Vitamin D Supplementation in Breastfed Infants: Do Video Counselling and Samples Improve Adherence?

Charmaine Ngo, B.Sc.(Pharm.); Connie Harris, B.Sc.(Pharm.), Pharm.D.



Introduction

Although preventable, vitamin (vit) D-deficiency rickets persists in Canada at an annual incidence of 2.9 cases per 100 000. Additionally, several northern Vancouver Island breastfed infants recently exhibited early rachitic changes.

Because breast milk is an unreliable vit D source, Health Canada recommends supplementation for all breastfed infants to prevent vit D-deficiency. Though effective and accepted by health professionals, the persistence of vit D-deficiency suggests inconsistent application and poor parental adherence with the guideline.

Professional counselling has been positively correlated with vit D supplementation rates in infants.² In the Vancouver Island Health Authority (VIHA), consistent education for new parents combining video counselling and vit D sample with the current pamphlet was thus proposed to improve parental adherence. No research has prospectively investigated their effects on parental adherence with vit D supplementation in breastfed infants.

As such, this study will add to the current literature, and be used to implement a new vit D education program within VIHA to ultimately improve parental adherence with vit D recommendations and thus, the health of VIHA's infants.

Objectives

Primary Objective:

 To determine if the addition of video counselling and vit D sample improves parental adherence with Canadian vit D supplementation recommendations for breastfed infants compared to the provision of a vit D pamphlet alone

Secondary Objective:

To identify potential factors influencing parental adherence with vit D supplementation recommendations

Methods

Design: Single centre, prospective, single-blinded, randomized control trial

Inclusion Criteria:

- Consenting caregivers who:
 - Are breastfeeding
 - Delivered a healthy, term infant (> 37 weeks) at Victoria General Hospital (VGH)
 - Can understand English
 - Are available for follow-up interview via telephone

Exclusion Criterion: Caregivers with a substance use problem

Sample Size: Total of 150 participants

Power Calculation: 92% power (with a 2-sided alpha of 0.05) to detect a 25% difference in vit D adherence, assuming 60% adherence in the control group

Procedure:

- Upon consent, participants provided demographic information
- Participants were randomized to one of two interventions:
 - Pamphlet only (control)
 - Pamphlet + video counselling + vitamin D sample
- 2-month (+/-14 days) standardized follow-up telephone interview conducted to assess adherence (interviewer blinded to group allocation)

Approved by VIHA Health Research Ethics Board

Methods (continued)

Exploratory Baseline Survey:

- Anonymous, voluntary survey run over 1.5 week period
- Distributed to 11 Vancouver Island public health units across 6 cities
- Purpose:
 - To gain a general indication if babies up to one year were receiving vit D
 - To determine if current vit D use differed across the island

Created vit D educational video with collaboration from VIHA nursing and nutrition departments, and the Victoria Native Friendship Centre

Instrumentation, Adherence Scales:

- Surveys and data gathering tools developed for this study (can view upon request)
- Telephone interview to include the following questions:
 - Primary Scale: "Think back to last week. How often did you miss giving your baby the daily dose?"

Adherence: No misses = 100%, 1-2 misses = 75%, 3-4 misses = 5-6 misses = 25%, 7 misses = 9%

 Secondary Scale: Estimation of vit D usage based on how much liquid is left in supplement bottle (full bottle, ¾ left, ½ left, ¼ left, almost done)

Analysis (determined a priori):

- Intention to treat
- Dichotomous variable: Adherent (≥ 75% adherence) or Non-adherent
- Dichotomous variables will be tested using chi square tests with Fisher's exact tests

C2007

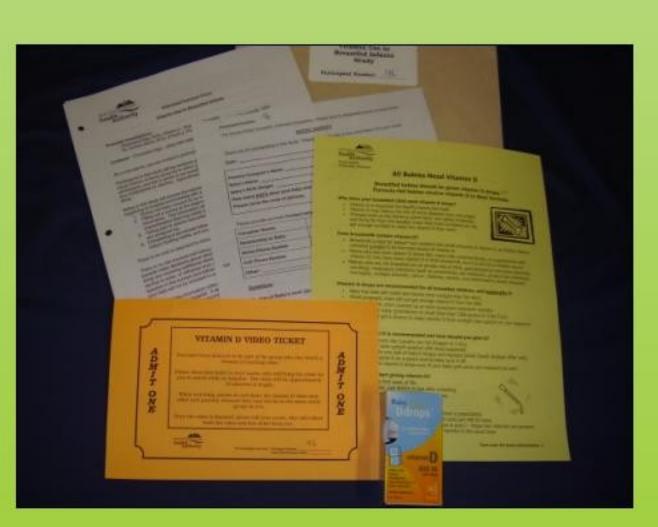




Figure 1: Pamphlet + video counselling + vit D sample intervention group:

Teaching video (top left and right),
Treatment envelope contents (bottom)

Results

- 95 Participants enrolled with one withdrawal as of May 15, 2008
- 5 follow-up interviews completed as of May 15, 2008
- Data analysis will be completed once participant enrollment complete

Discussion

- Future Plans: Complete participant recruitment and follow up interviews, analyze data
- Limitations:
 - Primary adherence scale dependent on participant reporting
 - Secondary adherence scale dependent on parental estimation of volume of supplement used
 - No objective adherence scale
 - Potential for responding bias with follow-up interviews
 - Participants so far showing trend of high education
 - Possible selection bias due to nature of informed consent process, exclusion of caregivers with substance use problems

Conclusions

- Study recruitment ongoing and will continue until sample size reached
- Analysis will be conducted once all follow-up interviews are complete
- As such, no conclusions at this time
- However, due to the trend of high education in caregivers consented so far, continuation of this study at additional sites may be necessary

Additional Impact

- Legacy: vit D educational video produced for this study will be used by VIHA public health units
- Facilitated interdisciplinary collaboration with VIHA nutrition, public health, and multimedia departments, and VGH perinatal ward
- Community collaboration with Victoria Native Friendship Centre
- Prompted nutrition initiative for vit D education for nursing, pharmacy, and pediatricians to take place after completion of study enrollment
- Discussion to conduct study at an additional central or north island site
- Study results will help to develop a consistent vit D education program for new parents within VIHA

Funding Sources

CSHP research grant; VIHA Pharmacy and Nutrition Departments

References

- 1) Ward LM, Gaboury I, Ladhani M, Zlotkin S. Vitamin D-deficiency rickets among children in Canada. CMAJ. 2007;177(2):161-6.
- 2) Dratva J, Merten S, Ackermann-Liebrich U. Vitamin D supplementation in Swiss infants. Swiss Med Wkly. 2006;136:473-81.