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Original Article

Effectiveness of PainAway® on hepatitis B intramuscular injection in term neonates: a randomized controlled trial

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Abstract

Background Routine immunization injections are the most common painful procedure in childhood and most of these injections are administered in early life. Immunizations can cause negative short- and long-term consequences for children. Children who experience high levels of pain during an immunization are more likely to have elevated distress level of subsequent injections.

Objective To evaluate the effectiveness of pain away in reducing pain associated with hepatitis B intramuscular injection in term neonates.

Methods An open randomized controlled trial on healthy term neonates was conducted between November 2009 and December 2009 at Sanglah Hospital in Denpasar, Bali. Subject were selected randomized using six-blocked randomization. The samples were divided into two groupsto either recieve intramuscular hepatitis B injection using PainAway® and or standard hepatitis B intramuscular injection. The pain response was assessed using Douleur Aiquedu Noureanu-né (DAN) scale. Mann-Whitney test was used to analyze the data. The confounding factor that may have influenced the pain response was analyzed using multivariate analysis (ANCOVA).

Results Out of 66 subject, DAN scale was significantly lower in intervention group (median 5.0) compared to control (median 7.0) with $P < 0.0001$. Multivariate analysis showed that the difference in the intervention given was the only variable that influenced the pain response ($P < 0.0001$).

Conclusion PainAway® can reduce the pain secondary to hepatitis B intramuscular injection on term neonates. **[Paediatr Indones. 2010;50:214-9]**.

Keywords: *PainAway®, intramuscular injection, term neonates*

The development and administration of immunization cause positive impact on disease prevention and reduction of death. An infant will get at least seven shots by age 6 months based on the current immunization schedule.[1] Immunizations are the most frequently occurring painful procedures performed in pediatric settings. The long-term negative effects of pain are becoming more apparent; inadequately treated pain, particularly in the neonatal period, can have a negative impact on development and exaggerate affective and behavioral responses during subsequent painful events.[2-4]

The risks and benefits of pain management techniques must be considered on an individual basis within the context of the type and severity of the painful stimulus. Interventions would ideally be inexpensive, noninvasive and rapidly applied to improve pediatric pain control. One device that is not yet proven is PainAway®, a plastic device that was pressed against the skin during injection. It

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requires no advance preparation and has no known side effects. The PainAway® has a number of short blunt contact points on the underside that are placed directly on the skin before injection with a central hole for administering the infection.[5] The blunt points stimulate the Aβ fibers, close the gates of pain to the central nervous system, blocking the sharp pain signals from the injection and decrease the pain associated with intramuscular (IM) injections.[6] This simple device is called PainAway® or Shot Blocker®. Based on the theory we conducted this study to evaluate the effectiveness of PainAway® in reducing pain associated with hepatitis B intramuscular injection in term neonates.

Methods

This randomized controlled trial was conducted between November and December 2009 on Neonatology division at Sanglah Hospital, Bali. The samples were recruited consecutively from the neonates who were admitted in Bakung Timur Ward, Sanglah Hospital. This study was approved by the Ethics Research Committee of Medical School, Sanglah Hospital, Denpasar. Written informed consent was obtained from the parents. We included all term neonates, 37 to 42 weeks gestation and appropriate weight for gestational age (AGA) which were born via normal delivery or cesarean section (CS). Neonates with major congenital anomalies, APGAR score less than seven in the first minute, born via CS but assisted with vacuum extraction before, needed invasive procedure and neonates whose parents refused to participate in this study were excluded. All samples who met the inclusion and exclusion criteria were enrolled in this study.

All samples were randomized using block randomization (6 in each block). Sequentially numbered, sealed sample enrollment envelopes were prepared before the initiation of the study. Once informed consent was obtained, the seal was broken and the sample's assignment to either the intervention or control group was completed.

