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Providing Safe and Effective Preventative Antiretroviral Prophylaxis to HIV-Exposed Newborns Via a Novel Drug Delivery System in Tanzania

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Abstract

Background—In developing countries, antiretroviral therapy provides life-saving treatment to HIV-positive women and their children before, during and after birth. However, supply chain challenges such as long distances, medication shortages and non-facility deliveries often compromise consistent access to prophylactic treatment for at-risk infants. A proposed intervention to address these challenges, often referred to as the “Pratt Pouch”, allows for liquid formulation medications, such as nevirapine (NVP), to be repackaged into single-dose pouches. These pouches are distributed antenatally.

Methods—HIV-positive women at Kilimanjaro Christian Medical Centre (KCMC) in Moshi, Tanzania received fourteen pouches each containing a single dose of NVP for prevention of mother-to-child transmission. Women were trained on how to open the pouch and dispense the medication to their infant after delivery. All participating women were asked to return to KCMC 7–14 days after delivery, where infant blood spots were collected to assess NVP levels.

Results—All enrolled women (21/21) administered NVP to their infants within 24 hours of birth. All enrolled infants (22/22) had NVP blood concentrations over 100ng/ml and exhibited no health concerns attributable to over or under dosing.

Conclusions—The Pratt Pouch intervention provides a clinically appropriate solution for addressing liquid formulation antiretroviral access challenges in developing countries.

Keywords

PMTCT; vertical transmission; HIV-exposed infants; DBS testing; nevirapine

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Introduction

Liquid formulation nevirapine (NVP) is commonly recommended as prophylaxis for HIV-exposed infants. Due to its low-cost and efficacy, it remains one of the most widely distributed non-nucleoside reverse transcriptase inhibitors in developing countries. Unfortunately, numerous challenges prevent mothers in these countries from accessing NVP for their infants including country, regional and district-level medication shortages and stock-outs. Furthermore, long distances from healthcare facilities and high rates of homebirths can prevent newborns' access to immediate treatment.

According to the 2010 Tanzanian Demographic and Health Survey, approximately half of all Tanzanian births occur outside of a health care facility, often at home.[1] Interestingly, the low health facility birthrate has not be shown to be an indicator of access to antenatal care, which has remained consistently high at 96%.[1] Despite access to antenatal care, in 2010 Tanzania reported an estimated 70% of HIV-positive pregnant women received prevention of mother-to-child transmission (PMTCT) services and approximately 76% of HIV-exposed infants received prophylactic NVP. The resulting national mother-to-child transmission rate was estimated to be 9.8%.[2,3] To prevent mother-to-child transmission (MTCT), it is essential that HIV-exposed newborns receive HIV prophylaxis soon after birth and during breast feeding and that the blood concentration levels of their medication are maintained above the prophylactic threshold. For NVP, the effective level for prophylaxis is commonly set at 100ng/ml (10 times the in vitro IC50 against wild-type virus).[4–6]

In order to increase access to prophylactic NVP in developing countries, it is not uncommon for liquid formulation medication to be repackaged into smaller containers such as urine collection cups or empty medication bottles. This greatly increases the risk of contamination, spillage and spoilage. Previously, PATH (Washington, USA) and Elizabeth Glazer Pediatric AIDS Foundation (EGPAF; Washington DC, USA) have attempted to address both the access and dosing challenges by providing pre-dosed NVP antenatally in single-use Baxter Exacta-Med (Colorado, USA) oral syringes.[7–9] According to the package insert, NVP had stability of two months in this syringe. Given that women could receive the filled syringes antenatally at any point during their nine month pregnancy, the limited storage properties were found unsuitable.

