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Research Article

A randomized control trial study, single blinded, the effect of gamelan and oral glucose solution intervention toward infants' pain respond in immunization

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ABSTRACT

Background: Immunization injection procedure can cause pain in infants, so that non-pharmacological techniques approach is required to overcome it. Distraction techniques are used to reduce pain in infants including oral glucose administration and the distraction of music. How oral glucose effects in reducing pain in infants when compared with the distraction of music is not known. The research objective is to analyse and compare the effect of oral glucose intervention, gamelan music, and combined of oral glucose and gamelan music to the infant's pain response in immunization.

Methods: This study is a randomized controlled trial with only posttest design. Respondents were divided into four groups: the oral glucose group, the gamelan group, the combined group of gamelan and oral glucose, and the control group. The study was conducted at the Baki public health center, Sukoharjo, Central Java, Indonesia, from July to August 2014. The total number of respondents was 135 infants aged 2-6 months who do pentavalent immunization by intramuscular injection. Assessment scores pain response was conducted by two single-blinded independent assessors. They were using instruments FLACC (face, legs, activity, cry and consolability) at four times. They were when rubbing the skin, in the injection, three minutes after injection and five minutes after injection. Data were analyzed using Kruskal Wallis and Mann Whitney post hoc.

Results: The glucose group had a significant average rank score that is lower in pain response when compared to the control group at the time of injection ($p = 0.029 < 0.05$), at three minutes after injection ($p = 0.000 < 0.05$), and five minutes after injection ($p = 0.000 < 0.05$). The gamelan group had a significant average rank score that is lower in pain response when compared to the control group at three minutes after injection ($p = 0.023 < 0.05$), and five minutes after injection ($p = 0.006 < 0.05$). The combined group of gamelan and glucose had a significant average rank score that is lower in pain response when compared to the control group at five minutes after injection ($p = 0.043 < 0.05$). The glucose group had a significant average rank that is lower in pain response scores compared to the gamelan group at the time of injection ($p = 0.045 < 0.05$). The glucose group had a significant average rank score that is lower in pain response when compared to the combined group of gamelan and glucose at three minutes after injection ($p = 0.012 < 0.05$).

Conclusions: Intervention glucose orally 2 ml affected the ranking of the average scores of the fastest pain response in infants who conducted immunization intramuscular injection, further distraction gamelan and the combination group of gamelan and oral glucose.

Keywords: Oral glucose, Gamelan music, Decrease, Pain, Immunization

INTRODUCTION

Pain in infant that is not addressed properly can affect affective response towards the following procedures may cause pain. Immediate effects on pain in infants are anger, fear, sleeping disturbances, increased oxygen consumption, ventilation perfusion changes, increased gastric acidity, and the loss of nutrition.[1] Based on these considerations it is always advisable to reduce pain in infants.[2]

Immunization procedures given by injection can cause pain. Infant's facial expressions of pain immediately after penetration of the needle at the time of immunization were high-pitched crying, the rigidity of the body and limbs.[3] To overcome the pain in infants required non-pharmacological approach technique that is safe and easy to implement. Katherina Comfort Colcaba in theory states that nursing interventions must be done so that the client becomes a relief, ease and trancendence.[4]

Non-pharmacological techniques to reduce pain in infants include giving oral glucose. The use of oral sweetener for painful procedures is known and recommended by international guidelines.[5] However, there is one study reported the side effects of oral administration of glucose is desaturation and choking in premature newborns.[6]

Distraction is needed when the baby will be done painful procedure. It is to overcome their fears and lessen the pain.[7] The use of music is recommended as a distraction media and non-pharmacological therapy that is easy and cheap, without side effects.[8] Gending is a Javanese gamelan music that can provide a relaxing effect and peace.[9]

The effects of music on pain remains controversial, whether the music as a complement to overcome pain or music can reduce pain.[10] Perhaps the Javanese gamelan can be used to reduce pain in infants. But the evidence needed to support research for Gamelan.

