

Citation:

Chien YC, Huang YJ, Hsu CS, Chao JC, Liu JF. Maternal lactation characteristics after consumption of an alcoholic soup during the postpartum 'doing-the-month' ritual. *Public Health Nutr.* 2009;12(3):382-8. Epub 2008 Apr 22.

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Study Design:

Non-Randomized Crossover Trial

Class:

C - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

The aim of this study was to determine whether the traditional Chinese alcoholic diet (CSSR) affects lactation parameters and causes short-term changes in the maternal milk and blood composition.

Inclusion Criteria:

- Healthy pregnant women
- Non-smoking
- Chicken soup flavored with sesame oil and rice wine (CSSR) was a part of the subject's normal diet after delivery
- Informed consent was obtained

Exclusion Criteria:

- Men and non-pregnant women
- Unhealthy pregnant women
- Women who smoke
- Women who do not consume CSSR as part of their normal diet after delivery

Description of Study Protocol:**Recruitment**

- Recruited from the gynecology and obstetrics clinics at Taipei Medical University Wan-Fang Hospital

Design

- Individual Randomized Crossover Trial
- Within-subject repeated measurement

Intervention

- Subjects were asked to refrain from alcohol consumption for three days prior to experiment
- Subjects were asked to fast for 8 hours before intervention
- Two servings of a cereal snack (~150 kcal) were provided to the women after baseline samples were taken
- At the first test day, women were randomly assigned to receive a soup with rice wine or a non-alcoholic chicken soup
- The second test day (1-week interval between) the subjects received the other soup
- Alcoholic soup (CSSR) had an alcohol level of 40 mg/ml by continuous boiling for 65 minutes
- Target alcohol dose of 0.3 g/kg body weight
- One hour after the cereal snack was given, subjects consumed ~8 ml of soup per kilogram of body weight within 15 minutes

Statistical Analysis

- Summary statistics are expressed as means and standard deviations
- Student's *t*-test was used to compare differences in blood and milk composition between baseline and specific time points post-treatment
- Paired *t*-test was applied to test significance of exposed (CSSR) and control (NASC) groups
- Value of $P < 0.05$ (two-tailed) was considered statistically significant

Data Collection Summary:

Timing of Measurements

- Intervention was completed at approximately 15 days postpartum
- Each subject was tested on two days with a 1-week interval
- Milk from each breast was sampled the morning of the study and used as baseline levels
- Blood samples were taken the morning of the study and used as baseline levels
- Milk samples were taken after consumption of the soup at 10, 20, 30, 40, 60 and 90 minutes for alcohol analysis
- After 120 minutes after consuming the soup, the milk from both breasts were emptied and pooled. The volume excreted and the time required for ejection of the first milk droplet were recorded.
- Blood samples were drawn after consumption of the soup at 20, 40, 60 and 90 minutes for alcohol analysis
- After 150 minutes after consuming the soup, blood samples were taken and analyzed for test constituents

Dependent Variables

- Blood constituent levels
 - 10 ml was drawn for baseline and at 150 minutes after consuming the CSSR and NASC soups

- Samples drawn by an in-dwelling venous catheter
- Blood alcohol levels
 - 2 ml were obtained at 20, 40, 60 and 90 minutes after consumption of the CSSR and NASC soups
- Blood samples were drawn into Vacutainer tubes containing heparin salt
- Volume of milk excreted and time until first droplet: milk samples
 - Milk from each breast was emptied by using an electric breast pump for baseline sample
 - 2 ml samples were obtained by means of an electric breast pump at 10, 20, 30, 40, 60 and 90 minutes after soup consumption for alcohol analysis
 - After 120 minutes after soup consumption, milk was emptied from both breasts using an electric breast pump (15 minutes for each breast)
 - The volume excreted and time until first droplet were recorded
- Both blood and milk samples were centrifuged at 2,000 and 4,000 rpm, respectively, and the supernatants were then stored at -80°C until further analysis
- Blood composition was analyzed using commercial RIA-based test kits in a certified laboratory
- Milk constituents were analyzed by commercial test kits

