was recorded and the length (cm) of (FTUML) expelled from the syringe was also measured and recorded by the principal investigator using the standard and validated inelastic tape ruler. The Assistant investigator re-measured the FTUML of the applied cream using inelastic tape in another cubicle, blinded to the previous measurement. There were two testing days and the same procedure was adopted for day 2. The data were analyzed using descriptive statistics of mean, standard deviation and Pearson's product moment correlation. There was significant correlation between the volume of methyl salicylate cream expelled from the 5mm nozzle on both days of testing ($r=0.94$, $p = 0.001$). There were also significant correlations between the volume of methyl salicylate cream expelled from the 5mm nozzle and FTUML measured by both testers on day one ($r=0.94$, $p=0.001$; $r=0.95$, $p=0.001$). Generally, a high correlation range between 0.83 and 0.98 ($p = 0.001$) were established for all measurements using both Syringe and FTUML. It was concluded that the 5mm nozzle modified syringe is a reliable and valid tool for quantifying topical methyl salicylate cream.

Keywords:

Reliability and Validity, Clinical Syringe with 5mm-Nozzle, Finger Tip Unit Metric Length, Methyl Salicylate

1. Introduction

There is increasing evidence supporting transdermal application against oral drugs especially in pain management for common neuropathic and musculoskeletal conditions and the effect-risk ratio of topical formulations is currently being considered as topmost priority [1,2]. There are lower systemic side effects of topical medications compared to other conventional routes. The topical application of Non-steroidal Anti-inflammatory Drugs (SAIDs) had been reported to provide bioavailability and plasma concentrations of between 5% and 15% when compared to those which are delivered through the systemic and this because the bioavailability is improved by avoiding first pass hepatic metabolism and enzymatic or PH associated deactivation [2].

Quantifying appropriate and effective therapeutic dose of relevant medications has been the major bane of providing qualitative care for clients. Aside this; bioavailability assessment and determining drug concentration in the skin layers for topical formulations remains a great challenge. It also appears that little focus is placed on adequacy of dosage and specificity for transdermal administration [3]. In clinical practice, it has been a huge challenge to quantify the specific dose for creams or ointments for specific body regions and it is essential to use correct dosage to avoid risk of side effects [4]. In view of this, it is important to avoid indiscriminate use of dosages for topical medications.

There are currently three major concepts being adopted in the quantification of topical medications, namely; the idea of generous application, use of Fingertip unit (FTU) and Dosage card. The dosing card is a calibrated tool that ensures accurate dosage but only very few pharmaceutical companies manufacture it for dosage specificity. Appreciable efforts had been made to provide quantification for topical cream and gel/cream using Finger Tip Unit (FTU) but it is still a subjective description without metric value or precise measurement, hence, it has been very difficult to quantify the specific dose for cream or ointment [4,5]. Long and Finlay defined FTU as the amount of ointment, cream or other semi-solid dosage form expressed from a tube with a 5mm diameter nozzle, applied from the distal skin-crease to the tip of the index finger of an adult [6]. One FTU has been documented to be enough for treating an area of the skin twice the “handprint” where 2 FTUs are equivalent to 1g [7]. According to a UK report, 1 FTU was found to weigh 0.49g and 0.43g in men and women respectively; and that 1 FTU would cover 312 cm² in men and 257cm² in women [8].

Despite the introduction of pharmacology education into most training programmes, there appears to be no specific teaching for dosages of topical medications and less attention is given to accurate dosage of topical medication, and this is a potential source of side-effects and treatment failure [9,10]. Osborne et al reported that approximately one-third of patients with psoriasis had treatment failure using topical calcipotriol and they attributed this to likely inadequate dosage [9]. It has been

documented that, treatment success with topical treatments is currently difficult to achieve [11,12].

Nobuo et al reported that one-third of community pharmacists gave inadequate instructions on the amount of topical steroid application [13]. The methods of dosage prescription for topical medications compared to oral and injectable forms are largely considered to be an inaccurate procedure [14]. Finger Tip Unit is used in clinical practice as guide for the amount of topical drugs that should be applied on the skin in order to minimize side effects and encourage adherence to therapy. Recently, Onigbinde et al determined normative data and predictive equation for Finger Tip Unit Metric Length (FTUML) [15]. In a previous report of Onigbinde et al [15], concerted efforts were made to determine the reliability of Flexible Meter Ruler in quantifying topical Methyl Salicylate cream, however, the tool could still be considered as inappropriate for clinical use. There is still a need for devising measuring tools to clarify the amount of ointment to prescribe [12]. It is being considered that adopting the use of a clinical syringe may be more appropriate than meter rulers, hence, there is need to determine a clinically accepted means of quantifying topical medication. The objectives of this study were to determine the relationship between volume of topical medication ejected from a 5mm nozzle syringe as Finger Tip Unit (FTU) on two different testing days (test-retest interval of 1 week) and to determine the validity of the modified syringe as an alternative to the FTU. It was hypothesized that there would be no significant relationship between the volume of topical medication ejected from a 5mm nozzle syringe on two different days, and Finger Tip Unit Metric Length (FTUML).