Research objectives was 1). To analyze the effect of the intervention on oral glucose solution, gamelan, and the combined of oral glucose and gamelan to the pain response in infants in immunization. 2). To compare the effect of the intervention of oral glucose solution, gamelan, and the combined of oral glucose and gamelan with the control group of the pain response in infants immunization.

METHODS

This research is quantitative, using a randomized controlled trial with only post test design. In this study, the respondents were divided into four groups is gamelan group, oral glucose group, the combined group of gamelan and oral glucose, and the control group. Random allocation is done by using a random number table to determine the subject of research. Block randomization technique is intended that each group has a comparable number of subjects at a time.

The study was conducted at the Baki Public Health Center, Sukoharjo, starting from July to August 2014. The study was conducted after obtaining ethical clearance of the Ethics Committee of the Faculty of Medicine, University of Gadjah Mada and research permit from the Regional Development Planning Agency Sukoharjo.

Population of this research is the baby in the health center and conducted DPT-HB-Hib (pentavalent). Inclusion criteria were: the respondents are willing to be proven with the informed consent of the parents, infants aged 2-6 months, obtaining type of immunization is DPT-HB-Hib (pentavalent) intramuscularly. Exclusion criteria were: babies are sick or have a history of serious illness, mental or physical disability so difficult to measure pain responses.

In this study, the overall number of respondents who obtained is 135, there are 12 respondents were excluded, so that respondents were included research to processing as many as 123 respondents, as shown in the flowchart (Figure 1).

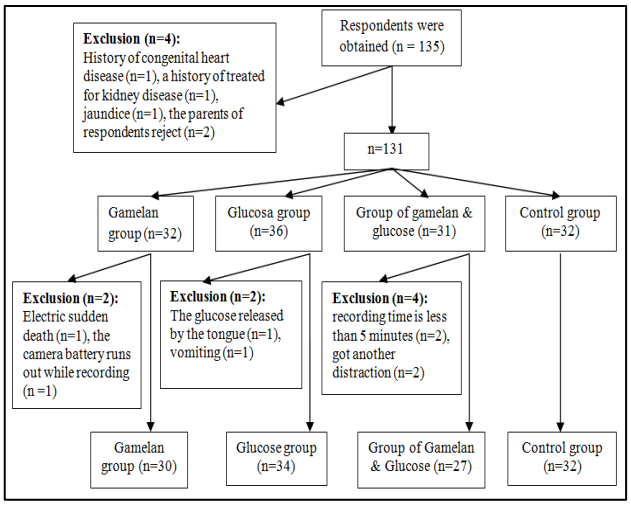

Figure 1: Sample research.

Research preparation phase

Setting the soundproof room and air-conditioning installed temperature's room between 24-26 degrees Celsius so that the baby does not feel cold. Selecting 2 independent assessors in pain response. They are two master nursing students with work experience of over 3 years. Testing the level of agreement (degree of agreement) using Cohen's kappa coefficient. The test results K = 0.918, showed the value of inter-rater measurements by two independent assessors having the same consistency.

Research implementation phase

Providing an explanation to parents of respondents about the study. Asking informed consent of the respondents' parent. Ensuring that the baby is drinking within thirty minutes to an hour before the research carried out, to avoid the baby feel thirsty. Determining the groups randomly with the aid of a computer using block randomization table. Respondents came into the room one by one according interventions available. Data characteristics of the respondent is written consisting of initials, age, immunization history, birth weight and gestational age.

In the group of gamelan, the respondents before the injection of immunization, listen to gamelan "gending Subositi" (Javanese gamelan instrumental music, the music is smooth, with a low tone), played by MP3, placed approximately 30 cm from the respondents that will be conducted immunization, gamelan still played up to 5 minutes after immunization. Operational of music performed by assistants 1.