An alternative technology is a pouch-based drug delivery system created at Duke University (North Carolina, USA). This drug delivery system, commonly known as the Pratt Pouch, is a flat, foilized polyethylene bag that can be torn open by the caregiver and the contents emptied into the infant's mouth. The pouch can be packaged, stored and distributed in rural communities via healthcare workers based out of clinics and other healthcare centers. It can be integrated into medical supply chains as either a "bridge" or a "full" intervention. In the bridge intervention, a pharmacist packages and nurses distribute a limited supply of pouches to HIV-positive pregnant women during antenatal care visits. Should the child be born outside of a health facility, mothers are able to immediately dose their child with NVP and are advised to follow-up at their healthcare facility to receive a full bottle of NVP syrup. In the full intervention, a complete six weeks supply is packaged and distributed to mothers before or after birth.

Laboratory testing has shown that the active ingredients contained in all three commonly prescribed infant ARV medications (NVP, AZT, 3TC) can be safely stored in the Pratt Pouch for at least twelve months with negligible moisture and preservative loss, while maintaining clinical potency.[10–12] This characteristic makes the pouches more suitable as an antenatal medication delivery mechanism than previously studied pre-dosed syringes. Comprehensive user testing on the 'original' Pratt Pouch revealed that it had an emptying percentage of 75%.[13] Through design improvements, the emptying percentage has now been improved to 90% in the 'updated' Pratt Pouches.[14]

Ensuring accurate dosing and access to antiretroviral medication remain challenging in developing countries. A study in Mozambique found that participating HIV-positive women struggled to dose liquid-formulation zidovudine (AZT) accurately, with up to 50% committing dosing errors while using either a cup or syringe.[15] Alternatively, a study in Ecuador has documented the Pratt Pouch's dosing accuracy to currently be 101%, when overfilled to account for incomplete emptying.[14] In Zambia, introduction of the pouch has ensured an almost three fold NVP access rate increase for infants born outside of a health facility (35% to 94%).[16]

This study documents the first time that infants' prophylactic NVP treatment via the original Pratt Pouch has been assessed based on NVP blood levels obtained after HIV-positive women followed a home-based dosing regimen. The effectiveness of the pouch as a clinically appropriate medicine delivery system is discussed, as well as user feedback reports and observations during the healthcare worker training.

Materials and Methods

This study was an open label clinical trial of the original Pratt Pouch bridge intervention that was conducted at Kilimanjaro Christian Medical Centre (KCMC) in Moshi, Tanzania. HIV-positive, pregnant women attending KCMC antenatal care clinic (ANC) between June 2014 and December 2014 were evaluated by the study nurse for possible inclusion. Inclusion criteria were that the participant: (i) be at least 18 years old; (ii) have a documented HIV infection; (iii) be at least 20 weeks gestation and (iv) not be in active labor. The obstetrical care provider determined gestational age by ultrasound and/or last menstrual period. Eligible women and their infant(s) were enrolled after providing written, informed consent.

The study nurse was trained to teach participants to correctly dispense NVP from the original Pratt Pouch using materials previously developed and piloted in Zambia.[16] In addition, fifteen labor and delivery nurses were also trained to know and understand the pouch in preparation for women who delivered at KCMC hospital. This training was validated by the study coordinator observing nurses opening the pouch and pouring NVP from pre-filled pouches into disposable cups.

Two pharmacists were trained on two occasions to fill, seal, and stockpile original Pratt Pouches (3 1/4″ × 1 3/4″ polyethylene, Sorbent Systems, PAKVF4) with precisely dosed standard stock liquid formulation NVP (50mg/5ml; Aurobindo Pharma Limited, Bachupally, India) using a 3ml syringe (Norm-Ject, A3, General Laboratory Supply Inc., Pasadena, TX)

and a 14 gauge dispensing tip (Metcal, TT14-DHUV-PK, Techcon Systems, Garden Grove, CA). Packaging was not performed in a pharmacy hood as complete sterility was not required. Previous filling protocols found insignificant biological and microbial contamination when packaging the pouch in clean, non sterile conditions typical of a pharmacy.[12]

