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The effect of the application of topical shallots on infant pain post-immunization

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ABSTRACT:
One of factors that influences the immunization coverage below the global target is immunization adverse events as well as local reactions, such as pain. The aim of this study was to measure the effect of topical shallots and whether they reduce the incidence of immunization adverse events in infants aged 0 - 11 months, especially the level of pain. This study used a quasi-experimental design with a pre-post design. The sample was infants aged 0 - 11 months. The experimental group consisted of 15 participants and the control group consisted of 15 participants. The pain was measured using the NIPS (Neonatal Infant Pain Scale). In this study, the experimental group was given shallots (*Allium Cepa* L. Var *aggregatum*) topically before they were rubbed around the area of the injection. The control group was not given any intervention. We measured the pain every day until 3 days post-immunization. The data was analyzed using the Wilcoxon Sign Rank test. The study showed that there were changes in the level of pain in the experimental group on day 1, day 2, and day 3 post-immunization ($p < 0.05$). There were also changes in the level of pain in the control group on day 1, day 2 and day 3 ($p < 0.05$). The frequency distribution data showed that no respondents experienced pain in the experimental group, whereas in the control group, there were still two respondents who experienced mild pain. This study recommends using shallots topically, where they are rubbed around the injection area to reduce the local reaction and pain.

KEYWORDS: shallots, pain, infant, immunization, *Allium Cepa* L. Var *aggregatum*

INTRODUCTION:

The data showed that 65 WHO member countries still have an immunization coverage below the global target, specifically below 90% [1]. It is estimated that 1 in 5 children, around 21.8 million children worldwide have not had their immunizations. In Indonesia, the Complete Basic Immunization (IDL) has reached 86.8%. This needs to be increased to reach the target of 93%. Furthermore Universal Child Immunization (UCI), which has reached the target of 82.9%, needed to be increased to reach 92% in 2019 [2].

One of the factors that influences immunization coverage below the global target is immunization adverse events[3], as well as local reactions [4, 5]. Immunization adverse events caused the parents to be reluctant or to dropout of re-immunizing their children due to their lack of information[4] as well as lack of knowledge[6, 7]. Based on the data from RISKESDAS, 33.4% out of the 91.3% people who are immunized experience immunization adverse event or local reactions, such as pain, redness (20.6%), swelling (20.2%), high fever (6.8%), and pus (6.0%)[2].

The incidence of immunization adverse events as well as local reactions such as pain can be reduced with traditional plants such as shallots (*Allium Cepa* L. Var *aggregatum*) [8]. Shallots are believed to be beneficial to health, they can be used to reduce fever and pain in children [9]. Shallot extracts contain flavonoid antioxidants such as quercetin and kaempferol. In addition, shallots are a source of antioxidant compounds such as diallyl disulfide, diallyl trisulfide, and allyl propyl disulfide. It is also a source of vitamins and minerals[10]. Shallots are additionally anti-inflammatory [11] as well an analgesic [12]. It can improve blood circulation [13]. It can therefore be concluded that shallots are used as traditional medicine or combined with other medicinal ingredients to treat various diseases [13].

Our pilot study still showed that the rate immunization adverse events among infants in Banjar Regency, Kalimantan, Indonesia was 30.47%. This number was not high. However, it will have an impact on the discomfort of the parents and infants (0 -11 months) who are being given the immunizations[14-16], therefore treatment is needed. Our study used shallots to reduce pain among infants post immunization. Based on this background, the aim of this study was to measure the effect of topical shallots on reducing the incidence of immunization adverse events in infants (0-11 months), especially the level of pain. It is expected that shallots can reduce the rate of immunization adverse events among infants (0-11 months) easily, thus promoting immunization among parents who have a baby.

MATERIAL AND METHODS:

Participants and Procedure

This study used a quasi-experimental design with a pre-post design. The samples were selected randomly. The sample consisted of infants aged 0-11 months. A total of 30 respondents were randomly allocated to two groups. The experimental group consisted of 15 participants and the control group consisted of 15 participants [17].