In the glucose group, respondents were given an oral glucose solution Dextrose 30%, 2 ml, it was dropped into the baby's mouth using a pipette gradually, given 2 minutes before the immunization. The actions were carried out by the oral glucose administration assistant 2. In the combined group of gamelan and glucose, respondents listen to gamelan "gending Subositi" for 10 minutes then given 30% Dextrose solution 2 ml. It was added to the baby's mouth through the pipette slowly. After 2 minutes of administration of Dextrose 30% The infant was then given immunization injections, the music was still played until 5 minutes after injection. Operational intervention of gamelan and oral glucose administration is done by assistants 1 and 2 assistants.

In the control group, respondents were given immunization according to the standard immunization injections care without additional intervention. Immunization procedures were performed equally on all respondents both in the gamelan group, oral glucose, combined group of gamelan and oral glucose, and the control group. The position of the respondent at the time of immunization is on the mother or caregiver's lap. Immunizations were given intramuscularly in musculus vastus lateralis to the left, the vaccine used was Pentabio at a dose of 0.5 ml, using a syringe One ject 24 G x 1 disposable. Immunizations were performed by two special officers who have obtained the decree of the head of the health center B and had experience of clinical work more than ten years. Recording of the response to pain was done in all groups by the assistant cameraman at beginning time of immunization, officer rubbed cotton with warm water on baby's skin up to five minutes after injection. Respondents recording assistant cameraman gave the code to avoid errors in data retrieval. When he finished recording, video was copied double and given to two independent appraisers to assess the pain response. Independent assessors do not know which intervention was given to the respondents but still can listen to the sound of gamelan in the video. Assessment of pain response using instruments FLACC (face, leg, activity, cry and consolability) were assessed at four time, when immunization officer rubbed the skin, in injection, three minutes after injection and five minutes after the injection.

RESULTS

Homogeneity test shows that all data in the intervention group and the control group is homogeneous. Normality test showed innormal distribution of data so that the next data analysis was using Kruskal Wallis and Mann Whitney post hoc test.

Table 1: Demographic data of respondents by age, immunization history, birth weight and gestational age (N=123).

Group	N	Age (month)	The number of immunization by the injection	Birth weight (grams)	Gestational age (months)	Gender	
						Male (%)	Female (%)
Gamelan	30	1.74-2.26	2.63-3.17	2.889-3.268	38.62-39.38	60	40
Glucose	34	1.16-2.21	2.46-3.12	3.055-3.375	38.81-39.60	61.7	38.3
Gamelan & glucose	27	1.40-2.08	2.12-2.92	2.975-3.281	38.81-39.64	55.6	44.4
Control	32	1.75-2.31	2.66-3.34	2.986-3.212	38.76-39.43	59.4	40.6

At the time of rubbing the skin and at the time of injection, the difference in average rank in the four groups did not contribute significant effect on pain response scores. At three minutes after injection and five minutes after the injection, the difference in all four groups had a significant effect on pain response scores on infant immunization.

At the time of injection, the glucose group had a significant average rank that is lower in pain response scores compared to gamelan group ($p = 0.045 < 0.5$). At three minutes after the injection, the glucose group had a significant average rank score that is lower in pain response when compared to the combined group of gamelan and glucose ($p = 0.012 < 0.05$).

Table 2: Effect of intervention on pain response at the time of rubbing the skin, while injection, three minutes and five minutes after injection with the Kruskal-Wallis test.

Pain response	Group	Mean rank	p value
Rubbing the skin	Gamelan	66.02	0.631
	Glucose	56.50	
	Gamelan & Glucose	61.17	
	Control	64.78	
Injection	Gamelan	67.88	0.057
	Glucose	50.57	
	Gamelan & Glucose	64.07	
	Control	66.88	
3 minute after injection	Gamelan	60.20	0.001
	Glucose	44.04	
	Gamelan & Glucose	66.89	
	Control	78.64	
5 minute after injection	Gamelan	57.60	0.001
	Glucose	48.91	
	Gamelan & Glucose	62.41	
	Control	79.69	

Table 3: Differences in response to pain in the intervention group and the control group by the Mann Whitney test post hoc.