The intervention group (group A) was given hepatitis B injection intramuscular with PainAway®. The control group (group B) was given hepatitis B injection intramuscular without PainAway®. The skin cleaned with an alcohol swab prior to injection, and allowed to dry for 30 seconds.[7] Injection was done

Table 1. DAN (Douleur Aigue du Nouveanu-né): a behavioral acute pain rating scale for neonates

Measure	Score
Facial expression	
Calm	0
Snivels and alternates gentle eye opening and closing	1
Determine intensity of one or more of: eye squeeze, brow bulge, nasolabial furrow:	
Mild, intermittent with return to calm	2
Moderate	3
Very pronounced, continuous	4
Limb movements	
Calm or gentle movements	0
Determine intensity of one or more of the following signs: pedals, toes spreads, legs tensed and pulled up, agitation of arms, withdrawal reaction:	
Mild, intermittent with return to calm	1
Moderate	2
Very pronounced, continuous	3
Vocal expression	
No complaints	0
Moans briefly; for intubated patient, looks anxious or uneasy	1
Intermittent crying; for intubated patient, gesticulations of intermittent crying	2
Long lasting crying, continuous howl; for intubated patient, gesticulations of continuous crying	3

Table 2. Baseline characteristics

	Group A With pain away n=33	Group B Without pain away n=33
Gender		
Male, n	20	14
Birth weight, grams, mean (SD)	3156.4 (337.7)	3154.6 (329.9)
Birth length, cm, mean (SD)	49.5 (2.1)	49.3 (1.5)
Age, hours, mean (SD)	18.8 (7.8)	21.8 (8.5)
Delivery, n		
Spontaneous delivery	27	27
Cesarean Section	6	6
Nutrition, n		
Breast milk	19	13
Formula milk	5	4
Breast milk and formula milk	9	16
Number of children, n		
1	14	11
2	11	10
3	7	9
≥ 4	1	3
Mother age, years, mean (SD)	28.1 (6.4)	28.8 (5.9)
Mother educational background, n		
Primary school	4	4
Elementary school	5	6
High school	15	21
University	9	2

Table 3. Pain scores using DAN scale

	DAN scale Median (Interquartile range)	P
With pain away	5.0 (4.8 to 6.0)	
Without pain away	7.0 (6.0 to 7.0)	< 0.0001¶

¶ Mann-Whitney test, significant if P< 0.05

on the anterolateral thigh muscle and the needle darted into the skin at 90° angle. Hepatitis B vaccine, produced by PT. Biofarma, was given using a 25-gauge 5/8 inch (16 mm). All injections were performed by the same nurse. The nurse was instructed to place the pain away with the contact points touching the baby's skin and pressed it firmly for 10 seconds on the injection site. Hepatitis B was injected through the central opening.

At the beginning of the procedure, the baby was placed on his back, free to move. The mother was not allowed to cuddle and fed her baby while recording was on progress. If the baby cried before the procedure was done, it had to wait till the baby stopped crying. The procedure was recorded using video camera, before, during and after injection. Each recording was observed, analyzed and scored by two pediatric residents who were previously trained. The residents were not aware of the study objective. The pain response was assessed using DAN (Douleur Aigue du Nouveanu-né) pain scale (**Table 1**). A preliminary study was done using 25 samples to look for inter-rater reliability between the two observers.

This study required 33 subjects per group to obtain 90% power and 5% significance level ($P < 0.05$). Statistical analysis was performed using computer software. Characteristic data were presented

Table 4. Inter-variables relations that affected pain response

	Mean square	F	P*
Gender	1.535	1.241	0.273
Nutrition	1.074	0.868	0.429
Mother educational background	0.447	0.361	0.781
Intervention	34.514	27.894	< 0.001

