The Effect of Katuk Leaf (Sauropus androgynus L. Merr.) Biscuit Consumption toward Increasing Breastmilk Volume on the 10th Day

S Handayani*, I Setyawati, D S R Ariendha, Y S Pratiwi, S Idyawati, and N Fatmawati
STIKes Yarsi Mataram, Indonesia.
*sri.kurniawan87@gmail.com

Abstract. The research aimed to analyze the effect of katuk leaf biscuit consumption toward increasing breastmilk volume on the 10th day. The research subjects are postpartum mother and baby on the first day at the health center of Bandung city. The research was RCT post-test only control group design with a double-blind approach with sample consisted of n1=n2=50 respondents. First treatment group were given the katuk leaf biscuit and the control group were biscuit not katuk leaf, for 9th days. Data were collected and analyzed by the Mann Whitney test. The result of the research shown the significant effect of katuk leaf biscuits towards increasing breastmilk volume on the 10th day of postpartum with a high percentage of 79.6%. The result from counting Number Needed to Treat (NNT) breastmilk volume gained NNT =3. The increased of breastmilk volume caused by katuk leaf were contained fitosterol and papaverin that can increase the prolactin and oxytocin hormone. It is also containing nutrition as the material for breastmilk production. The conclusion of the research there was a significant effect of katuk leaf biscuit consumption towards increasing breastmilk production volume. So that the biscuit can be used as a supplement to increase the breastmilk volume.

Keywords: biscuit, breastmilk volume, katuk leaf

1. Introduction
Infant Mortality Rate (IMR) and Toddler are still high in Indonesia, which is 32 and 40 per 1,000 live births respectively[1]. Global commitment in the Millennium Development Goals (MDGs) in the 4th goal sets the target for reducing AKB to 23 per 1000 live births and toddler to 32 per 1000 live births[2]. The high mortality rate is caused by nutritional factors, diarrhea, and pneumonia [3]. Optimal breastfeeding can prevent 1.4 million deaths worldwide in infants every year[4]. Achievement of exclusive breastfeeding in Indonesia is still far from the national target (80%), which is equal to 54.3%. The percentage of exclusive breastfeeding in West Java Province (33.65%) was the second-lowest after Maluku Province (25.21%)[3]. Percentage of exclusive breastfeeding in the city of Bandung around 20.7% [5]. The proportion of exclusive breastfeeding for infants aged 4 months in urban areas (44.3%) was lower than in rural areas (52.8%) [6].

Less milk production is one of the factors causing exclusive breastfeeding failure. The results of a preliminary survey conducted on 39 respondents from 16 provinces in Indonesia obtained data, 33.3%
said the amount of breast milk was less. Most (69.2%) mothers complained that the amount of breastmilk was less primipara [7]. Nutritional and hormonal factors (prolactin and oxytocin) were the main factors affecting breast milk production [8,9]. One way to increase the volume of breast milk is by giving galactagogue. Most of the people (93.3%) use katuk leaves to multiply breast milk during breastfeeding by using 1-3 cups per day of salted and clear use. Improper dosing and processing methods can reduce the nutritional content and beneficial effects of katuk leaves and can cause side effects[7]. In Indonesia, katuk leaf extract is also available in the form of tablets and capsules.[8] but the incidence of breast milk production is still low.[7]

Acute and teratogenic toxicity tests in mice showed that katuk leaves were not toxic and did not cause fetal defects.[10] The administration of old katuk leaf extract at a dose of 173.6 mg/kg body weight mice was able to increase prolactin and oxytocin gene expression,[11] whereas giving katuk leaf extract to breastfeeding mothers at a dose of 900 mg/day can increase the breast milk volume by 66.7 ml or 50.7% and reduce the number of breast milk less subjects by 12.5%.[8] Increased breast milk volume caused by katuk leaves contains phytochemical compounds, namely alkaloids (papaverine),[11] and sterols (phytosterol) [12] which can increase levels of prolactin and oxytocin, and contain nutrients that can be used as raw material for breast milk synthesis.[8]

During the puerperium, energy requirements increase and the intake of nutrients, such as carbohydrates, fats, and proteins is closely related to the volume of breast milk produced per day.[13-16] Biscuits are made with a balance between flour, sugar, fat, and eggs, and are snacks that most preferred by mothers during breastfeeding.[7,17] Wheat flour as raw material for making biscuits can be substituted with katuk leaf flour.[18] In this study, flour was substituted with thick extract of katuk leaves which was expected to increase the volume of breast milk.