Pouches were filled with 20mg (2ml) of NVP and were sealed using an impulse hand heat sealer (TISH105, TEW Electric Heating Equipment, Taipei, Taiwan). The delivered dose was set at15mg (1.5ml) for infants weighing over two kilograms based on residual NVP calculations i.e. pouches were overfilled to account for 75% emptying associated with the original Pratt Pouch.[13] Filled pouches were labeled with a single 3/4″ × 1″ laser inkjet label (Gaylord, PermaPlus, 341L) according to KCMC pharmacy standards (medication name and concentration; fill volume; fill and expiration dates and batch number). Pharmacists placed fourteen filled pouches and a pictorial user instruction sheet into a small, transparent, sealable plastic bag (Figure 1). This training was validated by two separate study coordinators on two separate occasions, performing weight and burst spot-checks on filled pouches with a weight scale (acc. = 0.1g) and an 8cm metallic tube squeezer key.

Enrolled women were verbally trained by the study nurse to administer NVP via the pouch. Participants were given a single plastic bag filled with pouches to take home and keep nearby in case of delivery outside of KCMC. However, participants were strongly encouraged to return to KCMC for delivery. Infants who were born at KCMC were administered the first dose of NVP via the pouch by a trained nurse; subsequent dosing was administered by the trained mother outside of KCMC without nurse supervision. Women delivering an infant outside of KCMC were instructed to administer the all NVP doses from the pouches. These women were asked to notify the study nurse and return to KCMC as soon as possible after delivery. Women were instructed to dose at the same time every day; however, if the initial NVP dose was given at an inconvenient time after delivery, the subsequent dose could be given at a more convenient time as close to 24 hours later as possible.

All women were asked to return to KCMC with their infant between seven and fourteen days after delivery for a final follow-up visit. During this visit, infants were weighed and assessed by the study coordinator and study nurse. Venipuncture (2–3ml of blood) was performed and blood was pipetted to fill five dried blood spots (DBS) on a Whatman Protein Saver Card (Whatman 10534612) and stored. DBS cards were sent for analysis to Micobac Laboratories, Inc. (North Carolina, USA) for quantification of NVP blood level. The average NVP concentration and standard deviation of all suitable blood spots (max. 5) were measured for each participant and compared to prophylactic and treatment thresholds.[17, 18]

Travel reimbursement for the study visit was provided in proportion to the distance travelled. All communications were performed in the local language (Swahili) by the study nurse and/or study coordinator.

Ethical Review

This study was approved by the KCMC Institutional Review Board (IRB); Duke University School of Medicine IRB; Tanzania Food and Drug Authority and the National Institute for Medical Research, Tanzania.

Results

A total of 22 women and 23 infants were enrolled; one woman gave birth to twins. One infant was born premature at 33 weeks and remained in the hospital for the first nine days of life. Pouches for this infant were administered at KCMC by the nurse or father and not the mother, and the infant was discharged with a NVP bottle and syringe. Furthermore, the dried blood spot was performed on the weekend upon discharge and improperly handled; thus, this woman and infant were excluded from the data analysis.

Of the remaining 22 infants: 20/22 (91%) were born at KCMC; one infant was born at a different health care facility and one was born at home. The average distance traveled to KCMC for birth was almost 25km (min: 4km; max: 100km). The average infant birth weight was 2.9kg +/− 0.5kg (min: 2.0kg; max: 3.9kg). All pregnant women received triple antiretroviral therapy (ART) with either a first-line efavirenz (EFV) or a second-line protease inhibitor (PI) backbone; none included NVP. One woman was switched from first-line to second-line early in the study due to virologic failure and is represented as receiving second-line during the study.

Participants returned to KCMC with their infants after an average of 10 days. The average infant weight at this visit was: 2.9kg +/− 0.6kg. Health concerns were noted in six infants and included: maternal report of fever (2); oral thrush (1); low Ballard score (1); small conjunctival hemorrhage (1) and hypoxia (1). No events were considered treatment-related. Further socio-demographic and clinical characteristics of the enrolled participants are summarized in Table 1.