* Multivariate analysis using ANCOVA, significant if P < 0.05

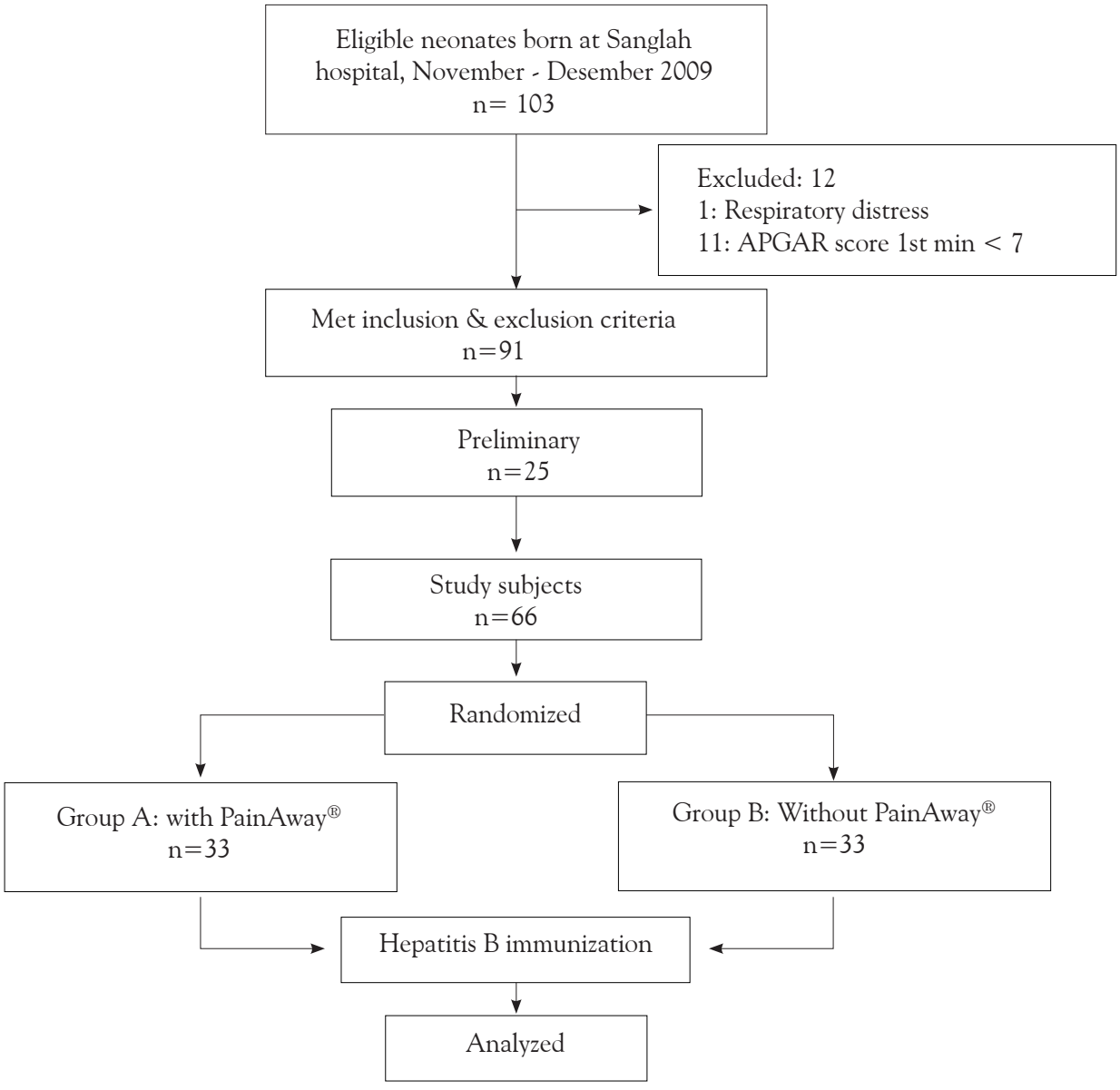

Figure 1. Study result

as mean and proportion for each study group. Independent t-test was used to analyze differences between groups if the data were normally distributed. If the distribution was not normal, it was transformed using logarithmic scale. If the distribution of the log-transformed variables was normal, independent t-test was applied, but if the result was not normal, Mann Whitney test was applied. A multivariate analysis (ANCOVA) was performed to determine if there were any confounding factors that may have influenced the pain response.