Pain response	Group	Mean Rank	Z	p value
Rubbing the skin	Gamelan	31.75	-0.115	0.909
	Control	31.27		
	Glucose	31.35	-1.053	0.292
	Control	35.78		
	Gamelan & Glucose	29.13	-0.397	0.691
	Control	30.73		
Injection	Gamelan	31.77	-0.152	0.879
	Control	31.25		
	Glucose	29.26	-2.180	0.029
	Control	38.00		
	Gamelan & Glucose	29.26	-0.395	0.693
	Control	30.62		
3 minute after injection	Gamelan	26.47	-2.267	0.023
	Control	36.22		
	Glucose	24.76	-3.992	0.000
	Control	42.78		
	Gamelan & Glucose	26.87	-1.369	0.171
	Control	32.64		
5 minute after injection	Gamelan	25.48	-2.739	0.006
	Control	37.14		
	Glucose	25.81	-3.746	0.000
	Control	41.67		
	Gamelan & Glucose	25.41	-2.026	0.043
	Control	33.88		

Table 4: Differences between groups' effect of the intervention on pain response.

Pain response	Group	Mean Rank	Z	p value
Rubbing the skin	Gamelan	35.45	-1.331	0.183
	Glucose	29.90		
	Gamelan	30.05	-0.553	0.581
	Gamelan & Glucose	27.83		
	Glucose	29.91	-0.616	0.538
	Gamelan & Glucose	32.37		
Injection	Gamelan	36.73	-2.003	0.045
	Glucose	28.76		
	Gamelan	29.90	-0.544	0.586
	Gamelan & Glucose	28.00		
	Glucose	28.49	-1.433	0.152
	Gamelan & Glucose	34.17		
3 minute after injection	Gamelan	36.93	-1.869	0.062
	Glucose	28.59		
	Gamelan	27.47	-0.770	0.441
	Gamelan & Glucose	30.70		
	Glucose	26.12	-2.513	0.012
	Gamelan & Glucose	37.15		
5 minute after injection	Gamelan	35.08	-1.274	0.203
	Glucose	30.22		
	Gamelan	27.93	-0.573	0.566
	Gamelan & Glucose	30.19		
	Glucose	28.09	-1.730	0.084
	Gamelan & Glucose	34.67		

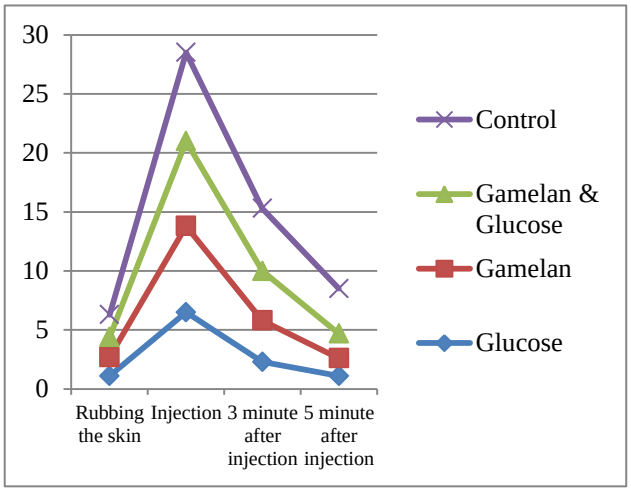

Figure 2: Comparison of average curve response to pain in the intervention group.

DISCUSSION

Intervention of gamelan, glucose, or a combination of interventions gamelan and glucose, does not have significant effect on pain response at the time of rubbing the skin. It means that at the time of rubbing the skin, using intervention or without intervention, it does not affect the score of the pain response in infants.