Measures

Immunization adverse events, especially pain, were measured using NIPS (Neonatal Infant Pain Scale). The NIPS consists of 6 behavioral indicators in response to painful procedures among infants, including their facial expression, crying, breathing patterns, motor activity, and state of arousal. The total score ranged from 0 - 7[18].

Interventions

In this study, the experimental group were given shallots (*Allium Cepa* L. Var *aggregatum*) topically and the control group were not given an intervention. We assessed the base level of pain before conducting the intervention. The topical shallots were made using 2 - 3 cloves of squeezed shallots cut into small slices dissolved in one teaspoon of coconut oil. The mixture was then rubbed around the area of injection without directly going over the scar. The shallots were applied for 1 hour, 2 times a day (morning and evening) for 3 days. We measured the pain every day until 3 days post-immunization.

Statistical assessment

The data was analyzed using the Wilcoxon Sign Rank test were a $p < 0.05$ was considered significant.

Ethical considerations

The procedure of this study was approved by the ethical review board Politeknik Kesehatan Banjarmasin, Indonesia, number 252/KEPK-PKB/2018.

Results

Table 1 shows the characteristic of participants. Most of participants are predominantly bay age between 0-3 months old (40.0%) and most of participants had moderate pain (63.3%).

Table 1. Characteristic of participants

Characteristics	n	%
Age (months)		
0 - 3	12	40.0%
4 - 6	3	10.0%
7 – 9	8	26.7%
10 – 12	7	23.3%
Level of pain		
None	0	0.0%
Mild	8	26.7%
Moderate	19	63.3%
Severe	3	10.0%

Table 2 shows the distribution of the level of pain in the experimental group. The table shows that 15 minutes post-immunization before the intervention (T0), more than half of the respondents (60%) experienced moderate pain. One day post-immunization after receiving the intervention (T1), the results show that more than half of the respondents (60%) experienced mild pain. One day post-immunization and after receiving the intervention for two days (T2), and 93.3% of respondents experienced no pain. Three days post-immunization (100%) after receiving the intervention (T3), and all respondents experienced no pain.

Table 2. Distribution of the level of pain in the experimental group

	Level of Pain	Frequency	Percentage
15 minutes post-immunization (T0)	No pain	0	0
	Mild pain	3	20
	Moderate pain	9	60
	Severe pain	3	20
	Total	15	100
One day post-immunization and received shallots (T1)	No pain	2	13.3
	Mild pain	9	60
	Moderate pain	4	26.7
	Severe pain	0	0
	Total	15	100
Two days post-immunization and received shallots (T2)	No pain	14	93.3
	Mild pain	1	6.7
	Moderate pain	0	0
	Severe pain	0	0
	Total	0	0
Three days post-immunization and received shallot (T3)	No pain	15	100
	Mild pain	0	0
	Moderate pain	0	0
	Severe pain	0	0
	Total	15	100

Table 3 shows the distribution of the level of pain in the control group. The table shows that most of respondents (66.7%) experienced moderate pain after 15 minutes post-immunization. One day post-immunization (T1), 86.7% of respondents experienced mild pain. Two days post-immunization, 73.3% of respondents experienced mild pain and there were two respondents who still experienced mild pain.