2. Research Methodology

The ingredients used for making katuk leaf biscuits are a thick green extract of katuk leaves that are dark green, flour, cornstarch, refined sugar, egg yolk, margarine, skim milk, salt, baking soda, emulsifier, essence, and baking oil. The material used in making biscuits without katuk leaves is almost the same as the ingredients in katuk leaf biscuits, except that katuk leaf extract on biscuits without katuk leaves is replaced with water. The tools for making biscuits are ovens, mixers, pans, cake molds, basins, scales, plastic gloves, embosses, aprons, masks, and headgear.

The preparation and manufacturing process of katuk leaf biscuits includes: 1) Determination of katuk leaf plants; 2) Preparation of katuk leaf simplicia which includes preparation of ingredients (the process of selecting and collecting katuk leaves), and drying and grinding of katuk leaf simplicia; 3) Extract of the leaves of simplicia leaves katuk with 70% ethanol, maceration, for 3 × 24 hours, and determine the specific gravity of the katuk leaf extract; 4) Characterization and phytochemical screening of simplicia flour and thick leaf extract of katuk; 5) Check the stigmasterol of katuk leaf thick extract by Thin Layer Chromatography (TLC) method; 6) Katuk leaf biscuit formulations; 7) Organoleptic test based on differences in essence used and evaluation of biscuits; 8) Extract of leaf biscuits with ethyl acetate for 2 hours; 9) Phytochemical screening of katuk leaf biscuit extract; 10) Test the quality of biscuits (water content by the oven method, protein content with the Kjedhal method, fat by the Soxlet method, carbohydrates with the Luff Schooel method, and energy with the Atwater method); and 11) Making katuk leaf biscuits and without katuk leaves and packaging.

Both katuk leaves and without katuk leaves were made by substituting flour with katuk leaf thick extract (treatment group) and water (control group) with a ratio of 38.77: 0.9. The use of katuk leaf extract on the substitution of wheat flour is based on a dose that has been clinically tested, which is 900 mg/day.[8] The biscuits are made on a base of 100 g, as many as 9 pieces per day, 6.1 cm in diameter, weighing 9.5 g, with the addition of pandan flavoring, and given for 9 days, from the first day to the 9th day of puerperium. Giving biscuits with pandan flavoring is based on the results of organoleptic tests, where the biscuits with the addition of pandanus flavor have the best color, aroma, texture, and taste compared to vanilla flavor and coco pandan.
The subjects in this study were the first-day postpartum mothers in Bandung City Health Center who met the sample criteria. Inclusion criteria: primiparous mother and a baby aged 1 day; mothers who give birth to the term, single, and healthy babies; mothers do not use other drugs to increase milk production; baby's birth weight ≥2500 grams; and mothers who are willing to become respondents. Exclusion criteria: mothers who have breast problems, namely flat/sunken nipples and a history of surgery on the breast; mothers and/or babies who experience severe complications and need treatment; mothers with diabetes mellitus and or hypertension; mothers who smoke and or drink alcohol; and babies who experience congenital abnormalities. The pair of mothers and babies are declared drop out if the mother does not consume biscuits 2 days in a row; Mother resigns when intervention or control is given; mother moves an unknown address; mother and / or baby experience pain and need care; and babies are given formula milk or nutrient intake other than breast milk.

This research is a double-blind post-test only control RCT study. Sampling was done randomly with permutation blocks. The sample in this study was n1 = n2 = 50 respondents. The treatment group received katuk leaf biscuits and was controlled by giving biscuits without katuk leaves, for 9 days. The independent variable in this study was the administration of katuk leaf biscuits, the dependent variable was the volume of breast milk, and the confounding variables were maternal age, maternal nutritional status, frequency of breastfeeding, and stress.

The variable age of the mother is assessed immediately after the baby is born or before the mother leaves the Puskesmas. Maternal nutritional status and stress were assessed on the 10th day postpartum. Nutritional status was measured by calculating the Body Mass Index (BMI), and stress was assessed by the Perceived Stress Scale (PSS-10) questionnaire. Breast milk volume measurement was carried out on the 10th day with the breast milk manual unimom mezzo pump before the baby suckles or 2 hours after the baby suckles to return milk production to the volume before feeding to the baby, both breasts are pumped for ± 30 minutes or until no milk is released after being pumped for 2 minutes. Pumping results are measured using a measuring tube in ml units.

