

Background

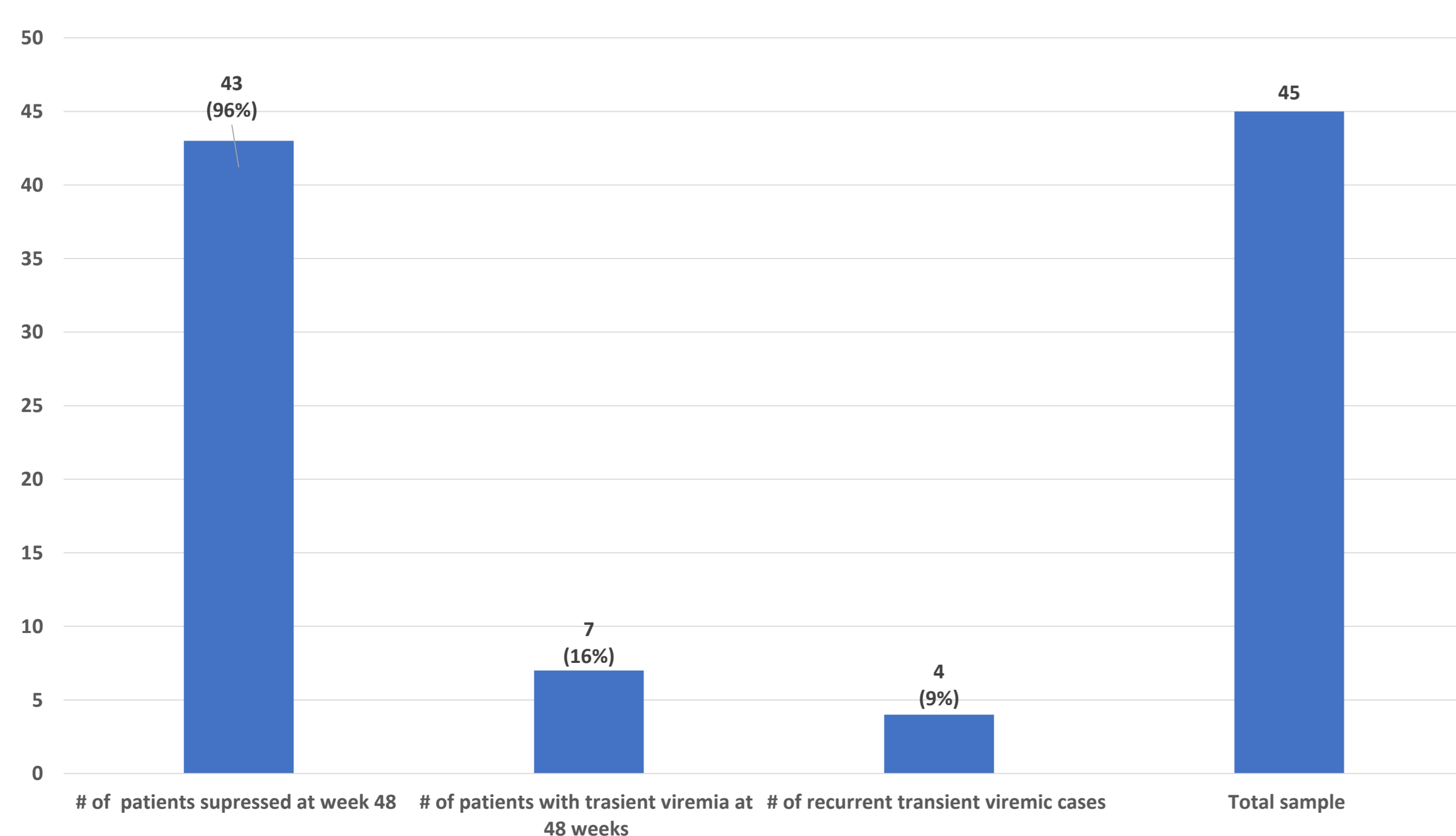
Although the promise of the World Health Organization's goals of HIV control ("90-90-90") has been achieved in many target populations, this is not the case among those becoming infected through injection drug use (IDU). In this group, 50% or less have achieved or maintained full virologic suppression even in our own province of British Columbia, Canada. This is true in other HIV-infected IDU populations¹⁻³. These observations relate to the fact that many of the target population remain disengaged from care and cannot be successfully re-engaged using the traditional medical model. We have designed a novel outreach model to identify HIV-infected IDU who are not receiving care and to administer antiretroviral therapy in the context of patient-centered multidisciplinary programs (including addiction care) that would allow for the administration of antiretroviral therapy in a way that would maximize its success. This is supported by the availability of potent, easily administered single tablet regimens proven in clinical trials to produce maximal virologic suppression in > 90% cases. In a prospective, observational study, we have shown that prescription of single tablet TAF/FTC/bictegravir (Biktarvy) within our model of care leads to sustained virologic suppression in 43/45 (96%) cases. In this analysis, we sought to extend our findings to demonstrate additional benefits of this intervention, in terms of reducing the incidence of low-level virologic breakthrough ("blips") requiring additional medical interventions in this population.

