

See discussions, stats, and author profiles for this publication at: <https://www.researchgate.net/publication/304672279>

Comparison of effect of kangaroo mother care, breastfeeding and swaddling on Bacillus Calmette–Guerin vaccine injection pain score in healthy term neonates by a clinical trial

Article in *The Journal of Maternal-Fetal & Neonatal Medicine* · June 2016

DOI: 10.1080/14767058.2016.1205030

CITATIONS

29

READS

348

4 authors, including:



Razieh Fallah

Shahid Sadoughi University of Medical Sciences and Health Services

51 PUBLICATIONS 511 CITATIONS

SEE PROFILE



Farzad Ferdosian

Shahid Sadoughi University of Medical Sciences and Health Services

39 PUBLICATIONS 887 CITATIONS

SEE PROFILE



Fariba Binesh

Shahid Sadoughi University of Medical Sciences and Health Services

117 PUBLICATIONS 698 CITATIONS

SEE PROFILE

Comparison of effect of kangaroo mother care, breastfeeding and swaddling on Bacillus Calmette-Guerin vaccine injection pain score in healthy term neonates by a clinical trial

Razieh Fallah MD, Naeimah Naserzadeh MD, Farzad Ferdosian MD & Fariba Binesh MD

To cite this article: Razieh Fallah MD, Naeimah Naserzadeh MD, Farzad Ferdosian MD & Fariba Binesh MD (2016): Comparison of effect of kangaroo mother care, breastfeeding and swaddling on Bacillus Calmette-Guerin vaccine injection pain score in healthy term neonates by a clinical trial, The Journal of Maternal-Fetal & Neonatal Medicine, DOI: [10.1080/14767058.2016.1205030](https://doi.org/10.1080/14767058.2016.1205030)

To link to this article: <http://dx.doi.org/10.1080/14767058.2016.1205030>



Accepted author version posted online: 30 Jun 2016.
Published online: 30 Jun 2016.



Submit your article to this journal [↗](#)



View related articles [↗](#)



View Crossmark data [↗](#)

Title: Comparison of effect of kangaroo mother care, breastfeeding and swaddling on Bacillus Calmette-Guerin vaccine injection pain score in healthy term neonates by a clinical trial

Running title: BCG vaccine pain

Authors: Razieh Fallah¹ MD, Naeimah Naserzadeh² MD, Farzad Ferdosian³ MD, Fariba Binesh⁴ MD

1. Pediatric neurologist, Associate Professor, Department of Pediatrics, Growth Disorders of Children Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

2. Pediatrician, Shahid Sadoughi Hospital, Yazd, Iran

3. Subspecialty in Pediatric Infectious Disease, Assistant Professor, Department of Pediatrics, Growth Disorders of Children Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

4. Pathologist, Professor, Department of Pathology, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Address for correspondence:

Fariba Binesh MD

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Shahid Sadoughi Hospital, Ave - Sina Blvd, Shahid Ghandi Blvd, Yazd, I.R.Iran

Phone number: 00983518224000

Fax: 00983518224100

Email: binesh44@yahoo.com

Title page

Title: Comparison of effect of kangaroo mother care, breastfeeding and swaddling on Bacillus Calmette-Guerin vaccine injection pain score in healthy term neonates by a clinical trial

Running title: BCG vaccine pain

Abstract

Background/aim: The purpose of this research was to compare analgesic effect of kangaroo mother care (KMC), breastfeeding and swaddling in Bacillus Calmette-Guerin (BCG) vaccine injection in term neonates.

Methods: In a randomized 120 healthy term neonates who received routine BCG vaccination in first day of their life distributed into three groups.

In group I, neonates breastfed two minutes before, during and one minute after BCG vaccination.

In group II, neonates received KMC ten minutes before, during and one minute after vaccination and in group III, they were swaddled ten minutes before, during and one minute after vaccination.

Primary outcomes include pain score during, one minute and two minutes after BCG vaccine injection and obtaining of pain score of less than three during vaccination .

Results: Pain scores during, one minute and two minutes after vaccine injection in group I were lower than in groups II and III .group I had higher success rate in doing of painless vaccination and had lower crying duration in comparison to another groups ($p<0.05$)

Conclusion: Breastfeeding was more effective than KMC and swaddling in reduction of BCG vaccination pain in healthy term neonates.