The collected data were processed by non-parametric tests, namely the Mann Whitney test. Clinically, this study was calculated based on the NNT value. NNT shows the number of patients who must be treated to obtain an additional 1 good result or avoid 1 failure. NNT can be calculated as follows [19].

\[
\text{NNT} = \frac{1}{\text{ARR}}
\]

\[
\text{ARR} = \frac{\text{CER} - \text{EER}}{\text{CER}}
\]

\[
\text{CER} = \frac{a}{a+b}
\]

\[
\text{EER} = \frac{c}{c+d}
\]

Explanation:
NNT: number needed to treat
ARR: absolute risk reduction
CER: control event rate
EER: experimental event rate

This study seeks to uphold scientific and ethical attitudes in research and try to minimize the possible losses and maximize research.
3. Results and Analysis

Table 1. Characteristics of Education, Employment, Nutritional Status, Stress, and Frequency of Breastfeeding of Research Subjects in the Katuk Leaf Biscuit Group and Biscuits Without Katuk Leaves.

| Characteristics | Group | Value | p   |
|-----------------|-------|-------|-----|
|                 | Katuk Leaf Biscuits | Biscuits without katuk leaves |     |
|                 | N  | % | n | % |     |
| Education       |     |   |   |    |     |
| Primary school  | 2  | 9,1 | 2 | 8,7 | 0,956* |
| Junior high school | 7  | 31,8 | 7 | 30,4 |     |
| Senior high school | 9  | 40,9 | 11 | 47,8 |     |
| College         | 4  | 18,2 | 3 | 13 |     |
| Job             |     |   |   |    |     |
| Work            | 4  | 18,2 | 6 | 26,1 | 0,722** |
| Does not work   | 18 | 81,8 | 17 | 73,9 |     |
| Nutritional status |     |   |   |    |     |
| Low             | 5  | 41,7 | 7 | 58,3 | 0,559* |
| Is being        | 17 | 51,9 | 16 | 48,5 |     |
| High            | 0  | 0,0 | 0 | 0 |     |
| Obesity         | 0  | 0,0 | 0 | 0 |     |
| Stress          |     |   |   |    |     |
| Mild stress     | 9  | 52,9 | 8 | 47,1 | 0,672* |
| Moderate stress | 13 | 46,4 | 15 | 53,6 |     |
| Severe stress   | 0  | 0,0 | 0 | 0 |     |
| Frekuensimenyusui |    |   |   |    |     |
| <8 x/day        | 0  | 0,0 | 0 | 0 | 0,626* |
| 8-12 x/day      | 14 | 51,9 | 13 | 48,1 |     |
| >12 x/day       | 8  | 44,4 | 10 | 55,6 |     |

Explanation: *Chi-Square Test; **Fisher’s Exact Test

Table 1 shows that there is no difference in the proportion that means education, employment, nutritional status, stress, and the frequency of breastfeeding between groups given katuk leaf biscuits and biscuits without katuk leaves.

Table 2. Age Characteristics and Percentage of Compliance with Biscuit Consumption of Research Subjects in the group of Katuk Leaf Biscuits and Biscuits Without Katuk Leaves.

| Characteristics | Group | Value | p   |
|-----------------|-------|-------|-----|
|                 | Katuk Leaf Biscuits | Biscuits without katuk leaves |     |
|                 | Median (min–max) | Mean±s.d. | Median (min–max) | Mean±s.d. |     |
| Age             | 22,5 (17–28) | 21,7±3,4 | 22,0 (16–28) | 21,9±3,2 | 0,850* |
| Compliance      | 100,0 (92,9-100,0) | 98,1±3,1 | 100,0 (92,9-100,0) | 98,4±2,7 | 0,978** |

Explanation: *Unpaired t-test; **Mann-Whitney Test

Table 2 shows that there were no differences in age and compliance in consuming significant katuk leaf biscuits between groups given katuk leaf biscuits and biscuits without katuk leaves.
Table 3 The Effect of Katuk Leaves Biscuits on Increased Breast Milk Volume.

| 10th Day Breastfeeding Volume | Katuk Leaf Biscuits | Group Biscuits without katuk leaves | value p* | % |
|-------------------------------|---------------------|-------------------------------------|-----------|---|
| Median (min-max)              | 136.5 (52-364)      | 69 (22-238)                        | <0.001    | 79.6 |
| Mean±s.d.                     | 148.2±69.9          | 82.5±47.9                          |           |    |

Explanation: *) Mann-Whitney Test

Table 3 shows there are significant differences in the volume of breast milk on the 10th day of puerperium between groups given katuk leaf biscuits and biscuits without katuk leaves.

Clinically, it can be calculated with NNT. Changes in breast milk volume (low and high) were assessed by comparing the results of the breast milk pump with the average value of the breast milk volume of the treatment group, said to be low if <148.2 and high ≥ 145.2 ml; and the 15th-day breast milk volume was said to be low if <139.7 ml and high ≥139.7 ml.

