Journal of Anesthesia & Clinical Research
ISSN: 2155-6148

Rahaf et al., J Anesth Clin Res 2016, 7:8
DOI: 10.4172/2155-6148.1000656

Research Article Open Access

The Validity and Reliability of the Arabic Version of FLACC Scale: A Clinical Trial

Rahaf DA*, Hisham Shakhashero and Mohamad Basier Al-Monaqel

Damascus University, Syrian Arab Republic

***Corresponding author:** Rahaf Dak Albab, Damascus University, Syrian Arab Republic, Tel: Tel: 00963957506545; E-mail: rahaf.dds@hotmail.com

Received date: June 17, 2016; **Accepted date:** August 04, 2016; **Published date:** August 11, 2016

Abstract

Introduction and aim: It is difficult to determine pain level using (patient-based-pain) scales in children. Hence, there is a need to translate (Arabizate) of an international non-self-pain scale (FLACC) as an alternativeclinician-basedpain scale, and test its psychometric properties (validity and reliability).

Materials and methods: The study was carried out on (250) children who needed dental treatments, aged (6-14) years, their behavior were valuated as definitely positive or positive (according to Behavior Frankl Scale) in Damascus-University. Each child has received local injection in one side and a placebo (touching the oral mucosa with covered needle) in the other side. Children were filmed with a digital camera to record pain reaction. The reactions were evaluated by two examiners (blinded-injection type) using; FLACC (Face-Legs-Activity-Cry-Consolability) and SEM (Sound-Eye-Motor) scales.

Results: About 2000 non-self-assessments were obtained. FLACC scale showed high Construct Validity because of the rising of pain intensity from (0.13) with placebo into (3.6) with injection. Criterion Validity was good between FLACC and SEM. The scale showed high Internal Consistency Validity where values of correlation coefficients ranged (0.723-0.792) between scale items and its total degree. FLACC showed good reliability; correlation coefficient between external evaluators (r=0.805), Cronbach's alpha value was high (0.809), and Kappa value reached (0.952) for the first evaluator and (0.893) for the other. These positive values pointed to high reliability of the (FLACC) scale.

Conclusion: The Arabic version of (FLACC) scale characterized by validity and reliability, and it is recommended to use.

Literature Review

Children's Pain assessment can be conducted by three means: self-evaluating, selfless-evaluating by behaviour observation and recording, Physiological measurements [1]. However, according to some scientists; the ideal evaluation is the combined evaluation which includes self-evaluating for pain associated with one of the methods stated above [2], but this approach can be considered unpractical, inapplicable and useless for children in the phase before talking or whom are unable to talk, or those have perceptual problems, so some of scientists said that it is better to evaluate pain by selfless methods that depends on watching Child's reaction against pain alarm and registering it. The demand for using self-pain evaluating as "The gold standard" is a clear exaggeration due to the complications and factors that contribute in prejudicing the rather for himself when he asked to evaluate his pain by his self [3-5].

And FLACC scale, this scale was developed by Merkel et al in 1997, consists of five clauses, each clause's value ranges between (0-2) so the whole scale has a value between (0-10) [6], it is convenient for young children; their ages below 3 years, and it is used for low perceptual ability's children [7], and it has chosen with CHEOPS scale as the best pain evaluating scales by Von Baeyer and Spagrud systematic review [8]. FLACC scale was translated into four languages (Chinese, Thai, Swedish, and Brazilian Portuguese) [9-12].

SEM (Sound-Eye-Motor) scale has been used in many recent studies [13-17] and Baghdadi study in Syria [18], this scale concentrates on the changes in patient's sound, eyes and movement to evaluate patients relax or pain during treatment [19].

Aim of Study

To study the Psychometric properties (validity and reliability) of the Arabic version of selfless pain measurement FLACC.

Materials and Methods

An ethical approval was obtained from the local ethics committee prior to the commencement of the study, CONSORT Statement was followed when the current study was designed and conducted.

Current study had started On February 2014, and ended on March 2015. The sample included (250) children from the Department of Pediatric Dentistry of the Dentistry-Faculty of Damascus University. Their ages ranged between 6 and 14 years. Each of them needed intraoral local anesthesia for various treatment purposes (e.g: pulptomy, dental extraction, restorative treatment). Informed consent from one of the parents or the guardian of the child has been taken after the current study and its purposes had been explained. The included children were fit and healthy with no nervous disturbances, cooperative and classified as (absolute positive or positive) on Frankel's

classification scale. All children needed treatments that require intraoral anesthesia. None received any sedative or analgesic drugs in the last three hours prior to intraoral injection, and there was no abscess (acute or chronic) in the site of injection.

Randomisation

The randomization was conducted in this study by alternating the order of injection and placebo (see below) on the child according to the randomization distributing tables.