Sequence pain response scores from high to low is at the time of injection, three minutes after the injection, five minutes after injection and the lowest is when rubbing the skin. By the time the needle is inserted until the vaccine included pain response that scored highest when compared to other times. This is consistent with previous research that babies show facial expressions of pain immediately after penetration of the needle during the implementation of immunization.[3]

Effect of oral glucose intervention on pain response

Intervention oral glucose has a significant effect on pain response at the time of injection, three minutes and five minutes after the injection. This is affected because of the nature and mechanism absorption of oral glucose. Glucose is a simple monosaccharide, produced by the end product of photosynthesis from carbon dioxide and water. Sweetness contained in glucose is favored by babies as breast milk also has a sweet taste. It is affecting why babies easily consume glucose or other sweet solutions. In addition, according to the natural characteristics, infants aged 2-6 months are at an oral phase to obtain satisfaction with something that is inserted into orally.[11]

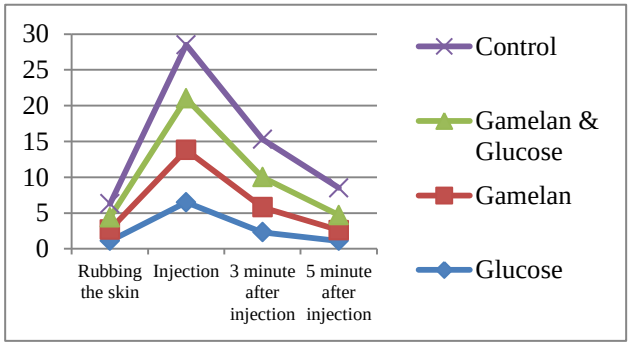

Figure 2: Comparison of average curve response to pain in the intervention group.

Glucose is a monosaccharide, after the glucose get into the baby's mouth it will immediately be absorbed because it does not require a breakdown anymore. Oral glucose absorption takes short since given and well tolerated by aterm neonates.[12,13]

Sweet solution give orall influences to two mechanisms in painful procedures, first to stimulate the tactile sense of taste in the mouth and the second stimulation sense of effecting the release of endogenous opioid analgesia.[14] Effect of glucose may be due to the release of beta-endorphin.[12,15] The presence of endorphins in the synapses of nerve cells causes decreased sensation of pain status. Endorphins will inhibit the transmission of pain messages by linking the opiate receptor sites in the brain and spinal nerves.[16]

Oral glucose administration of 2 ml of 30% significantly decreased pain scores in infants ages 5 and 12 months compared to placebo water at the time of immunization.[17] The oral glucose administration of 2 ml of a 30% decrease in pain scores were significant ($p < 0.0001$) compared to water placebo in healthy newborn infants aged 0-24 hours when conducted intramuscular injection of vitamin K.[18] Giving of 2 ml of glucose 30% at 2 minutes before action venipuncture provide the most effective pain relief in newborns compared to 10% glucose and 20%.[19]

Effect of intervention gamelan related to pain response

Intervention of gamelan has a significant effect on pain response at three and five minutes after the injection. It can be influenced by the characteristics of the musical that was played. Gising Subositi is Javanese musical instrument that is smooth, gently undulating, full of dignity and serenity, instrumental music without verse, has slow beats.[20-23] Gising is a music that can provide a relaxing effect and strains that can provide peace.[9] This is consistent with the type of music preferred by the baby. Baby likes rhythmic music monotonous, has slow beats, in the tone of a slow ride down into loud or of hard to be slow with repeated sound patterns 60-70 beats per minute[24]. Music with a slightly slower tempo, beats 50-70 per minute and subtle rhythms that can give peace.[25]

The results of observations at eight to ten minutes interventions gamelan, some respondents getting sleepy to show a response in the form of whining, fussing, hands rubbed his eyes, stretched, and yawned. Sleepy baby who actually are at the level of comfort but the response arising from the effects of drowsiness in some respondents with a whimper, fuss, rubbed his eyes, stretched and yawned may affect the assessment of pain response using FLACC.

