

Citation:

Mennella JA. Short-term effects of maternal alcohol consumption on lactational performance. *Alcohol Clin Exp Res*. 1998 Oct; 22 (7): 1,389-1,392.

PubMed ID: [9802517](#)

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:

To test the short-term effects of alcohol consumption by lactating women on the amount of milk available to the infant and milk composition. It was hypothesized that alcohol consumption would decrease the amount of milk produced and alter the milk composition.

Inclusion Criteria:

- Lactating women
- Had consumed at least one alcoholic beverage during lactation
- Women that had experience using a breast pump
- Informed consent obtained prior to participation in the study.

Exclusion Criteria:

- Women that had not consumed any alcohol during lactation
- Women that did not have experience using a breast pump.

Description of Study Protocol:**Recruitment**

Subjects were recruited from Women, Infant and Children (WIC) Centers in Philadelphia and from ads in local newspapers.

Design

- Non-randomized crossover trial
- This study occurred over two days separated by one week and used a within-subjects design, controlled for time of day. On the first testing day, half the women drank an alcoholic

beverage and the other half of the women drank the control beverage. The order was reversed for the second testing day. The authors reported that no effect of order was observed for any of the variables examined.

Intervention

- Testing occurred on two different days separated by one week (\pm two days)
- Subjects arrived at the testing center at approximately 9:30 a.m.
- After an acclimatization period, subjects pumped both breasts simultaneously using an electric breast pump
- Mothers stopped pumping when milk had not been secreted for five minutes
- The pumping and milk collection was repeated after two hours (baseline collection)
- Within a 15-minute period, mothers consumed either:
 - Alcohol in orange juice (0.3g per kg)
 - Orange juice alone (equal volume) for control subjects
- Milk was again pumped and collected two hours after beverage consumption (post-consumption collection)
- Order of testing was counterbalanced, with half of subjects beginning with one test and the other half beginning with the other test.

Statistical Analysis

- Repeated measures analysis of variance for each measure; repeated factors were:
 - Time of collection (baseline, two-hour post-consumption)
 - Type of beverage (control, alcohol)
- Paired T-tests were used to assess differences after significant interaction effects. P-values represented two-tailed tests.

Data Collection Summary:

Timing of Measurements

- Test days: Two days separated by one week (\pm two days)
- Mothers arrived at the same time on both testing days (approximately 9:30 a.m.)
- Three periods of pumping and milk collection were performed. Milk collection was stopped when no milk had been produced for five minutes. Milk collection periods were two hours apart as follows:
 - Standardization or familiarization collection
 - Baseline collection: After baseline collection, beverage was consumed
 - Post-consumption collection: Performed two hours after beverage consumption
- Adiabatic bomb calorimetry was used to determine the energy content of milk. The creatocrit technique was used to measure the fat content in milk.

Dependent Variables

- Latency to eject (seconds): Amount of time for the first droplet of milk to be ejected
- Milk yield (ml): Volume of milk pumped within each five-minute period
- Total length of collection period (minutes)
- Calorie content of milk (kcal per dL): Determined by triplicate analysis of milk pooled from both breasts
- Fat content of foremilk (g per L): Before pooling milk, fat content of foremilk and hindmilk was determined

- Fat content of hindmilk (g per L).

Independent Variables

- Type of beverage:
 - Control: Orange juice
 - Alcohol: Alcohol in orange juice
- Time of milk collection:
 - Baseline: Before beverage consumption
 - Post-consumption: Two hours after beverage consumption.

Description of Actual Data Sample:

- *Initial N*: 22 (nine primiparous and 13 multiparous)
- *Attrition (final N)*: 22; no attrition was reported
- *Age*: Age range was 24 to 42 years; mean age was 31.9 ± 1.1 years
- *Other relevant demographics*:
 - Infants (11 boys, 11 girls) of these mothers were average age was 4.6 ± 0.4 months
 - Alcohol consumption during pregnancy and lactation were estimated using a questionnaire:
 - During pregnancy: Mean \pm SEM= 2.9 ± 0.9 drinks per month; range zero to 16 drinks per month
 - During lactation: Mean \pm SEM= 7.9 ± 1.7 drinks per month; range less than one to 24 drinks per month
 - Authors stated that these numbers likely underestimate actual alcohol consumption
- *Location*: Monell Chemical Senses Center, Philadelphia, Pennsylvania.

Summary of Results:

Key Findings

- There was no difference observed in the energy content of milk when alcohol was consumed as compared to the control
- Alcohol resulted in a slight reduction (significant) in the amount of milk produced two hours after alcoholic beverage consumption as compared to the control beverage; 9.3% (± 4.1) less milk was produced after alcohol consumption
- Latency to eject milk was not impacted by alcohol consumption.

Other Findings

- Milk yield:
 - A significant interaction was observed between time of collection and type of beverage consumed
 - At baseline, no significant difference was observed in milk yield between alcohol and control conditions; paired $T(21df) = -1.06$; $P=0.30$
 - At two hours post-consumption, the milk yield was significantly less in the alcohol as compared to the control condition; paired $T(21df) = 2.45$; $P=0.02$
- Fat and calorie content of milk:
 - A significant effect of time of collection on fat and calorie content of milk was observed. Higher calorie milk was produced at baseline (midday collection) than at

two hours post-consumption (2:00 p.m. collection); on control day, paired T(21df) = 2.59; P=0.02; on alcohol day, paired T(21df) = 2.32; P=0.03)

- Type of beverage consumed did not impact energy or fat content of milk; interactions were not observed for time of collection times type of beverage consumed.

Author Conclusion:

- Alcohol consumption by lactating women slightly (significantly) reduced the amount of milk produced, thus supporting the hypothesis that alcohol may directly affect lactational performance
- Because the calorie content of milk was not affected by alcohol consumption, the authors emphasized the importance of determining whether and when infants compensate for reductions in intake. Also of interest is how reductions in intake impact mother-infant interactions.

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?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
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)	No
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?	No

5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
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.)	Yes
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?	Yes
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

Copyright American Dietetic Association (ADA).