Independent Variables

- Chicken soup flavored with sesame oil and rice wine (CSSR) containing black sesame oil, de-boned chicken breast, aged ginger and rice wine (alcohol 19.5%)
 - Alcohol concentration was 40 mg/ml and was stable under freezing for one month
 - Prepared and stored in individual portions for experimental use
 - Prepared three different times and the alcohol and macronutrient constituents were analyzed after each preparation
 - Target alcohol dose was 0.3 g/kg body weight which was achieved by providing ~8 ml of soup per kilogram body weight
- Non-alcoholic chicken soup flavored with sesame oil (NASC) was prepared using a similar method of the CSSR
- Standard methods of the Association of Official Analytical Chemists were used to analyze the macronutrient levels in the soup

Control Variables

- Three day food records were obtained to ensure subject compliance of no alcohol consumption in the three days prior to the intervention

Description of Actual Data Sample:

Initial N: 23 women

Attrition (final N): 23 women

Average Age: 24.5±3.4 years

Ethnicity: Taiwanese (ethnic Chinese)

Other relevant demographics:

- 19 women were primiparous
- Four women were multiparous

Anthropometrics

- Average height: 158.8±6.5 cm
- Average weight: 62.5±9.6 kg
- Average BMI: 24.6±2.6 kg/m²
- Average body adipose rate: 37.1±6.6%

Location: Taipei, Taiwan

Summary of Results:

Key Findings

- After consuming the alcoholic soup, blood concentrations of triacylglycerol (TAG), insulin and lactate were significantly ($P < 0.05$) higher than the blood levels after consuming the control soup.
- After consuming the alcoholic soup, the breast milk concentrations of TAG and lactate were significantly ($P < 0.05$) higher than the breast milk concentrations after consuming the control soup
- The consumption of the alcoholic soup was associated with an increase in time (~52%) for ejection of the first milk droplet, 4.4 minutes vs. 2.9 minutes
- Less milk (~15%) was excreted after CSSR consumption compared with the NASC, but differences were N.S.

Other Findings

Macronutrient levels in the alcoholic and non-alcoholic soups

Nutrient	NASC (non-alcoholic)		CSSR (alcoholic)	
	Mean	SD	Mean	SD
Water (g/dL)	90.8	0.02	83.7*	0.00
Crude ash (g/dL)	0.42	0.02	0.41	0.01
Crude protein (g/dL)	1.39	0.01	1.39	0.01
Crude fat (g/dL)	1.1	0.10	1.95*	0.12
Carbohydrates (g/dL)	1.67	0.03	1.51	0.03
Energy (kJ/dL)	94.6	4.4	120.5*	4.4
Energy (kcal/dL)	22.6	1.10	28.8*	1.1

NASC=non-alcoholic sesame oil flavored chicken soup; CSSR=chicken soup flavored with sesame oil and rice wine

*Mean values were significantly different from those of the control (NASC) group, P<0.05 (t-test).

- Differences in water content between the soups was due to the fact that the CSSR was made with rice wine and the NASC used 100% water in the preparation
- Differences in fat and energy content was due to the higher amounts of fatty acids produced in the alcohol medium

Mean concentrations of constituents in blood samples of 23 lactating women after consuming soup containing 0.3 g alcohol/kg body weight or non-alcoholic control soup

Constituent	NASC (non-alcoholic)				CSSR (alcoholic)			
	Baseline		150 minutes		Baseline		After 150 minutes	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
TAG (mg/dL)	103.1	67.3	99.2	66	108.5	77.9	121.4**	72.6
Total protein (mg/dL)	7.1	0.4	6.8*	0.4	7.2	0.3	6.9*	0.5
Glucose (mg/dL)	86	11.1	84	6.6	84.7	7.7	81.3	9.7
Cholesterol (mg/dL)	190.1	40.7	177*	35.5	186.6	33	170.8*	33.2
GOT (U/I)	21.8	7.3	22.8	7.6	23	6.7	23.5	9
GPT (U/I)	28.4	11.2	26.5	13.4	29.1	11.8	27.1*	13.6
Insulin (μU/I)	6.7	5.9	4.6*	3.2	6.4	6.1	6.8**	4.3
Prolactin (ng/ml)	158.3	132.7	156	107.3	148.8	101.2	178.9	118
NEFA (mmol/L)	0.5	0.1	0.9*	0.4	0.5	0.1	0.8*	0.5
β-Hydroxybutyrate (mmol/L)	1.3	0.5	1.2	0.5	1.2	0.7	1.2	0.7
Lactate (mg/dL)	9.6	4.2	6.2*	3	10	4.1	9**	2.8
Alcohol ¹ (mg/dL)	NM	-	NM	-	4.83	1.23	9.78	4.52

