

Mother-to-child transmission Formula-Fed Infants of HIV-1-Infected Women A Randomized Clinical Trial

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Abstract

Context: Breastfeeding among women infected with human immunodeficiency virus type 1 (HIV-1) is associated with substantial risk of HIV-1 transmission, but little is known about the morbidity risks associated with formula feeding in infants of HIV-1-infected women in resource-poor settings.

Objective: To compare morbidity, nutritional status, mortality adjusted for HIV-1 status, and cause of death among formula-fed and breastfed infants of HIV-1-infected women.

Design: Randomized clinical trial conducted between 1992 and 1998.

Setting: Four antenatal clinics in Nairobi, Kenya.

Participants: Of 401 live-born, singleton, or first-born twin infants of randomized HIV-1-seropositive mothers, 371 were included in the analysis of morbidity and mortality.

Interventions: Mothers were randomly assigned either to use formula (n=186) or to breastfeed (n=185) their infants.

Main Outcome Measures: Mortality rates, adjusted for HIV-1 infection status; morbidity; and nutritional status during the first 2 years of life.

Results: Two-year estimated mortality rates among infants were similar in the formula-feeding and breastfeeding arms (20.0% vs 24.4%; hazard ratio [HR], 0.8; 95% confidence interval [CI], 0.5–1.3), even after adjusting for HIV-1 infection status (HR, 1.1; 95% CI, 0.7–1.7). Infection with HIV-1 was associated with a 9.0-fold increased mortality risk (95% CI, 5.3–15.3). The incidence of diarrhea during the 2 years of follow-up was similar in formula and breastfeeding arms (155 vs 149 per 100 person-years, respectively). The incidence of pneumonia was identical in the 2 groups (62 per 100 person-years), and there were no significant differences in incidence of other recorded illnesses. Infants in the breastfeeding arm tended to have better nutritional status, significantly so during the first 6 months of life.

Conclusions: In this randomized clinical trial, infants assigned to be formula fed or breastfed had similar mortality rates and incidence of diarrhea and pneumonia during the first 2 years of life. However, HIV-1-free survival at 2 years was significantly higher in the formula arm. With appropriate education and access to clean water, formula feeding can be a safe alternative to breastfeeding for infants of HIV-1-infected mothers in a resource-poor setting.

INTRODUCTION

We conducted a randomized clinical trial of breastfeeding and formula feeding in Nairobi, Kenya, and previously reported that the estimated risk of breast milk transmission of human immunodeficiency virus type 1 (HIV-1) was 16%.¹ Forty-four percent of all HIV-1 infections among those in the breastfeeding arm were attributable to breastfeeding. This result, in conjunction with results from

clinical trials of short-course antiretrovirals that have reported approximately 40% to 50% reductions in perinatal transmission rates, suggest that it may be possible to reduce substantially mother-to-child transmission of HIV-1 in the developing world with interventions of moderate cost.²

In resource-poor settings where the most prevalent causes of infant morbidity and mortality are infectious, there is the possibility that breast milk

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avoidance would be accompanied by an increase in mortality that might offset any gains achieved by decreasing HIV-1 transmission. To enable the formulation of safe infant-feeding policies for HIV-1-infected women in resource-poor settings, it is important to have accurate estimates of the risks associated with the use of artificial feeds by infants of HIV-1-seropositive mothers in developing countries.

The risk of mortality associated with the use of artificial feeding has been reported in a number of observational studies from developing countries.^{3,4} In a recent meta-analysis, the increased mortality risk due to infectious diseases among nonbreastfeeders was substantial, particularly among very young infants (odds ratio [OR], 5.8 for 0–2 months of age; OR, 4.1 for 2–3 months; OR, 2.6 for 4–5 months; and lower thereafter).⁴ Observational studies have reported substantially increased diarrhea risk in artificially fed infants, with highest risk being noted in the first 2 to 3 months of life.^{3,5} The protective role of breastfeeding with regards to other infectious diseases in developing countries has not been studied as extensively. However, there are some data that suggest that formula fed infants are at increased risk of pneumonia compared with breastfed infants.^{3,6}

One of the major mechanisms of the protection conferred through breastfeeding is by the passive transfer of antibodies, immune-competent cells, and cytokines.⁷ For mothers with HIV-1-related immunocompromise, it is unknown whether breastfeeding would confer the same magnitude of protection. No study to date has definitively evaluated the degree of protection that breast milk affords infants of HIV-1-infected mothers.

Our randomized clinical trial of breastfed and formula fed infants of HIV-1-seropositive women in Nairobi, Kenya, was conducted with the primary goal of determining the frequency of breast milk transmission of HIV-1. This unique trial also provided an opportunity to compare morbidity and mortality in children according to randomized feeding modality. We previously reported that 2-year mortality rates among children in the formula feeding and breastfeeding arms were similar.¹ In this companion article, we provide additional data regarding mortality as well as analyses of diarrhea, pneumonia, other childhood morbidities, and nutritional status.