The injections

A local anesthetic injection has been given to each child after drying the oral mucosa by sterilized cotton sticks and applying Benzocaine gel (20%) for two minutes, traditional local anesthetic has been given on the side that needed the dental treatment.

The operator has also pretended to give the child another "placebo" local anesthesia injection by touching lightly the oral mucosa by the injection site (while the injection needle was capped) without any pressure. So, the child has received one local intraoral injection, whereas he thought he has received two injections.

Hiding local anesthesia syringe from child's sight pattern has been applied on all sample's children in all ages, that because of the positive effects of hiding the syringe on the child's behaviour, those effects were approved by many global recent and old studies [20-23].

Recording

The child reaction was recorded during the injection procedure (in both groups) using a high definition digital camera (14 Mega pixel). The recordings were then edited to mask the type of injection given and therefore blind the assessors. All edited recordings were evaluated by external raters, each independently completes two clinician-based pain evaluation scales (SEM and FLACC).

Arabisation (Translation) of the FLACC scale

The FLACC pain scale has been Arabized using foreword-backward translation, and was used for the first time in Arabic in the current study.

Methods of studying the psychological properties of measurement scale:

Validity

The content and construct validities were tested as follows:

Content validity: This has been checked by a number of experts in the field of pain and education to ensure the content safety, language fluency, and the measurement ability to reflect its parts and purpose; which is defining the pain level.

Construct validity: This was examined by testing rising pain intensity during injection in comparison with placebo. The internal consistency between the scale's five elements was examined by checking their individual relation with the whole measurement. The construct validity was tested also by detecting Discrimination validity and the measurement ability on retrieving differences between children who suffered from the maximum pain level relatively with their companions who suffered from minimum pain level, and the criterion validity was detected by exploring the convergent validity, which conducted by detecting the engagement level of FLACC scale with other scales that applied.

Reliability: The reliability has been checked by: the method of testing and retesting, and calculating Cronbach's alpha factor, and inter-rater reliability, so the raters were tested (inter-rater reliability) to ensure their ability on evaluating pain trustfully, and to study the reliability of FLACC scale in selfless pain evaluating.

Results

The sample included (250) children, and the pain level was evaluated selflessly on selfless scales by external raters, which means there was (1000) selfless evaluation for pain for both in injection and placebo, so they were (2000) selfless pain evaluation in total, as shown in Table 1.

Content validity study's result suggested making no adjustments on test clauses and instructions because its clearance, and appropriateness for the purpose that they have been put for.

Construct validity for the Arabic version of FLACC scale was studied by testing the rising pain level during injection procedure in comparison with Placebo, and the results of this kind of validity was gained by calculating the degree of pain intensity in both procedures (injection, and placebo) then compared between these two values using t-student test.

Table 2 shows the result of that statistical test, it is clear from the previous table that the value of pain intensity was raised with injections into (3.6) in comparison with placebo (0.13) which was significant statistically on the significance level (0.05), which means FLACC test measures what it was put for, that indicates on Construct validity of FLACC test.

Internal Consistency Validity showed correlation between every clause of FLACC scale clauses, those correlations ranged between (0.792-0.723) as shown in Table 3, and it is positive and statistically significant on the significance level (0.01) which indicates high Internal Consistency for FLACC scale.

External Criterion Validity study (convergent validity) showed strong correlation between FLACC and SEM selfless scales.

Table 4 shows FLACC scale's correlation factor with SEM scale (external criterion) which was (0.799), that indicates criterion validity for FLACC scale.

Reliability study by testing and retesting method, which has been conducted through external raters examining the same investigated people at the same time independently, has shown strong correlation which indicates good reliability for FLACC scale, as shown in Table 5 rater's correlation coefficient value has reached (0.805).

Cronbach's Alpha factor has been calculated for FLACC scale and its value was high and reached (0.809), as shown in Table 6.

Research sample (250) child	Selfless pain scales the number of rates using

	First rater		Second rater		Total rates	
	SEM scale	FLACC scale	SEM scale	FLACC scale	SEM scale	FLACC scale
placebo	250	250	250	250	500	500
injection procedure	250	250	250	250	500	500
total rates	1000		1000		2000	

Table 1: shows the sample's distribution according to pain assessments by the external raters using selfless pain scales.

Correlation coefficient	0.233
significance level	0.579
the decision	insignificant

Table 2: Shows the correlation coefficient between pain level during placebo and injection procedure according to FLACC scale.

Internal consistency of FLACC parts			
The part	**Part significant**	**Correlation coefficient value**	**Dicision**
1	F	0.723**	significant
2	L	0.729**	significant
3	A	0.792**	significant
4	C	0.764**	significant
5	C	0.757**	significant
**significant on the significance level of 0.01			

Table 3: correlation coefficients between each part and the total grade of FLACC scale.