2. Materials and Methods

2.1. Materials: Participants

The participants of this study were apparently healthy individuals that were recruited at the Obafemi Awolowo University, Ile-Ife, Nigeria. The inclusion Criteria included apparently healthy students above the age of 16 and who were without musculoskeletal or neurological disorders in the upper extremities; and excluded were students with known allergies to methyl salicylate.

2.2. Instruments

The major test instruments were syringe with simulated 5 mm diameter nozzle measured to the nearest 0.1 milliliter (Figure 1), methyl salicylate cream, tape rule calibrated in centimeters (cm), height meter and bathroom weighing scale in kg (Camry, model: BR9011).



Figure 1. A modified syringe with a 5mm nozzle filled with methyl Salicylate cream.

The Sample size was determined to be 50 using an expected proportion based on previous studies or pilot studies (0.05) and an absolute error or precision of 0.065.

2.3. Sampling Techniques and Research design

The respondents were sample of convenience and the research design was a correlation study.

2.4. Procedure

Prior to the commencement of the study, ethical approval was sought and obtained from the Research and Ethical Committee of the Institute of Public Health, Obafemi Awolowo University, Ile-Ife, Osun State, Nigeria. Informed consent was obtained from each participant before the commencement of the study. The purpose and procedures of the of the research work were explained to each participant. A standard and validated inelastic tape measure was used to measure the Finger Tip Unit Metric Length (FTUML) and it is the distance between the distal skin-crease and the tip of the index finger of each participant (Figure 2), [12].

The principal investigator filled the syringe with Neurogesic cream and ensured no vacuum or air was trapped within it. The modified syringe was used to eject the cream from the 5mm nozzle of the syringe on the participant's index finger from the distal skin-crease to the tip (FTU), (Figure 3). The length of the amount of cream (FTUML) expelled from the syringe was then measured and recorded in ml from the calibration by the principal investigator using the standard and validated inelastic tape. The Assistant investigator then re-measured the length (FTUML) of the applied cream using the standard and validated inelastic tape by the principal investigator in another cubicle, blinded to the previous measurement. There were two testing days and the same procedure was adopted for day 2. The two testers recorded all measurements for the 2 days. This section should contain sufficient details so that methods can be appropriately cited and readers can assess whether the materials and methods justify the conclusions or not. It can be divided into subsections if several other methods need to be described. You need explain how you studied the topic, identify the procedures you followed, and structure this information as logically as possible.



Figure 2. One FTUML cream from a 5mm nozzle.



Figure 3. One FTUML cream from Syringe with a 5mm nozzle.

3. Results and Discussion

3.1. Data Analysis

The data were analyzed using descriptive statistics of mean and standard deviation. Also, Pearson's product moment correlation was used to determine relationship Fingertip Unit Metric Length (FTUML) of day 1 and day 2; and the volume of

expelled cream. The version 23 of Statistical Package for social Sciences (SPSS 23) was used to analyze the data.

3.2. Results

The participants comprised of 28 males (56.0%) and 22 females (44.0%). The mean age of the participants was 21.34 ± 2.13 years while height and weight were 1.69 ± 0.092 meters and 64.12 ± 6.33 kg respectively (Table 1). The mean FTUML for methyl salicylate cream measured by the first tester on day one was 2.70 ± 0.29 cm using the meter ruler while the volume of methyl salicylate cream expelled from the 5mm nozzle of the syringe to make up FTU was 0.67 ± 0.22 ml. The measurement of the second tester for the FTUML obtained from the volume of methyl salicylate cream ejected by the first tester on day one was 2.69 ± 0.28 cm. The mean FTUML for methyl salicylate cream measured by the second tester on day two was 2.70 ± 0.24 cm using the meter ruler while the volume of methyl salicylate cream expelled from the 5mm nozzle of the syringe to make up FTU was 0.69 ± 0.23 ml for first tester on day 2. The measurement of the second tester for the FTUML obtained from the volume of methyl salicylate cream ejected by the first tester on day two was 2.69 ± 0.24 cm.

Table 1. Mean values of age, height and weight.

	Mean	SD
Age	21.34	2.13
Height	1.69	0.09
Weight	64.12	6.33

Table 2. Correlation between selected anthropometric variables, FTUML and volume of methyl salicylate cream expelled.