Table 4. Number of respondents experiencing changes in breast milk volume (low and high)

| Group                          | Low | High |
|--------------------------------|-----|------|
| Katuk Leaf Biscuits            | 14  | 8    |
| Biscuits without katuk leaves  | 22  | 1    |

EER = \( \frac{14}{14+22} = \frac{14}{36} = 0.6 \)

EER = \( \frac{22}{22+1} = \frac{22}{23} = 1.0 \)

ARR = 1.0 − 0.6 = 0.4

NNT = \( \frac{1}{0.4} = 2.5 \)

That is, only 3 people are required to be given katuk leaf biscuits for 10 days, to be able to increase the volume of breast milk for 1 person. Lactation describes the secretion of breast milk from the mammary gonad and is the period of feeding the baby [20]. Statistically, the results of the study of the effect of giving katuk leaf biscuits to the increase in breast milk volume on the 10th day of puerperium showed significant differences between groups given katuk leaf biscuits and biscuits without katuk leaves with a value of p <0.05 and an increase in the percentage of 79.6%. Clinically, the NNT calculation results obtained NNT = 3.

Increasing the volume of breast milk caused by biscuits given to the treatment group was biscuits with the addition of katuk leaf thick extract of 0.9 g. Katuk leaf is one type of herbal galactagogue that is believed to be able to improve the quality and quantity of breast milk. Phytochemical screening of katuk leaves contains secondary metabolites, namely alkaloids (papaverine)[11] and steroids (phytosterols) [12] which can increase levels of prolactin and oxytocin, and contain nutrients that can be used as raw material for breast milk synthesis[8].

The highest content of fitosterol leaves of katuk is from selected food ingredients, namely, sesame seeds 443 mg / 100 g, beans 108 mg / 100g, and olive oil 91 mg / 100 g. The content of fitosterol from katuk flour extracted with 70% ethanol is 2.43% (2.43 g / 100 g) or 2433.4 mg / 100 g dry and if converted into fresh katuk leaves assuming 78.2% water content is 466 mg / 100 g.[21] The content of papaverine in 100 grams of fresh katuk leaves is about 580 mg.[21] Old katuk leaf papaverine is contained in higher amounts than the younger ones. The concentration of papaverine in the thick extract of old katuk leaves is 6.3 µg / ml. [11]

Phytosterols are analogous to cholesterol in the human body. ATP-binding cassettes sub-family G members 5 and 8 (ABCG5 / G8) limit intestinal absorption and promote biliary excretion of sterols [22]. Intake of 2 g / d of sterols reduces low-density lipoprotein (LDL) by 10%. The usual daily intake for sterols ranges from 150-400 mg / d [23].
Papaverine can increase prolactin and oxytocin gene expression because it can relax smooth muscle and dilate blood vessels, causing smooth circulation of the hormone prolactin and oxytocin through the bloodstream. Phystosteryl can function as c-AMP. The presence of c-AMP causes phystosteryl and papaverine to inhibit dopamine which plays a role in inhibiting prolactin and stimulating DARPP-32 thereby inhibiting PP-1 and causing an increase in oxytocin [24].

The results of this study are in line with Sa'roni's research, where the administration of katuk leaf extract with a dose of 3 × 300 for 15 days in postpartum mothers can increase breast milk production by 66.7 ml or 50.7% more than mothers who are not given leaf extract katuk [8]. Katuk leaves also contain high nutrients that help synthesize breast milk. 100 g of fresh katuk leaves contain 79.8 g of water, 7.6 g of protein, 1.8 g of fat, 6.9 g of carbohydrate, and energy value of 310 kJ [25]. In this study, biscuits were made with the addition of ingredients that would add to the nutritional value of the biscuits. During the puerperium, the mother's need for nutrition also increases. A study conducted on mice in lactation showed that breastfeeding mice fed a high-fat diet (20 g / 100 g) significantly increased milk production compared to those given a low-fat diet (2.5 g / 100 g) [14]. A high-protein diet is also able to increase breast milk production[15] and a low-protein diet will be reflected in low protein concentrations in milk.

Biscuits with the substitution of katuk leaf flour tested in vivo proved to be safe and have a lactagogue effect. This is evidenced by the significant effect of increasing breast milk production as indicated by the rat weight gain observed for 15 days [18].

4. Conclusion
The conclusion of the research there was a significant effect of katuk leaf biscuit consumption towards increasing breastmilk production volume. So that the biscuit can be used as a supplement to increase the breastmilk volume.

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