Inter-rater reliability test for each rater showed high and positive Kappa's factors for both raters as shown in Table 7. They were close to complete one and reached (0.952) for the first one and (0.893) for the second rater, which means high compatibility for both raters, and indicates high inter-rater reliability for FLACC scale.

Correlation coefficient	0.799**
significance level	0
decision	Significant
**significant on the significance level of 0.01	

Table 4: shows correlation coefficient's values between FLACC and SEM scales (external criterion).

Correlation coefficient value for the FLACC scale between the external raters	
correlation coefficient	0.805**
significance level	0
Decision	significant
**significant on the significance level of 0.01	

Table 5: shows the correlation coefficient value between the first and the second ratters.

Total level	**Cronbach's Alpha factor**
	0.809

Table 6: reliability factors for FLACC scales using Cronbach's Alpha factor.

Inter-rater reliability study	Rater	Compatibility factor's value	Significance levels value	The significance of compatibility	Compatibility intensity
	First rater	0.952	0	there is significant compatibility	excellent
	Second rater	0.893	0	there is significant compatibility	excellent

Table 7: Inter-rater reliability of FLACC scale using Kappa compatibility factor's method.

Discussion

FLACC scale has been chosen as the best, first, easiest and the most compatible scale with self-evaluating scales, which their grades ranges between 0 and 10 simultaneously with FLACC scale, and that was according to von Baeyer's systematic review [8].

FLACC scale has been appointed as a standard scale for convergent validity investigations for some common scales [24], or recently innovate [25,26] so the researcher tries to approve its innovated scale's convergence or exceeding in comparison with FLACC scale, to get the acceptance and propagation for his scale [27].

In the current study, FLACC scale has fulfilled the construct validity, due to the rising of pain level during injection procedure in comparison with placebo, which agreed with many studies like Voepel-Lewis et al., Tsze et al., and Tomlinson et al. [6,28-30].

According to this study's results, FLACC showed criterion validity, so it converged to SEM scale, and this validity was assured according to various studies like Tomlinson et al. in 2010 who indicated to the correlation between FLACC scale and parent's scale, correlation coefficient value ranged between (0.65-0.87), Malviya in 2006 also registered strong correlation for FLACC scale with self-pain evaluating for the sample's children and their parents, the correlation coefficient ranged between (0.65-0,87), Voepel-Lewis et al. registered the value of (0.84) for FLACC scale's correlation coefficient with selfless COMFORT scale, and that study indicated good criterion convergent validity [6,27,28,31].

In the way of studying the reliability of FLACC scale by testing and retesting, the correlation value between the external raters, who defined the pain level in this study, has reached (0.805), this value converged with the value that Gomez et al. has gained in 2013, which was (0.95) [32]. Nevertheless, an indicator of the scale reliability was Cronbach's alpha factor's value, which was (0.809), and its convergence with many studies like Voepel-lewis et al. their factor's value was (0.882) [6], it was higher than Cronbach's alpha factor in Fathi et al. study in 2010, which was (0,85) [28].

Internal consistency validity study cleared high values for each part of the scale, those values ranged between (0.723-0.792), and it was convergent to the values registered by Tomlinson et al. in 2010, which ranged (0.76-0.9) [31].

Summary

The Arabic version of FLACC scale showed good psychometric properties, so the scale was valid and reliable, which made it applicable scale in selfless pain level assessment.

Acknowledgment

The authors gratefully acknowledge Damascus University and Prof. Adel Moufti for great help and support.