Key words: Neonate, Vaccination Pain, Kangaroo Mother Care, Breastfeeding, Swaddling

Introduction

Neonates can experience pain and they react to pain by autonomic changes such as increases in heart rate and blood pressure, alternation in cortisol and catecholamine hormones and behavioral responses.⁽¹⁾ Harming complications of frequent painful exposures in neonates include change in pain sensitivity which may continue up to adolescence, constant neuroanatomical and behavioral abnormalities and long term adverse effects such as emotional, behavioral, and learning disabilities.⁽²⁾

In neonates, nonpharmacologic interventions such as nonnutritive sucking with or without sucrose or glucose, breastfeeding, swaddling, kangaroo mother care (KMC), and sensorial saturation (use of touch, massage, voice, smell, and sight) has been shown to reduce mild to moderate pain of minor procedures in both preterm and term newborns.^(3, 4)

Close skin-to-skin contact between mother and infant in KMC method and resting of neonate between the mother's breasts can reduce stress and pain responses of neonates by facilitating maternal-infant co-regulation and stimulating of ventral tactile and proprioceptive systems and it is a simple, effective and safe pain relieving method for single painful procedure.^(5, 6)

Swaddling by different techniques in many countries can alleviate pain, improve neuromuscular development and reduce physiologic distress in preterm infants and also might decrease excessive crying in children with cerebral damage.⁽⁷⁾

In term neonates, breastfeeding or oral formula feeding is more effective than oral sucrose or glucose for pain control of heel-lancing.⁽⁸⁾

In healthy preterm neonates, KMC is more effective than 25 percent glucose to reduce pain of heel lancing.⁽⁹⁾

The routine vaccines that may be injected intramuscularly, subcutaneously or intradermal are the most common sources of iatrogenic pain during infancy and childhood.⁽¹⁰⁾ Control, management and decreasing of pain of immunization and other minor procedures of routine medical and nursing care of neonates are necessary.⁽²⁾

Theory/calculation

According to vaccination programs of Ministry of Health and Medical Education of I.R. Iran, all neonates should receive intradermal injection of Bacillus Calmette-Guerin (BCG) vaccine in hospitals which they are delivered, routinely in first day of their life. Since other studies have prove that breastfeeding, swaddling and kangaroo mother care are more effective than sucrose or glucose in reducing of pain ⁽⁵⁻⁹⁾, therefore , this research was done to answer this question that which one of these three non-pharmacological interventions (KMC, breastfeeding and swaddling) , can cause less pain of intradermal BCG vaccine injection and the purpose of this study was to compare analgesic effect of KMC, breastfeeding and swaddling in BCG vaccination of healthy term neonates.

Materials and methods

In a randomized single-blind clinical, parallel group trial, all healthy term neonates who received routine BCG vaccination in first day of their life in Shahid Sadoughi Hospital, Yazd, Iran from March to June 2015 were enrolled in the study.

Sample size was assessed to be 37 neonates in each group based on Z formula and a confidence interval of 95% with 80% power to detect a difference of 30% in doing reduced pain vaccination between the groups with type one error (alpha) of 0.05 and 40 neonates in each group were recruited to account for missing data and dropouts.

Eligible participants included term neonates (gestation age of 37–42 weeks) who were product of normal vaginal delivery, awake and alert before vaccine injection , without systemic illness ,in a

healthy medical condition and with birth weight of 2500–4000 grams .

Exclusion criteria consisted of moderate to severe birth asphyxia, severe congenital malformation and receiving sedative hypnotic or analgesic drugs within the past 24 hours.

The trial used computer generated equal simple randomization by random numbers and allocation ratio was 1:1 for the three groups.

Since, neonates usually breastfeed within 3- 5 minutes and length of swaddling and KMC should be at least ten minutes, and interventions and their length were different, so, blinding of parents of the participants, the nurse of hospital , the Data collector and the outcome assessor, was not possible and data analysts were only kept blinded to the allocation. But, concealment was done by writing down the intervention for each serially participating neonate in a numbered and sealed opaque envelope which was opened by the pediatric neurologist of research immediately before intervention. Randomisation and concealment were done by a researcher with no clinical involvement in the trial.

The neonates were randomly distributed into three groups. In group I, breastfeeding started two minutes before vaccination and continued during and one minute after BCG vaccination. In group II, neonates received KMC ten minutes before, during and one minute after BCG vaccination and in group III, they were swaddled ten minutes before, during and one minute after vaccination.

The neonates were awake, quiet and alert and had clean diapers at the time of vaccines injection.

