We previously reported that LPV/r exposure from a 20% to 40% syrup bottles, and represent an alternative formulation for young children unable to swallow unpleasant taste was similarly reported among young children taking minitabs and syrups 

1. METHODS

Background LPV/r “pellets” (pellet) provided similar exposure to LPV/r syrup in the CHAPAS-2 trial. After 12 weeks, they were more acceptable than syrup for young children, but older children preferred tablets. Here we describe acceptability at 48 weeks.

Methods CHAPAS-2 was a randomized trial comparing exposure to LPV/r in HIV-infected children taking first- or second-line ART with 2 NRTIs+LPV/r from 2 clinics (“JCRC,” “PIDC”) in Uganda. Infants aged 3–<12 months and older children aged 1–<13 years were recruited. Children aged 1–<4 years (group B) and children aged 4–<13 years (group C) were randomized to tablets or syrup pellets.

Acceptability data were collected at weeks 4, 12, 28, and 48. 12 weeks were measured at week 48. Results for groups A and B, overall, the proportion preferring pellets increased between weeks 0 and 12 and decreased at week 48 (group A 37%, 72%, 64%, and 60% respectively). However at week 48, group A’s preferences differed between JCRC and PIDC: 70% JCRC vs 0% PIDC preferred pellets. For older children (group C), minitabs were progressively less preferred to tablets over time: 41%, 19%, 13% at weeks 0, 12, 48 respectively. For Groups A & B, the proportion of parents preferring pellets increased during follow-up to 48 weeks (group A 37%, 72%, 64%, and 60% respectively, vs 20%, 13%, 13% at week 12). Formulations taken in the previous 4 weeks reflected preferences: Groups differed on JIRC, who was more likely to be on pellets at week 48 (60% LCJ 15% JCRC, p=0.009). Acceptability was similarly reported among young children taking minitabs and syrup pellets (72% JCRC vs 0% PIDC preferred pellets). Generally, the proportion declined with follow-up period. Also, children at JCRC were more likely to prefer pellets at week 48 than at week 12.

4. RESULTS

4.1 Parent preference for pellets

Figure 1: Design of the CHAPAS-2 trial

A: Infants aged 3–<12 months

Arm 1 A: Group A (pellets vs syrup in infants 3 to <12 months)

Arm 2 A: Group B (pellets vs syrup in children 1 to <4 years)

Arm 3 A: Group C (pellets vs tablet in children 4 to <13 years)

B: Children aged 1–<4 years

Arm 1 B: Group B pellets vs syrup

Arm 2 B: Group B syrup vs pellets

C: Children aged 4–<13 years

Arm 1 C: Group C pellets vs tablets

Arm 2 C: Group C tablets vs pellets

77 children were recruited from two clinics in Kampala: the Joint Clinical Research Centre (JCRC) and the Paediatric Infectious Disease Clinic (PIDC). Main reasons for enrolment were: parental request; children were randomized to tablets or syrup at week 4. Acceptability data were collected at weeks 4, 12, 48.

4.2 Problems with formulations during follow-up

For those preferring syrups, key issues with pellets were their bitter taste, problems with making this taste with food and needing to sweeten food with sugar or honey which is expensive, and problems with giving the whole dose.

5. CONCLUSIONS

In groups A and B, the proportion reporting unpleasant taste was similar for group pellets and pellets, while for group C pellets were worse than tablets. No problems were reported with transportation/storing pellets, unlike syrups.

For those preferring syrups, key issues with pellets were their bitter taste, problems with making this taste with food and needing to sweeten food with sugar or honey which is expensive, and problems with giving the whole dose.

4.3 Pellet use in the previous 4 weeks

4.4 Virological response

Of 19/77 (25%) children with viral load assayed at week 48, 14 were <50c/ml and all were <1000c/ml

5. CONCLUSIONS

For infants and young children overall, pellets were more acceptable than syrups for young children, but older children preferred tablets.

In this study we evaluated acceptability of pellets to syrup and tablets up to week 48.

In groups A and B, the proportion reporting unpleasant taste was similar for group pellets and pellets, while for group C pellets were worse than tablets.

No problems were reported with transportation/storing pellets, unlike syrups.

For those preferring syrups, key issues with pellets were their bitter taste, problems with making this taste with food and needing to sweeten food with sugar or honey which is expensive, and problems with giving the whole dose.

The proportion of children taking pellets in the last 4 weeks reflected parent preferences, and differed by clinic. Generally, the proportion declined with follow-up period. Also, children at JCRC were more likely to prefer pellets at week 48 compared to children at PIDC.

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