References

1. Walco GA, Conte P, Labay L, Engel R, Zeltzer L (2005) Procedural distress in children with cancer: self-report, behavioral observations, and physiological parameters. Clin J Pain 21: 484-490.
2. Champion GD (1998) Self-report measures of pain in children. Measurement of pain in infants and children. Pain Res Manag 10: 123-160.
3. de C Williams AC, Davies HT, Chadury Y (2000) Simple pain rating scales hide complex idiosyncratic meanings. Pain 85: 457-463.
4. Hodgins M (2001) Interpreting the meaning of pain severity scores. Pain Res Manag 7: 192-198.
5. Anand K, Craig KD (1996) New perspectives on the definition of pain. Pain 67: 3-6.
6. Voepel-Lewis T, Zanotti J, Dammeyer JA, Merkel S (2010) Reliability and validity of the face, legs, activity, cry, consolability behavioral tool in assessing acute pain in critically ill patients. Am J Crit Care 19: 55-61.
7. Puntillo KA (1997) Relationship between behavioral and physiological indicators of pain, critical care patients' self-reports of pain, and opioid administration. Crit Care Med 25: 1159-1166.
8. von Baeyer CL, Spagrud LJ (2007) Systematic review of observational (behavioral) measures of pain for children and adolescents aged 3 to 18 years. Pain 127: 140-150.
9. Bai J, Hsu L, Tang Y, van Dijk M (2012) Validation of the COMFORT Behavior scale and the FLACC scale for pain assessment in Chinese children after cardiac surgery. Pain Manag Nurs 13: 18-26.
10. Suraseranivongse S, Santawat U, Kraiprasit K, Petcharatana S, Prakkamodom S, et al. (2001) Cross-validation of a composite pain scale for preschool children within 24 hours of surgery. Br J Anaesth 87: 400-405.
11. da Silva FC, Santos Thuler LC, de Leon-Casasola OA (2011) Validity and reliability of two pain assessment tools in Brazilian children and adolescents. J Clin Nurs 20: 1842-1848.
12. Johansson M, Kokinsky E (2009) The COMFORT behavioural scale and the modified FLACC scale in paediatric intensive care. Nurs Crit Care 14: 122-130.
13. Lee SH, Lee NY (2013) An alternative local anaesthesia technique to reduce pain in paediatric patients during needle insertion. Eur J Paediatr Dent 14: 109-112.
14. Kreider KA, Stratmann RG, Milano M, Agostini FG, Munsell M (2001) Reducing children's injection pain: lidocaine patches versus topical benzocaine gel. Pediatr Dent 23: 19-23.
15. Nayak R, Sudha P (2006) Evaluation of three topical anaesthetic agents against pain: A clinical study. Indian J Dent Res 17: 155.
16. Asl Aminabadi N, Mostofi Zadeh Farahani R (2008) Correlation of parenting style and pediatric behavior guidance strategies in the dental setting: preliminary findings. Acta Odontologica 66: 99-104.
17. Aminabadi NA, Ghoreishizadeh A, Ghoreishizadeh M, Oskouei SG (2011) Can drawing be considered a projective measure for children's distress in paediatric dentistry? Int J Paediatr Dent 21: 1-12.
18. Baghdadi ZD (1999) Evaluation of electronic dental anesthesia in children. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 88: 418-423.
19. Kotb RM, Abdella AA, El Kateb MA, Ahmed AM (2009) Clinical evaluation of Papacarie in primary teeth. J Clin Pediatr Dent 34: 117-123.
20. Maragakis G, Musselman R, Ho C (2007) Reaction of 5 and 6 year olds to Dental Injection after Viewing the Needle: pilot study. Journal of Clinical Pediatric Dentistry 31: 28-31.
21. Munshi A, Hegde A, Bashir N (2002) Clinical evaluation of the efficacy of anesthesia and patient preference using the needle-less jet syringe in pediatric dental practice. Journal of Clinical Pediatric Dentistry 25: 131-136.
22. De Menezes Oliveira Maria Angélica H, Bonfim OCR (2010) Device for covering a syringe and needle in order to alleviate the fear and anxiety experienced during pediatric medical and odontological procedures, such as the administration of anesthetics and the like.
23. Glassman P, Peltier B (1995) Guidelines for the administration of local anesthesia in fearful dental patients. J Calif Dent Assoc 23: 23.
24. Armfield JM, Milgrom P (2011) A clinician guide to patients afraid of dental injections and numbness. SAAD Dig 27: 33-39.
25. Schnakers C, Chatelle C, Vanhaudenhuyse A, Majerus S, Ledoux D, et al. (2010) The Nociception Coma Scale: a new tool to assess nociception in disorders of consciousness. Pain 148: 215-219.
26. Nuttall NM, Gilbert A, Morris J (2008) Children's dental anxiety in the United Kingdom in 2003. J Dent 36: 857-860.
27. Beyer JE, McGrath PJ, Berde CB (1990) Discordance between self-report and behavioral pain measures in children aged 3-7 years after surgery. J Pain Symptom Manage 5: 350-356.
28. Fathi A, Al-Sharabasy AA (2012) Threshold of Pain Perception to Intraoral Anesthetic Injections among Egyptian Children. Life Science Journal 9: 1480-1483.
29. Tomlinson D, von Baeyer CL, Stinson JN, Sung L (2010) A systematic review of faces scales for the self-report of pain intensity in children. Pediatrics 126: e1168-1198.
30. Tsze DS, von Baeyer CL, Bulloch B, Dayan PS (2013) Validation of self-report pain scales in children. Pediatrics 132: e971-979.
31. Malviya S, Voepel-Lewis T, Burke C, Merkel S, Tait AR (2006) The revised FLACC observational pain tool: improved reliability and validity for pain assessment in children with cognitive impairment. Pediatric Anesthesia 16: 258-265.
32. Gomez RJ, Barrowman N, Elia S, Manias E, Royle J, Harrison D (2013) Establishing intra-and inter-rater agreement of the Face, Legs, Activity,

Cry, Consolability scale for evaluating pain in toddlers during immunization. Pain Research & Management: The Journal of the Canadian Pain Society 18: e124.