The BCG vaccine of the research were products of Pasteur Institute of Iran and in all of the neonates, the vaccine was injected in similar conditions, similar needles and by a trained nurse.

Dosage of the BCG vaccine was 0.5 milliliter that was injected intradermal with a 27 mm gauge needle into the area of right deltoid muscle, at a 90° angle.

In KMC group, the mother hold the neonate wearing only a diaper under her gown between her bare breasts in an upright position with maximum skin-to-skin, chest-to-chest contact.

Hip and knees of the neonates in swaddling group, wrapped in the blanket with mild tightness and their hands and heads were free.

The intervention was delivered by a nurse of hospital and primary and secondary outcomes were assessed by the pediatric resident of research.

Primary outcomes included baseline pain score five seconds before, during, one minute and two minutes after BCG B vaccine injection, and obtaining of pain score of less than three during BCG vaccine injection (less pain vaccination). Pain score when the needle was inserted to the skin, was assessed based on Neonatal/Infant Pain Scale (NIPS). Parameters of NIPS include facial expression, cry, breathing patterns, position of arms, position of legs and state of arousal. The score for each item is summed and total score ranges from 0 – 7. It is recommended for children of less than one year of age and a score greater than three indicates pain.⁽¹¹⁾

Obtaining of pain score of less than three based on NIPS during the needle insertion to skin was considered as success in reducing of pain and less pain procedure.

Secondary outcome was duration of neonate crying during BCG vaccine injection that was calculated from the onset of crying (when the needle was inserted) until crying was stopped for five seconds.

The data were analyzed using Statistical Package for the Social Sciences version 17 (SPSS, Chicago, Illinois, USA) statistical software. Recorded data were assessed for normal distribution using the Kolmogorov-Smirnov test and Chi-square test was used for data analysis of categorical variables and continuous and mean variables were compared using one-way analysis of variance (ANOVA) test between three groups. Differences were considered significant at P values of less than 0.05.

Informed consent was taken from neonates parents before enrolling participating neonates and this research has been approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

This research is registered in Iranian clinical trials with registration number:

IRCT201505142639N16

Results

The design and conduct of this trial was straightforward, we did not have any losses or exclusions and 50 girls and 70 boys with mean birth weight of 3.14 ± 0.33 kilograms were evaluated in the three groups.

By Kolmogorov-Smirnov test, the data had normal distribution.

Comparison of demographic characteristics of the children in the three groups is shown in Table.1 which indicates that no statistically significant differences were seen from viewpoints of sex distribution, mean of weight and means of height.

Table.2 shows comparison of pain scores in the three groups and indicates that baseline pain score before BCG vaccine injection was not statistically significant different in three groups, but pain scores of during, one minute and two minutes after BCG vaccine injection in breastfeeding group were lower than in kangaroo mother care or swaddling groups.

Comparison of frequency of doing less pain BCG vaccination (obtaining of pain score of less than three during BCG vaccine injection) and duration of baby crying during vaccine injection are presented in Table.3 which shows that breastfeeding group had higher success rate in reduced pain vaccination and lower crying duration in comparison to kangaroo mother care or swaddling groups.

Discussion

Non-pharmacological methods are the first choice for analgesia in newborns immunization⁽¹²⁾ and this research showed that breastfeeding was more efficient than KMC and swaddling in reduction of BCG vaccine injection pain. Cignacco et al. in their systematic review of 13 randomised controlled studies and two meta-analyses, concluded that only non-nutritive sucking, swaddling and facilitated tucking had reducing pain effect.⁽¹³⁾

In a study in Tabriz, Iran, breastfeeding was more efficient than oral sucrose, combination of oral sucrose and breastfeeding and no intervention in reduction of pain of intramuscular diphtheria, tetanus, pertussis (DTP) vaccine injection in less than three months infants.⁽¹⁴⁾

In a study in Mashhad, Iran, breastfeeding was more efficient than kangaroo mother care or no intervention in reduction of pain of intramuscular DTP vaccine injection in two, four and six months old infants.⁽¹⁵⁾

In a study in Tehran, Iran, KCM ten minutes before and during intramuscular injection in healthy term neonates was more effective than no intervention in reduction of cumulative Neonatal Infant Pain Scale score immediately after injection.⁽¹⁶⁾

Kostandy et al. study showed analgesic effect of skin-to-skin contact in hepatitis B vaccine injection in healthy term neonates.⁽¹⁷⁾ A study in Quebec, Canada, analgesic effect of KMC for 30 minutes before routine heel sticking of preterm neonates within 10 days of birth, was more than swaddling.⁽¹⁸⁾

Possible explanation for the discrepancy may be related to differences in age, procedures, type of vaccine and route of injection.