When getting sleepy, some babies respond become restless and cranky, looking impatient, into tantrums and crying, or yawning continuely.[26] Some sleepy baby becomes fussy and it is not clear what he wants.[27]

At three minutes and five minutes after the injection, gamelan intervention had a significant effect on pain response. This is consistent with the mechanism of music affect neurotransmitter pain. Music as a sound wave to be received and collected by ear fit into the external acoustic meatus up to the tympanic membrane. Furthermore, the sound energy will be enlarged to 25-30 times with hydraulic and lever action by the tympanic membrane along the chain ossicular to move the fluid medium perilymph and endolymph. Vibration will be forwarded

to the organ of corti in cochlea and vibration is converted from conduction system to the nervous system via the auditory nerve as electrical impulses.[28]

Electrical impulses through nerve fibers from the spiral ganglion of corti toward the dorsal cochlear nucleus and ventralis located on the upper part of the medulla. At this point all the fibers and neuronal synapses forwarded to level two opposite sides of the brainstem and ends in the nucleus olivarius superior. Auditory impulse propagation continues upward through lateral lemniscus then forwarded to kolikulus inferior. The next impulse goes to genikulata medial nucleus, where all fibers bersinap, and finally through the auditory radiasio to the auditory cortex located in the temporal lobe gyrus superior. Of the auditory cortex located in the cerebral cortex area 41, pathways towards the limbic system through the ring of the cerebral cortex called the limbic cortex. Cortex surrounding the sub-cortical limbic structures serves as a transitional zone that is passed by signal transformed the cortex into the limbic system and also in the opposite direction. Of the limbic cortex auditory pathway continues to the hippocampus, where one end of the hippocampus bordering amigdaloid nuclei. The amygdala is an area of consciousness behavior that works on a subconscious level, will receive signals from the cortex and limbic menjalarkannya to the hypothalamus.

In the hypothalamus, regulating the function of vegetative and endocrine functions of the body, passed on to the auditory pathway as a conduit reticular formation impulses toward autonomic nerve fibers. The nerve fibers of nerve that has two sides of the sympathetic nervous system and the parasympathetic nervous system. Both of these affect the nervous system of contraction and relaxation of the organs. Relaxation can stimulate the feeling of happiness that as ejector of a sense of relaxation and tranquility in mid brain would emit gamma butyric amino acid (GABA), enkephalin, beta-endorphin. These substances can cause analgesic effect that will eliminate pain neurotransmitter in the central somatic sensory perception and interpretation of the brain.[29,30]

Intervention of passive music provides a beneficial effect on reducing pain scale on the respondents adolescent immunization techniques.[31] Interventions music without headphones can reduce pain for adolescents aged 13-15 years during routine vaccination is better than wearing headphones.[32] Javanese gamelan and music of Mozart proved reduce pain scale on active phase of the first stage of labor on nulliparous.[33]

Effect of intervention gamelan and oral glucose on pain response

The combined intervention of the gamelan and oral glucose does not have a significant effect on pain response at the time of rubbing the skin, while injection and three minutes after the injection, but it has a significant effect on the pain response in five minutes after the injection.

Based on the initial prediction giving the combined intervention of gamelan and oral glucose would have faster response pain decrease when compared to oral glucose intervention or gamelan, but the combined intervention of the gamelan and the oral glucose has an effect on pain response at the latest.

Based on observations during the study, at eight to ten minutes to gamelan music played, the baby began to feel sleepy. The response shown in the form of a baby to be calm, the movement declined, but some respondents showed the opposite response that evaporate constantly, cranky and restless. At this time the baby is given an oral glucose 2 ml. Giving oral glucose actually stimulate the baby to drink more, it appears from the response shows the baby whimper after completion of oral administration of glucose, hand reaching for the pipette and insert into the baby's mouth and the response to the nipple. Due to the uncomfortable response is possible distraction of music and the release of endorphins takes longer to affect response to pain, so that the new fifth minute after injection of the combined intervention of the gamelan and the oral glucose has a significant effect.

CONCLUSION

Intervention using Dextrose 30% orally 2 ml gives the fastest affect in reduceing pain in infants' immunization using intramuscular injection, then distraction gamelan and combined intervention of gamelan and oral glucose.

The researcher suggests that at the time of immunization to infants, it is expected to use non-pharmacological interventions to help reduceing the pain response due to the injections and the inclusion of vaccines, by providing an oral glucose or intervention gamelan music as an action of distraction.

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