All women self-reported that the first dose of NVP had been administered to their infant within 24 hours after birth. One participant reported that her infant's initial dose was administered via oral syringe, however all subsequent doses were administered via the pouch. A blood sample was collected from this infant 12 days after the initial dose. Another woman reported forgetting to administer a single NVP dose to her infant. This infant returned for follow-up visit on day of life 15 when the DBS was collected. Both of these infants were included in the DBS NVP measure analysis. The average collected blood NVP concentration was: 4,800ng/ml +/− 200ng/ml (min: 420ng/ml; max: 14,000ng/ml). Infants that weighed between 2.0 – 2.4kg at follow-up were found to have an average blood NVP level of averaged 7,500ng/ml; infants weighing between 2.5 – 2.9kg averaged 6,500ng/ml and infants weighing 3.0 – 4.0kg averaged 2,600ng/ml. All enrolled infants had average NVP blood concentration above the prophylactic threshold of 100ng/ml.

Discussion

This study confirms the safety of the Pratt Pouch as a drug delivery system for liquid formulation NVP to HIV-exposed newborns by the caregiver in a home and/or hospital setting. Twenty-two enrolled infants exhibited NVP blood concentrations above the prophylactic threshold set at 100ng/ml. This threshold is consistent with both the World Health Organization(2013)and Tanzanian Ministry of Health (2012) guidelines for preventing infant HIV infection.[19, 20] Fourteen participants (64%) surpassed the typical therapeutic NVP blood concentration threshold of 3,000ng/ml.[4] As none of the enrolled women were receiving NVP during pregnancy or after birth, the observed NVP level in the infants' blood can be attributed solely to the NVP administered via the Pratt Pouch.

There was a large interpatient variability of the infants' blood NVP levels (min: 420ng/ml; max: 14,000ng/ml) most likely due to differences in infant weight and timing of the most recent infant NVP dose prior to drug level. NVP has a mean half-life of 40 hours; therefore infants receiving NVP most recently would still be expected to have a higher level of NVP as compared to those whose last dose was nearly 24 hours prior to blood sample.[21] Furthermore, the variability could be attributed to the inverse correlation between patient follow-up weight and measured NVP blood level observed. Infants with a low weight at follow-up (2.0 – 2.4kg) had an average of 7,500ng/ml NVP in their blood, whereas infants weighing more (3.0 – 4.0kg) averaged 2,600ng/ml NVP. This result is consistent with available literature and would suggest that infants with a lower weight received slightly more than the recommended dose of NVP, but without apparent toxicity.[22, 23] No adverse events were attributed to NVP toxicity. The rash recorded was due to oral thrush, as opposed to cutaneous, and the participants with reported fever resolved without sequella. One fever case was subjective and reported by the mother days prior to the follow-up exam, while the other had been admitted to a different hospital for a sepsis evaluation.

Infants were expected to weigh between two and four kilograms, with an average weight of three kilogram. This assumption was based on national birth weight averages found in the Tanzanian Health Research Bulletin.[24] The average birth weight of enrolled infants in the study was: 2.9kg (min: 2.0kg; max: 3.9kg). Although no infants weighed less than 2.0kg, such infants would have been switched to a syringe based dosing regimen as quickly as possible after birth to ensure accurate dosing.