NASC=non-alcoholic sesame oil flavored chicken soup; CSSR=chicken soup flavored with sesame oil and rice wine; TAG=triacylglycerol; GOT=glutamic oxaloacetic transaminase; GPT=glutamic pyruvic transaminase; NEFA=non-esterified fatty acids; NM=not measured

¹The lower limit of the reportable range for blood alcohol level was 10 mg/dL

*Mean values were significantly different from those at baseline P<0.05 (paired t-test)

**Mean values were significantly different from those of the control (NASC) group P<0.05 (paired t- test)

Mean concentrations of constituents in breast milk¹ of 23 lactating women after consuming soup containing 0.3 g alcohol/kg body weight or non-alcoholic control soup

Constituent	NASC (non-alcoholic)				CSSR (alcoholic)			
	Baseline		150 minutes		Baseline		After 150 minutes	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Total protein (mg/dL)	17	2.5	18.4*	2.6	17.7	3.5	18.9*	3.9
TAG (mg/dL)	8.7	2.3	12.3*	3.1	9.6	2.7	14.8*§	3.2
Lactose (mg/dL)	6.7	0.5	6.6	0.5	6.7	0.6	6.6*	0.5
Energy (kJ/dL)	468.6	87.9	602.9	118.8	504.6	102.9	697.9	119.7
Energy (kcal/dL)	112	21	144.1	28.4	120.6	24.6	166.8	28.6
EGF (ng/ml)	36.2	14.3	36.1	19.7	41.1	30.5	47.3	35.5
NEFA (mmol/L)	0.1	0.1	0.2*	0.1	0.1	0.1	0.2*	0.1
β-Hydroxybutyrate (mmol/L)	0.4	0.2	0.5	0.3	0.5	0.4	0.7*	0.6
Lactate (mg/dL)	0.5	0.2	0.6*	0.4	0.6	0.8	0.8*§	0.6
Alcohol ² (mg/dL)	NM	-	NM	-	0.36	0.9	9.05*	5.21

NASC=non-alcoholic sesame oil flavored chicken soup; CSSR=chicken soup flavored with sesame oil and rice wine; TAG=triacylglycerol; NEFA=non-esterified fatty acids; EGF=epidermal growth factor; NM=not measured

¹Milk was emptied from both breasts at 120 min post-exposure and pooled. Since this procedure took 30 minutes (15 minutes for each breast), the mid-point (135 minutes) was adopted as the sampling time.

²The lower limit of the reportable range for blood alcohol level was 10 mg/dL

*Mean values were significantly different from those at baseline P<0.05 (paired *t*-test)

§Mean values were significantly different from those of the control (NASC) group P<0.05 (paired *t*-test)

Mean lactation parameters of 23 lactating women after consuming soup containing 0.3g alcohol/kg body weight or non-alcoholic soup

Lactation performance	NASC (non-alcoholic)		CSSR (alcoholic)	
	Mean	SD	Mean	SD

Time to eject (minutes)*	2.9	1.7	4.4§	2.8
Volume excreted (ml)*	47.6	33.9	41.3	28.9

NASC=non-alcoholic sesame oil flavored chicken soup; CSSR=chicken soup flavored with sesame oil and rice wine

*At 120 minutes after consuming CSSR or NASC, milk was emptied from both breasts (15 minutes for each breast) using an electric breast pump. Volume excreted and time required for the first milk droplet to be ejected were recorded.

§Mean values were significantly different from those of the control (NASC) group, P<0.05 (paired *t*-test)

Author Conclusion:

The consumption of an alcoholic soup affected the composition of maternal blood (TAG, insulin and lactate levels) and breast milk (TAG and lactate levels), along with a delay in time of milk ejection. The study suggests that the ingestion of alcoholic drinks and foods should be avoided during lactation.

Reviewer Comments:

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

- | | | |
|----|---|-----|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | N/A |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

Validity Questions

- | | | |
|----|---|-----|
| 1. | Was the research question clearly stated? | Yes |
|----|---|-----|

1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	Were study groups comparable?	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A

4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blinding used to prevent introduction of bias?	N/A
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes

7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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