Method

Study Population and Procedures

The methods of the randomized clinical trial were published in our original article,¹ including a detailed description of the study population, study procedures, feeding intervention, laboratory testing, criteria for infant HIV-1 infection status, ethical approval, and data and safety monitoring board

deliberations. In brief, HIV-1-seropositive women were recruited from antenatal clinics in Nairobi and randomly assigned to breastfeed or to use formula to feed their infants. Mother/infant pairs were followed-up for 2 years after delivery.

At each visit, information was obtained about feeding status, current and interim morbidity, and history of hospitalization. A physical examination was conducted, including measurement of weight and recumbent length. Ill children received outpatient care from the study clinicians. In the event of diarrhea, mothers were advised to initiate the use of oral rehydration solutions before bringing the child to the research clinic. Children requiring hospital admission were managed by Kenyatta National Hospital staff and pertinent clinical information was abstracted from the hospital records. Verbal autopsies were conducted to assign a possible cause of death for all children who died outside of Kenyatta National Hospital.

Current morbidity was determined by study clinicians using standard diagnostic criteria. Interim infant morbidities were based on maternal history. Diarrhea was defined as the passage of 3 or more loose or watery stools during a 24-hour period for at least 2 days. Chronic diarrhea was defined by diarrhea lasting for more than 1 month. Dehydration was defined as the presence of 1 or more of the following clinical signs and symptoms: abnormal thirst, dry oral mucosa, reduced skin turgor, sunken eyes, or decreased urine output. A diagnosis of pneumonia was made if a child had a cough with tachypnea. A presumptive clinical diagnosis of malaria was made in children with history of travel to a malaria-endemic area who presented with fever (axillary temperature >37.5°C) in the absence of any localizing site of infection. Weight for height was used to evaluate nutritional status. We calculated Z scores using EpiNet (Centers for Disease Control and Prevention, Atlanta, Ga) and values below–2 SD were used to define malnutrition.⁸

All data were analyzed using SPSS 10.0 for Windows (SPSS, Chicago, Ill) or S-Plus 2000 (MathSoft, Inc, Seattle, Wash). Comparisons were made on an intent-to-treat basis. Pearson χ^2 test and Fisher exact test were used to compare categorical variables and the Mann-Whitney U test to compare continuous variables. Infant mortality in the 2 randomization groups was compared using Kaplan-Meier analysis. Cox regression was used to compare survival in the 2 groups adjusted for HIV-1 infection status as a time-dependent covariate. A child was considered to have an unknown HIV-1 infection status if the last HIV-1 test was more than 3 months before the last determination of vital status and if they had a negative test result at that time.

used as an adjunct data analysis tool. Dimensional analysis is a systematic inquiry into the “parts, attributes, interconnections, context, processes, and implications” of a phenomenon (Schatzman, 1991, p. 309). Following each interview, extensive analysis was done, theoretical questions were raised, and questions were developed for subsequent interviews.

Analysis of the first three interviews (all nurses) revealed that they engaged in a host of strategies that were directed at assessing how patients understand their situations. This included assessing whether the patient’s understanding was similar to that of the health care provider (e.g., whether it was “realistic” from the provider’s perspective) and whether decisions patients made seemed “reasonable” from the nurses’ perspectives. Analysis of these initial interviews also revealed that providers engaged in a host of strategies aimed at assisting patients in coming to a more realistic understanding of their situations and in making more reasonable decisions. Although these strategies could be viewed as paternalistic, they also offered an opportunity to explore these issues in greater depth. Subsequent interviews were designed to gain an understanding of what the providers were doing, what was directing their assessments as well as their efforts to alter patient perceptions, and whether these strategies changed over time.

Deliberate theoretical sampling of providers who did and did not engage in these strategies was not possible because there was no way to make this distinction before interviewing. Therefore, theoretical sampling was built into the design of the interviews. This was accomplished by adding questions to the interviews that would identify whether the provider participant engaged in such assessments and perspective-altering strategies and would explore how they understood these actions and what they were trying to accomplish.

Common to all those who described such strategies was a goal of either preventing a “bad death” or hoping to achieve a “good death.” Providers who were concerned about how realistic the patient’s understanding was described the relationship between the patient’s understanding, the decisions that resulted from that understanding, and the consequences of those decisions for the quality of their death.

This analysis raised the question of what these providers actually meant by the good death that they were trying to achieve and the bad death they were trying to avoid. Interview questions were altered to enhance understanding of these notions and to understand the relationship between being-

realistic and these two possible outcomes. Analysis of the subsequent interviews (as well as reanalyzing previous interviews) revealed that these providers had experiences with patients whose unrealistic understandings led to burdensome treatment decisions and thus to deaths with unnecessary pain, suffering, overly aggressive treatment, and unresolved family issues. At this point a theoretical decision was made to pursue an understanding of the processes of shifting goals and treatment decisions.

Subsequent theoretical sampling was designed to discover whether any predictable or patterned differences existed among provider types (e.g., nurses and physicians), work settings (e.g., acute or home care), and work experience (e.g., experienced or novice). It was hypothesized that these might explain which providers or what conditions were likely to result in a provider engaging in strategies to achieve a good death or avoid a bad one and which were not. Further exploration of this relationship in subsequent interviews suggested that experience with dying patients was common to providers who were concerned about and organized their strategies around quality of death. Experience itself, however, did not necessarily lead to such an approach. Additional theoretical sampling was done in order to provide some comparisons around length of experience as a health care provider and, in particular, with patients who were dying.