In present research, breastfeeding was the most efficient analgesia in neonatal BCG vaccination and analgesic effects of breastfeeding in reducing of vaccination pain in less than six months old

infants⁽¹⁹⁾, in healthy term neonates during routine heel sticking⁽²⁰⁾ and venepuncture^(21,22) have been shown in other researches.

Analgesic and lowering stress effect of breastfeeding might be due to its helping mothers and neonates to cope with the stressful situations. On the other hand, breastfeeding can amend vaccines response, decrease risk of unsuitable reactions of vaccines in sensitive infants and change metabolism of ethyl mercury derived from some vaccines.⁽²³⁾

Some research showed that non-pharmacological pain management methods in newborns were much more efficient when used in combination with other non-pharmacological interventions including music therapy, swaddling, facilitated tucking, KMC and non-nutritive suction.⁽²⁴⁾

In conclusion, based on result of present study, breastfeeding was more effective than KMC and swaddling in reduction of BCG vaccination pain in healthy term neonates, but, skin to skin contact or KMC, also decreased immunization pain and therefore, combination of breastfeeding and kangaroo mother care may be more effective. so, health provider can alleviate vaccination pain in neonates with this simple, easy, cost effective and available strategy.

Acknowledgments

This study was funded by a grant from the Deputy for Research of Shahid Sadoughi University of Medical Sciences, Yazd, Iran. The research was also a thesis presented for obtaining the specialty of Pediatrics degree by Naeimah Naserzadeh MD.

Conflicts of interest: No conflicts of interest declared

References

1. Anand KJ, Aranda JV, Berde CB, Buckman S, Capparelli EV, Carlo W, et al. Summary proceedings from the neonatal pain-control group. *Pediatrics* 2006; 117(3 Pt 2):S9-S22.
2. American Academy of Pediatrics Committee on Fetus and Newborn; American Academy of Pediatrics Section on Surgery; Canadian Paediatric Society Fetus and Newborn Committee, Batton DG, Barrington KJ, Wallman C. Prevention and management of pain in the neonate: an update. *Pediatrics*. 2006; 118(5):2231-41.
3. Hall RW. Anesthesia and analgesia in the NICU. *Clin Perinatol* 2012; 39(1):239-54.
4. Pillai Riddell RR, Racine NM, Turcotte K, Uman LS, Horton RE, Din Osmun L, Ahola Kohut S, Hillgrove Stuart J, Stevens B, Gerwitz-Stern A. Non-pharmacological management of infant and young child procedural pain. *Cochrane Database Syst Rev* 2011; 10: CD006275.
5. Johnston C, Campbell-Yeo M, Fernandes A, Inglis D, Streiner D, Zee R. Skin-to-skin care for procedural pain in neonates. *Cochrane Database Syst Rev* 2014; 1:CD008435.
6. Neu M, Hazel NA, Robinson J, Schmiede SJ, Laudenslager M. Effect of holding on co-regulation in preterm infants: a randomized controlled trial. *Early Hum Dev* 2014; 90(3):141-7.
7. van Sleuwen BE, Engelberts AC, Boere-Boonekamp MM, Kuis W, Schulpen TW, L'Hoir MP. Swaddling: a systematic review. *Pediatrics* 2007; 120(4):e1097-106.
8. Weissman A, Aranovitch M, Blazer S, Zimmer EZ. Heel-lancing in newborns: behavioral and spectral analysis assessment of pain control methods. *Pediatrics* 2009; 124(5):e921-6.
9. Freire NB, Garcia JB, Lamy ZC. Evaluation of analgesic effect of skin-to-skin contact compared to oral glucose in preterm neonates. *Pain* 2008; 139(1):28-33.