Two women did not give birth at KCMC. One woman had precipitous labor and gave birth at home while the other delivered at a health facility closer to her home because she lived 30km from KCMC. It is unlikely that either of these women would have been able to provide NVP to their children soon after birth if they did have had access to the Pratt Pouch. In Tanzania, over half of women deliver at home and the rates can be higher in other countries.[1]

Training staff was a vital component in guaranteeing the effective use of the pouch. A total of 15 labor and delivery nurses, two pharmacists, and the study nurse were trained and passed validation. One pharmacist was re-trained because she failed a spot check that was performed before pouches were distributed. In a related study in Zambia, pharmacists

needed two training experiences before being able to correctly package pouches.[16] There remains some concern over the filling, sealing and labeling responsibilities associated with the Pratt Pouches not being intuitive to pharmacists and therefore, a more tailored, individual training period is recommended. Although the personnel cost and time needed to fill pouches was not formally investigated, the pharmacists and nurses at KCMC (a busy referral hospital) were able to successfully integrate the program into their daily schedules. In previously unpublished work, practiced pharmacists took an average of 17 seconds to fill and seal each pouch. Similar results have also been observed in Zambia.[16]

Limitations

Blood levels were only taken at a single time point without precise information on timing since the last NVP dose was administered. However, the results are promising and suggest that prolonged NVP treatment administered via the pouch could indeed sustain infant NVP blood levels above 100ng/ml. Follow-up data about the HIV status of the infant was not available, so a correlation between administering NVP via the pouch and infant HIV status could not be made. Further study limitations include the small sample size and the lack of control group for comparing NVP levels when using other alternate delivery methods such as syringes or dosing cups. Hematologic abnormalities and hepatotoxicity were not monitored.

Conclusion

The Pratt Pouch has been shown to be an effective medicine delivery system for infants as demonstrated by sustained blood NVP levels above 100ng/ml. It allows for caregivers to accurately administer medication regardless of whether birth occurs at home or at a health care facility.

By adopting the Pratt Pouch as a medicine delivery method, health care systems that have opted for using Option B plus could benefit from greatly enhanced access to rural patients as well as significant long term cost savings. Distributing an entire bottle of NVP for home-based infant HIV prophylactic treatment results in a lot of wasted medication that cannot be reused. In environments where ARV medication availability is greatly limited by supply chain challenges, optimizing currently available medication stocks is a priority in order to continue progress towards an HIV-free generation.

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Figure 1.

A photograph of the kit that was distributed to all participating HIV-positive pregnant women containing: fourteen labeled and filled Pratt pouches as well as Swahili-language user instructions.

Table 1

Socio-demographic and clinical characteristics of enrolled participants who completed the study. Infant birth weight was only available for health facility births (n=21). Plan B+ refers to the WHO policy that all HIV-positive, pregnant women should receive ART. The regimen is tenofovir (TDF), lamivudine (3TC), and efavirenz (EFV). Additional abbreviation: nucleoside reverse transcriptase inhibitor (NRTI).

	Total, No. (%)
Antenatal maternal ART regimen (n=22)	
Plan B+ (TDF/3TC/EFV)	18 (82%)
ART, first line other than Plan B+ (2NRTI + EFV)	1 (5%)
ART, second line (2 NRTI + PI)	3 (14%)
Estimated gestational age at enrollment (n=22)	
23 – 32 weeks	10 (45%)
33 – 36 weeks	77 (32%)
37+ weeks	4 (18%)
Unknown	1 (5%)
Infant Gender (n=22)	
Male	10 (45%)
Female	12 (55%)
Estimated gestational age at birth (n=22)	
35– 36 weeks	3(13%)
37 – 40 weeks	7 (32%)
41+ weeks	7 (32%)
Unknown	5 (23%)
Birth weight (average: 2.9kg +/−0.5kg, n=21; n=1 home delivery)	
2.0–2.4kg	4 (19%)
2.5 – 2.9kg	9 (43%)
3.0 – 3.4kg	5 (24%)
3.5 – 4.0kg	3 (14%)
Follow-up weight, average NVP level (average: 2.9kg +/− 0.6kg, n=22)	
2.0 – 2.4kg, 7,500ng/ml	5 (23%)
2.5 – 2.9kg, 6,500ng/ml	6 (27%)
3.0 – 4.0kg, 2,600ng/ml	11 (50%)