		Height	Weight	Volume 1	FTUML 1	FTUML 2	Volume 2	FTUML 3	FTUML 4
Age:	r	-0.01	-0.18	0.002	-0.04	0.01	-0.04	-0.03	-0.008
	p	0.92	0.20	0.99	0.79	0.93	0.77	0.82	0.956
Height:	r		0.73*	0.90**	0.83**	0.85**	0.92**	0.91**	0.89**
	p		0.001	0.001	0.001	0.001	0.001	0.001	0.001
Weight:	r			0.664**	0.65**	0.63**	0.69**	0.69**	0.71**
	p			0.001	0.001	0.001	0.001	0.001	0.001
Volume 1:	r				0.94**	0.95**	0.94**	0.92**	0.90**
	p				0.001	0.001	0.001	0.001	0.001
FTUML 1:	r					0.98**	0.87**	0.84**	0.83**
	p					0.001	0.001	0.001	0.001
FTUML 2:	r						0.88**	0.85**	0.85**
	p						0.001	0.001	0.001
Volume 2	r							0.98**	0.96**
	p							0.001	0.001
FTUML 3:	r								0.95**

Volume 1-Day 1 value for 1st investigator, FTUML1 - Day 1 value for 1st investigator, FTUML3 - Day 2 value for 1st investigator

Volume2 -Day 2 value for 1st investigator, FTUML2 - Day 2 value for 2nd investigator, FTUML4 - Day 2 value for 2nd investigator

*** Correlation is significant at the 0.001 level (2-tailed). Key: FTUML=fingertip unit metric length, r=correlation, p=significance*

The result of the Pearson Product Moment Correlation test showed that there was significant correlation between the volume of methyl salicylate cream expelled from the 5mm nozzle on both days of testing ($r=0.935$, $p=0.001$). There were also significant correlations between the volume of methyl salicylate cream expelled from the 5mm nozzle and FTUML measured by both testers on day one ($r=0.94$, $p=0.001$; $r=0.95$, $p=0.001$). Other correlations are presented in Table 2. There was no significant correlation between age, FTUML measured by both testers on days one and two and volume of methyl salicylate expelled from the 5mm nozzle on days one and two. However, there was significant correlation between the height of participants and volume of methyl salicylate expelled from the 5mm nozzle on day one ($r=0.900$, $p=0.001$). Other correlations are presented in Table 2.

3.3. Discussion

It has become increasingly imperative to test for reliability and validity of measuring tools as well as outcome measures in physiotherapy and in general, scientific studies. Also, there is need to develop guidelines that will improve the transmission of clear dosage regimen instructions and knowledge to patients and Health professionals [16]. Several previous clinical trials had found using subjective FTUs that are based on estimations to be effective [17,18,19,20,21] but this is inappropriate for clinical documentation and research purposes. The Finger Tip Unit is only a rough guide adopted to minimize side effects and encourage adherence to therapy [4]. Two FTU had been documented to be equivalent to one gram and that it is adequate to treat an area of the skin twice the “handprint”. The Rule of Hands states that “4 hand areas = 2FTU =1g”[5,7]. The use of quantitative method will provide accuracy, documentation and specific dosage for topical medications, and also enhance effectiveness and consistency.

The mean FTUML of 2.70cm found in this study was in tandem with the range reported in previous studies of Juan et al [14] and Onigbinde et al [15], where they reported that the Finger Tip Unit Metric Length (FTUML) of the participants ranged between 2.4 and 2.7cm. Generally, a high correlation ranging between 0.83 and 0.98 ($p = 0.001$) were established for all measurements using both Syringe and FTUML. There was a significantly high correlation within the principal tester and between the two testers with a test-re-retest interval of one week using the meter ruler (FTUML). This implied that the meter ruler has both intra and inter-tester reliability in quantifying topical methyl salicylate. Similarly, there was highly significant correlation between the volume of methyl salicylate cream expelled from the 5mm nozzle on day one and two; and also, FTUML measured by both testers on the two days. This also implied that that both syringe and FTUML have concurrent validity to quantify topical medications. Validity is the degree to which a measurement of a tool gives best possible approximation of its truth to what should be measured. Joppe reported that validity determines if a tool accurately measures what purport to measure [22].

In clinical practice, precision of doses is paramount; if topical medication is inadequate, it won't be effective and if overdose is massaged, there may be risk of side effects [23]. The clinical implication of this study is high as Concurrent validity

had been established for the syringe tube. Concurrent validity refers to the degree to which the result of a test correlates with the results of other tests used to measure the same construct, at the same time. [24]. The data obtained from the syringe measurements (volume of cream) correlated with the length of methyl salicylate cream expelled to make up a Finger Tip Unit, implying high homogeneity of volume of methyl salicylate cream on two testing days; establishing a concurrent validity [24]. Similarly, the clinical syringe tube has high Inter-rater reliability as it is the degree of agreement between testers.

There was no significant correlation between age and FTUML; and volume of methyl salicylate expelled from the 5mm nozzle but this contradicted the report of Onigbinde et al [15]. This may be attributed to the narrow age range of participants in this current study compared to the wide range of 1 - 70 years in the previous study. It is noteworthy that the outcome of this study cannot be generalized (low external validity) for other topical medications in gel, lotion or ointment forms except those in cream formulation like methyl salicylate.

4. Conclusions

This study concluded that the modified syringe tube is reliable and valid as a tool to quantify the dose of methyl salicylate cream if it is expelled from a 5mm nozzle.

Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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