10. Schechter NL, Zempsky WT, Cohen LL, McGrath PJ, McMurtry CM, Bright NS. Pain reduction during pediatric immunizations: evidence-based review and recommendations. *Pediatrics* 2007; 119(5):e1184-98.
11. Lawrence J, Alcock D, McGrath P, Kay J, MacMurray SB, Dulberg C. The development of a tool to assess neonatal pain. *Neonatal Netw* 1993; 12(6):59-66.
12. Carbajal R, Gréteau S, Arnaud C, Guedj R. Pain in neonatology. Non-pharmacological treatment. *Arch Pediatr*. 2015; 22(2):217-21. [Article in French]
13. Cignacco E, Hamers JP, Stoffel L, van Lingen RA, Gessler P, McDougall J, Nelle M. The efficacy of non-pharmacological interventions in the management of procedural pain in preterm and term neonates. A systematic literature review. *Eur J Pain* 2007; 11(2):139-52.
14. Sahebihag MH, Hosseinzadeh M, Mohammadpourasl A, Kosha A. The effect of breastfeeding, oral sucrose and combination of oral sucrose and breastfeeding in infant's pain relief during vaccination. *Iran J Nurs Midwifery Res*. 2011; 16(1): 1-7.
15. Emami Moghaddam Z, Behnam vashani HR, Younesi z, Hasanzadeh F. Comparing the effect of kangaroo care and breast feeding on immunization injection pain in infants. *Journal of Sabzevar University of Medical sciences*, 2012; 19(1): 26-33. [Article in Persian]
16. Kashaninia Z, Sajedi F, Rahgozar M, Noghabi FA. The effect of Kangaroo Care on behavioral responses to pain of an intramuscular injection in neonates. *J Spec Pediatr Nurs* 2008; 13(4):275-80.
17. Kostandy R, Anderson GC, Good M. Skin-to-skin contact diminishes pain from hepatitis B vaccine injection in healthy full-term neonates. *Neonatal Netw* 2013; 32(4):274-80.

18. Johnston CC, Stevens B, Pinelli J, Gibbins S, Filion F, Jack A, Steele S, Boyer K, Veilleux A. Kangaroo care is effective in diminishing pain response in preterm neonates. *Arch Pediatr Adolesc Med.* 2003; 157(11):1084-8.
19. Dilli D, Küçük IG, Dallar Y. Interventions to reduce pain during vaccination in infancy. *J Pediatr* 2009; 154(3):385-90.
20. Gray L, Miller LW, Philipp BL, Blass EM. Breastfeeding is analgesic in healthy newborns. *Pediatrics* 2002; 109(4):590-3.
21. Carbajal R, Veerapen S, Couderc S, Jugie M, Ville Y. Analgesic effect of breast feeding in term neonates: randomised controlled trial. *BMJ* 2003; 326(7379):13.
22. Shah PS, Herbozo C, Aliwalas LL, Shah VS. Breastfeeding or breast milk for procedural pain in neonates. *Cochrane Database Syst Rev* 2012; 12:CD004950.
23. Dòrea JG . Breastfeeding is an essential complement to vaccination. *Acta Paediatr* 2009; 98 (8):1244-50.
24. Chromá J, Sikorová L. Effect of non-pharmacological methods for alleviation of pain in newborns. *Cas Lek Cesk* 2012; 151(6):294-8. [Article in Czech]

Table.1. Comparison of demographic characteristics of children in both groups

Groups		Breastfeeding	Kangaroo mother care	Swaddling	P. Value
Data					
Sex	Girl	16	17	17	0.8
	Boy	24	23	23	
Weight in kg (mean \pm SD)		3.16 \pm 0.32	3.15 \pm 0.34	3.11 \pm 0.31	0.7
Height in centimeter (mean \pm SD)		50.22 \pm 1.77	50.01 \pm 1.51	49.38 \pm 2.44	0.6

Table.2. Comparison of pain scores in the three groups

Groups		Breastfeeding	Kangaroo mother care	Swaddling	P. Value
Data					
Pain score before the vaccination (mean \pm SD)		0	0	0	1
Pain score during BCG vaccine injection (mean \pm SD)		1.81 \pm 1.16	2.92 \pm 1.34	3.48 \pm 0.96	0.001
Pain score 1 minute after vaccine injection (mean \pm SD)		0.79 \pm 0.3	1.19 \pm 0.97	1.61 \pm 1.01	0.001
Pain score 2 minutes after vaccine injection (mean \pm SD)		0.31 \pm 0.1	0.73 \pm 0.36	1.07 \pm 0.56	0.04

Table.3 .Comparison of frequency of doing less pain BCG vaccination and BCG injection crying duration in three groups

Groups		Breastfeeding	Kangaroo mother care	Swaddling	P. Value
Data					
Less pain BCG vaccination	Yes	40	38	36	0.04
	No	0	2	4	
Duration of baby crying in seconds(mean \pm SD)		26.61 \pm 11.7	45.12 \pm 23.41	63.25 \pm 16.98	0.001