Table 3. Distribution of the level of pain in the control group

	Level of Pain	Frequency	Percentage
15 minutes post-immunization (T0)	No pain	0	0.0
	Mild pain	5	33.3
	Moderate pain	10	66.7
	Severe pain	0	0.0
	Total	15	100
One day post-immunization (T1)	No pain	2	13.3
	Mild pain	13	86.7
	Moderate pain	0	0.0
	Severe pain	0	0.0
	Total	15	100
Two days post-immunization (T2)	No pain	4	26.7
	Mild pain	11	73.3
	Moderate pain	0	0.0
	Severe pain	0	0.0
	Total	15	100
Three days post-immunization (T3)	No pain	13	86.7
	Mild pain	2	13.3
	Moderate pain	0	0.0
	Severe pain	0	0.0
	Total	15	100

Table 4 shows the difference in the level of pain in both the intervention and control groups. In the intervention group, there was a difference in the level of pain between 15 minutes post-immunization (T0) and one day post-immunization (T1) ($p = 0.002$). There was a difference in the level of pain between 15 minutes post-immunization (T0) and two days post-immunization (T2) ($p = 0.001$). Furthermore, there was a difference in the level of pain between 15 minutes post-immunization (T0) and three days post-immunization (T2) ($p = 0.000$). In the control group, there was a difference in the level of pain between 15 minutes post-immunization (T0) and one day post-immunization (T1) ($p = 0.001$). There was a difference in the level of pain between 15 minutes post-immunization (T0) and two days post-immunization (T2) ($p = 0.000$). Furthermore, there was a difference in the level of pain between 15 minutes post-immunization (T0) and three days post-immunization (T2) (p= 0.000).

Table 4. Difference in the level of pain in both intervention and control group

	Intervention (N=15)				Control (N=15)			
	T0	T1	T2	T3	T0	T1	T2	T3
***p* value**	-	0.002	0.001	0.000	-	0.001	0.000	0.000

Discussion

Immunization is associated with local reactions such as pain and erythema. It is also related to immunization adverse events. These conditions are still a threat to public health, so there needs to be an intervention. The aim of this study was to measure the effect of shallots applied topically on reducing the incidence of immunization adverse events in infants (0-11 months), especially local reactions like the level of pain. This study is expected to help parents when managing local reactions post-immunization among their children through the use of traditional herbs and affordable plants such as shallots.

In the Asia, shallots are used for the treatment of various disease[19-21]. I They are used internally and externally to treat several diseases [12]. Shallots contain chemical substances such as quercetin which have pharmacological effects, including anti-inflammatory as an example [22]. It has a 5 to 10 times higher quercetin level than apples, broccoli, and blueberries [23].

This study shows that there were changes in the level of pain among infants (0-11 months) in the experimental group on day 1 (T1), day 2 (T2) and day 3 (T3) post-immunization. The results of this study are similar to those of the previous studies which mentioned that shallot extracts were effective as an anti-inflammatory [11]. A shallot compress had the effect of reducing the level of pain [8, 9].

There were also changes in the level of pain among the infants post-immunization in the control group on day 1 (T1), day 2 (T2) and day 3 (T3). We assume that the infants who experienced post-immunization pain were given warm

compresses and paracetamol. Paracetamol acts as an antipyretic[24] as well as an analgesic [25]. Previous studies states that management of immunization adverse Events, especially local reaction in the injection area <1 cm such as pain, erythema and swelling, includes water compress[26,27], paracetamol [28] and ibuprofen [29]. Pain can be decreased by certain massage[30,31]. In addition pain can be decreased by breastfeeding during immunization [32].

Based on the statistical tests, both the experimental and control groups experienced a significant change in pain level from day 1 post-immunization until day 3 post-immunization. The two groups continued to use the paracetamol and ibuprofen given by the health worker, while the management using shallots was a complementary alternative medicine given in the treatment group. However, the frequency distribution data showed that 3 days post-immunization, no respondents experienced pain in the experimental group, whereas in the control group, there were still two respondents who experienced mild pain.

The limitation of this study is that the sample size was relatively small, which has influenced the difference effect between the two groups. It was therefore rather difficult to make an accurate conclusion on the effect of intervention. Further study is needed to conduct study in big sample. However, regardless, the studies recommend using shallots. They can be rubbed around the injection area to reduce the local reaction or pain.

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CONFLICT OF INTEREST:
The authors declare no conflict of interest.

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