Methods

The population previously enrolled in our Biktarvy switch study were the subject of this analysis. Briefly, HIV-infected IDUs who had experienced incomplete virologic suppression in the previous year were offered the opportunity to include themselves in an observational study with their previous antiretroviral therapy being replaced with Biktarvy administered within a multidisciplinary model of care and prospective follow-up continued for 72 weeks. For this analysis, we identified the subjects who completed 48 weeks of follow up and in whom at least 4 measures of HIV RNA were available over the period of 48 weeks. In reviewing medical records, we then recorded viral load measures in the year that preceded the switch to Biktarvy. We recorded all plasma viral load measures > 200 copies/mL and identified them as virologic "blips". The endpoint was the comparison of blipping frequency among patients before and after Biktarvy switch. In addition, among those in whom blips were recorded while on Biktarvy, an exploratory analysis was conducted to identify correlates of such blips.

Results

Figure 1. Characteristics of transient viremia in our cohort at weeks 48



Results continued

Table 1. Demographics of cohort

Demographics	Sample size N= 45
Median age (range)	55 (34-66)
Median CD4 cell count (range)	620 (36-1490)
Male (n, %)	(40, 88.9%)
Drugs used (%)	
Cocaine	46.7%
Methamphetamines	42.2%
Opiates	26.7%
Fentanyl Users (n, %)	(41, 91.1%)
Median age (range)	51 (34-63)
Male (n, %)	(11, 78.6%)
OAT (n, %)	(13, 92.9%)
Opioid Agonist Therapy (n, %)	(25, 55.6%)
Median age (range)	55 (34-66)
Male (n, %)	(20, 80%)
Fentanyl users (n, %)	(13, 52%)

Table 2. Demographics of those who had viremic blips by week 72

Demographics	Sample size N= 8
Median age (range)	56 (48-58)
Caucasian	(6, 75%)
Male (n, %)	(8, 100%)
Drugs used (%)	
Cocaine	37.5%
Methamphetamines	62.5%
Opiates	100.0%
Fentanyl Users (n, %)	(8, 100%)
Opioid Agonist Therapy (n, %)	(6, 75%)

We identified 45 subjects in whom all of the required information was available and who had survived to week 48 of observation while on Biktarvy. Demographic characteristics are shown in Table 1. Median age 55 (24-66) years, 40 (88.9%) male; 21 (46.7%) cocaine/19 (42.2%) crystal/41 (91.1%) fentanyl users. Opiate agonist therapy was prescribed to 25 (55.6%) individuals (Table.1). At the time of initiation of antiretroviral therapy, we note median CD4 count 620 (26-1490) cells/ μ L, 44 (97.8%) HIV RNA < 40 copies/mL (1 detectable with HIV RNA 1450 copies/mL). It is of note of that 41 (91%) subjects were previously on multi-tablet regimens while 4 (9%) were on single tablet regimens where the most common regimens consisted of 1.TDF/3TC + DOL, 2.TDF/3TC +DRV/COBI, and 3.EVG/COBI/FTC/TDF. Overall, we documented 15 and 8 blip events before and after switching to Biktarvy, for an incidence of 25.83 vs. 13.61 cases/100 person-years. A total of 7 subjects on Biktarvy experienced blips, of which 4 cases, were recurrent episodes by the same subjects by week 48. As shown in Table 2, their demographic characteristics did not differ from those in the overall study population.

Conclusion

As previously demonstrated, among a group of inner-city HIV-infected IDUs, administration of Biktarvy in the context of a program of multidisciplinary care leads to near universal achievement and maintenance of virologic suppression. An additional benefit in this population is the significant reduction in the incidence of low-level viremia that may require investment of health care resources to ensure that this is not associated with high-level virologic breakthrough and to ensure that adherence to therapy is being maintained. This supplementary analysis of our Biktarvy switch study shows that the strategy we employed not only leads to more frequent and durable virologic suppression but is also associated with a reduction in health care interventions that would be required to address virologic blips, which occurred much less frequently after the Biktarvy switch.

References

1. Strathdee SA, Palepu A, Cornelisse PG. et al. **Barriers to use of free antiretroviral therapy in injection drug users.** JAMA 1998, 280: 547-549.
2. Celentano DD, Vlahov D, Cohn S, Shadle VM, Obasanjo O, Moore RD. **Self-reported antiretroviral therapy in injection drug users.** JAMA 1998, 280: 544-546.
3. Mocroft A, Madge S, Johnson AM. et al. **A comparison of exposure groups in the EuroSIDA study: starting highly active antiretroviral therapy (HAART), response to HAART, and survival.** J Acquir Immune Defic Syndr 1999, 22: 369-378.

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