Several procedures were integrated into the methodological design of this study to maximize the credibility of the results (Guba & Lincoln, 1989; Strauss, 1987). All interviews were transcribed verbatim, checked for accuracy, and entered into a computer software program designed to assist qualitative data management (QSR NUD*IST 4, 1997). Memos and matrices were used to track the evolving theory and the methodological choices made by the researcher during the study. The principal researcher met weekly with a multi-disciplinary grounded theory dimensional analysis group. The researcher was engaged in data collection and analysis for 22 months, but the majority of the data was collected during the first 16 months. Analysis and member checks continued until the study was completed. Member checks were ongoing throughout the study and included second interviews with three provider participants (chosen for the breadth and depth of their experience), fieldwork, and interactive presentations of findings to small groups of providers similar to those who participated.

Results

This section begins with a brief synopsis of the grounded theory of reconciling decisions near the end of life (Norton, 1999), which provides the con-

Reconciling Decisions Near the End of Life

Health care providers often described knowing a patient's death was imminent before the patient or family knew. When these providers believed a patient's death was near, they shifted the purpose of their interventions toward helping the patient achieve a good death. With that in mind, providers worked toward changing patients' and families' treatment decisions from what providers believed were unrealistic curative choices to more realistic palliative choices. In this context, unrealistic decisions were those intended to cure, and realistic decisions were those intended solely to palliate symptoms or to forego curative treatments.

Providers reported that when patients or families continued to make unrealistic (curative) treatment decisions near the end of life, the patient would probably not experience a good death, possibly even having a bad one. A good death was characterized by all providers in a similar way as one that includes time to resolve personal business, time to reconnect with family, time to forgive and be forgiven, time to achieve important goals, and time to say good-bye to loved ones, while maintaining good pain and symptom control. A difficult or bad death was characterized by not being able to say good-bye; having unfinished business, unresolved conflict and anger, and difficulty grieving; undergoing futile treatment, creating bad memories for the family; and having poor symptom and pain control.

According to providers, changing the patient's or proxy's understanding, that is, their "big picture," to one in accord with the providers' assessment led the patient and family to realistic goals and thus to palliative treatment choices. From the providers' perspective, the big picture was a gestalt of the patient's condition constructed from information about the diagnosis, test results, prognosis, general assessment findings (including physical, emotional, and spiritual factors), treatment options, treatment efficacy, treatment burdens, and patient goals. This information, filtered through providers' knowledge, insights, and experience, formed providers' overall picture of what was going on with the patient. In this context it was the big picture, as perceived by providers, that determined whether goals and treatment decisions were realistic.

Providers expressed a belief that understanding the big picture would probably lead to realistic decisions that in turn would lead to a good death. On the other hand, lack of understanding or acceptance of the big picture increased the likelihood of making unrealistic treatment decisions that would result in unnecessary pain and suffering and in missed opportunities for a good death (e.g., not being able to say good-bye to loved ones). Providers often imput-

ed a lack of understanding and/or acceptance of the overall big picture as the cause of patients' or proxies' adherence to unrealistic goals. Unrealistic goals were goals that the patients could not achieve and/or that led to burdensome aggressive treatments that made it difficult, if not impossible, for patients to achieve a good death. One provider described a dying patient who wanted to continue chemotherapy:

This patient was described as having an angry and bitter death. The provider was frustrated by the patient's unwillingness to accept a realistic big picture and her continued adherence to curative treatment decisions. It is the provider big picture that providers said must be shared by patients and family members in order for them to make realistic decisions. Therefore, changing the patient's big picture became the focus of provider interactions.

Providers responded differently to perceived unrealistic patient or proxy goals. These responses included: (a) avoiding interactions with the patient and family, (b) referring the patient and family to another provider, and (c) using strategies aimed at shifting patients' unrealistic goals and treatment decisions to more realistic ones. Providers' often responded to unrealistic patient or proxy goals and decisions by using strategies to shift the patient or family picture, and to increase their understanding of what was happening. Early on these strategies were intended to "lay the groundwork" for a new picture. Laying the groundwork was typically followed by strategies focused on shifting the patient or family to a new picture. Finally, once a patient had shifted to a new, more realistic picture, provider strategies focused on helping the patient and the patient's family to accept and keep that realistic picture. Once a patient and family accepted a new picture, their treatment decisions were most likely to be palliative and thus more likely to ultimately result in a good death (Fig. 1). The individual strategies presented in the following sections are grouped under general purposes. However, most strategies were used for more than one purpose (e.g., teaching could be used to lay the groundwork, to shift the understanding of a patient or family toward the patient's picture, and/or to help the patient or family accept a new picture).

Providers' perspectives are presented here. The intent was not to imply that only one picture exists, that all providers share one picture, or even that there is such a thing as an accurate picture. Rather, the intent was to illustrate providers' behaviors when they conclude that the patient or proxy does not have an accurate big picture.

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