Results

During the study period, there were 103 neonates born in Sanglah Hospital. One neonate was excluded due to respiratory distress and 11 neonates were excluded due to APGAR score less than seven in the first minute. Hence, there were 91 neonates who were eligible for this study, 25 neonates were included in the preliminary study. Study profile showed in **Figure 1**. Based on the preliminary study, the inter-rater reliability for DAN scale score was 0.913. Sixty six

neonates were randomized into 2 groups. Mean birth weight of neonates in group A was 3156.4 grams (SD 337.7) grwhile in group B was 3154.6 grams (SD 329.9). Grams **Table 2** showed baseline characteristics of the two groups.

There was significant difference in the DAN scale's score, analyzed with Mann-Whitney test, between group A (median 5.0; interquartile range, 4.8 to 6.0) and group B (median 7.0; interquartile range 6.0 to 7.0), P <0.0001 (**Table 3**). On multivariate analysis (ANCOVA), it was proven that only intervention which significantly affected the pain response, P <0.001 (**Table 4**).

Discussion

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.[8] It is essential to minimize painful procedures in neonates. The physiologic mechanism of pain perception in infant is similar to the adult. In general, pain management can be categorized as pharmacological and non-pharmacological. There are practical limitations to pharmacological pain management, such as time delay, expenses, and need for additional medical professional to be present. The institution of pharmacologic management for pain should always accompany and/or be preceded by non-pharmacologic management.[9,10]

Site pressure at the injection site would reduce the pain associated with immunization. This work is based on the gate-control theory of pain. The pressure on the pain site is designed to reduce needle-related pain by putting pressure on large diameter (Aβ) fibers, thus blocking pain transmission along smaller diameter (Aδ and C) fibers.[11] Little research exists, however, to support the theory that a device, like PainAway® or Shot Blocker®, can instantly blocks injection pains.

Chung et al[12] and Barnhill et al[13] found that the pressure group reported a slight but statistically significant reduction in the immediate pain of injection in adults. Foster et al[14] and Mennuti-Washburn[15] reported that the Shot Blocker®, in a randomized controlled trial, was ineffective in reducing immunization pain in children. That study was compromised probably by its broad range of age, 3 months to 17 years of age in study by Foster et al[14] and 4 years to 12 years of age in study by Mennuti-Washburn.[15] While another study done by Drago et al[16] reported a significant difference in using Shot Blocker® for reduction of pain associated with intramuscular injection although the samples also from broad age range, 2 months to 17 years of age. The difference between study done by Foster et al[14] and Drago et al[16] was the children in the earlier study received 1 to 7 immunizations during the intervention.

Studies associated with reducing intramuscular injection pain in neonates have been reported, but none used PainAway® or Shot Blocker®. There were no side effects of this device like swelling or redness on the pressure site. There was no difficulty of using this device by the nurse who gave the injection. This device can be used easily hence it is effective to use in outpatient clinics.

In this study, pain response was evaluated using DAN scale. DAN scale is a behavioral scale developed to rate acute pain in term and preterm neonates. Score range from 0 (no pain) to 10 (maximum pain). The scale is sensitive if all scores are obtained and is specific if it differentiates painful from non-painful procedures. In this study, the DAN scale has a good inter-rater reliability (r = 0.913). The pain response in group A (median 5.0) was lower than group B (median 7.0).

There were two limitations in this study. First, the physiologic and biochemical changes associated with pain could not be assessed due to lack of equipments in our institution. Second, the environment in the room where procedure was done could not be controlled, therefore the room temperature was different from one time to another. High room temperature might further agitate the baby and influence the pain score.

In conclusion, PainAway® is effective in reducing pain due to hepatitis B intramuscular injection. The result of this study might be able to provide information in pain management. This method can be used with other non-pharmacologic pain management, such as sweet solutions or non-nutritive sucking of pacifiers. We recommend to do further study using this method combined with sweet solutions or pacifiers.

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