

Background

- Studying the viral dynamics and immune-biology of HIV across anatomic compartments is key to the understanding of latent virus reservoirs.
- Conducting invasive procedures in clinical trials has become attractive to obtain biological samples to study HIV reservoirs in several biological sites.
- There is currently limited data on acceptability and safety of performing invasive procedures in the context of clinical research in low and middle income countries.

Objectives

- To describe the acceptability and safety of performing invasive procedures in the context of a specimen collection and analysis study at three clinical sites in East Africa.

Methods

- RV419 is a multi-site specimen collection protocol enrolling HIV infected and uninfected adult participants at clinical sites in East Africa.
- Potential participants are recruited from the general community and high-risk cohort studies.
- Participants consent for at least one of three invasive procedures; lumbar puncture (LP), lymph node biopsy (LNB) and rectal biopsy (RB).
- At the subsequent visits participants are free to drop all invasive procedures, select a different procedure or continue with the one they had at enrollment.
- For this analysis we conducted a retrospective review of the participant study.

Measurements

- Demographic data.
- Safety data including AEs.
- Procedures consented for.
- Actual procedures performed.

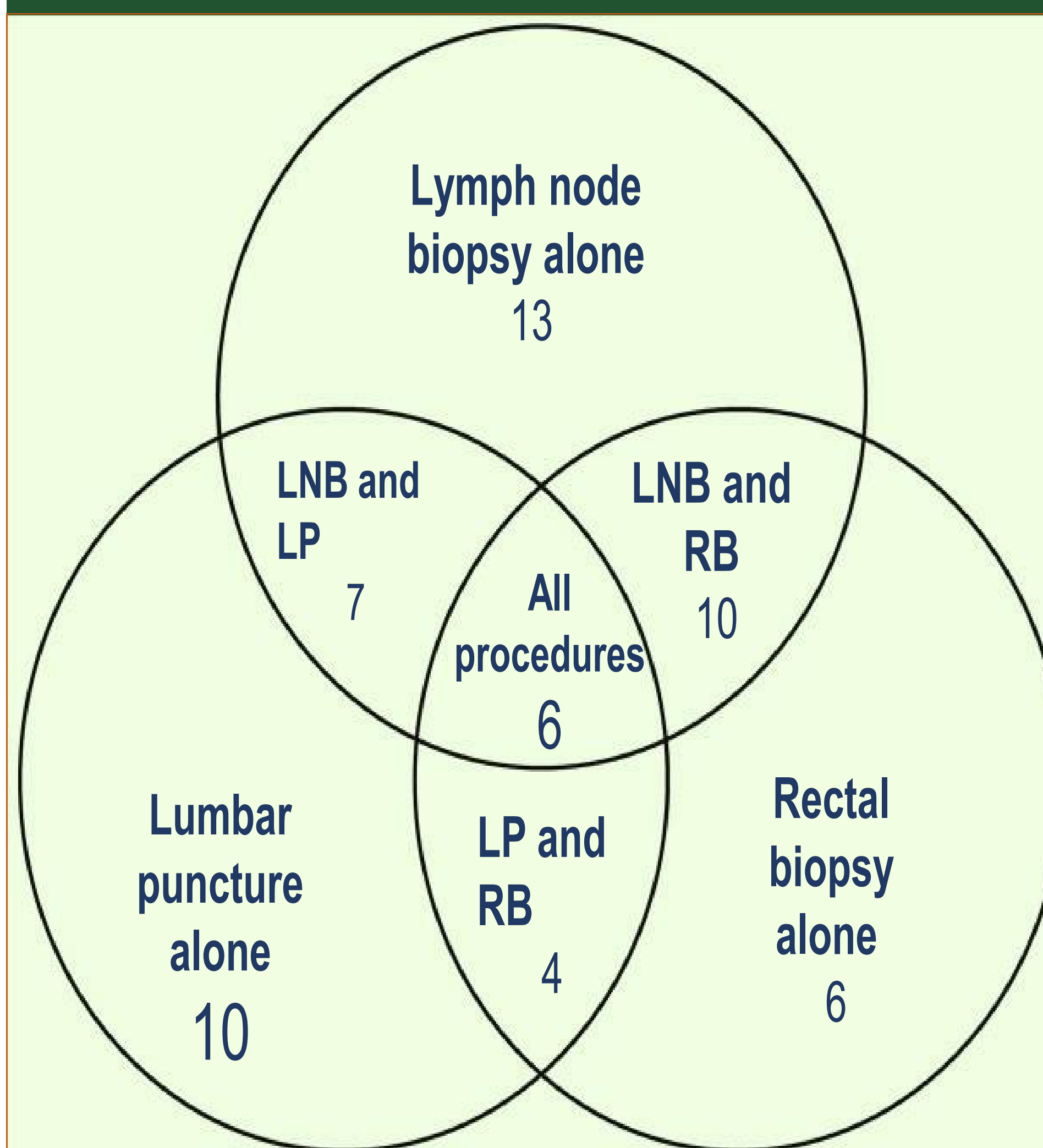
Analysis

- We used simple descriptive analysis to describe the acceptability and safety of performing invasive procedures.

Results

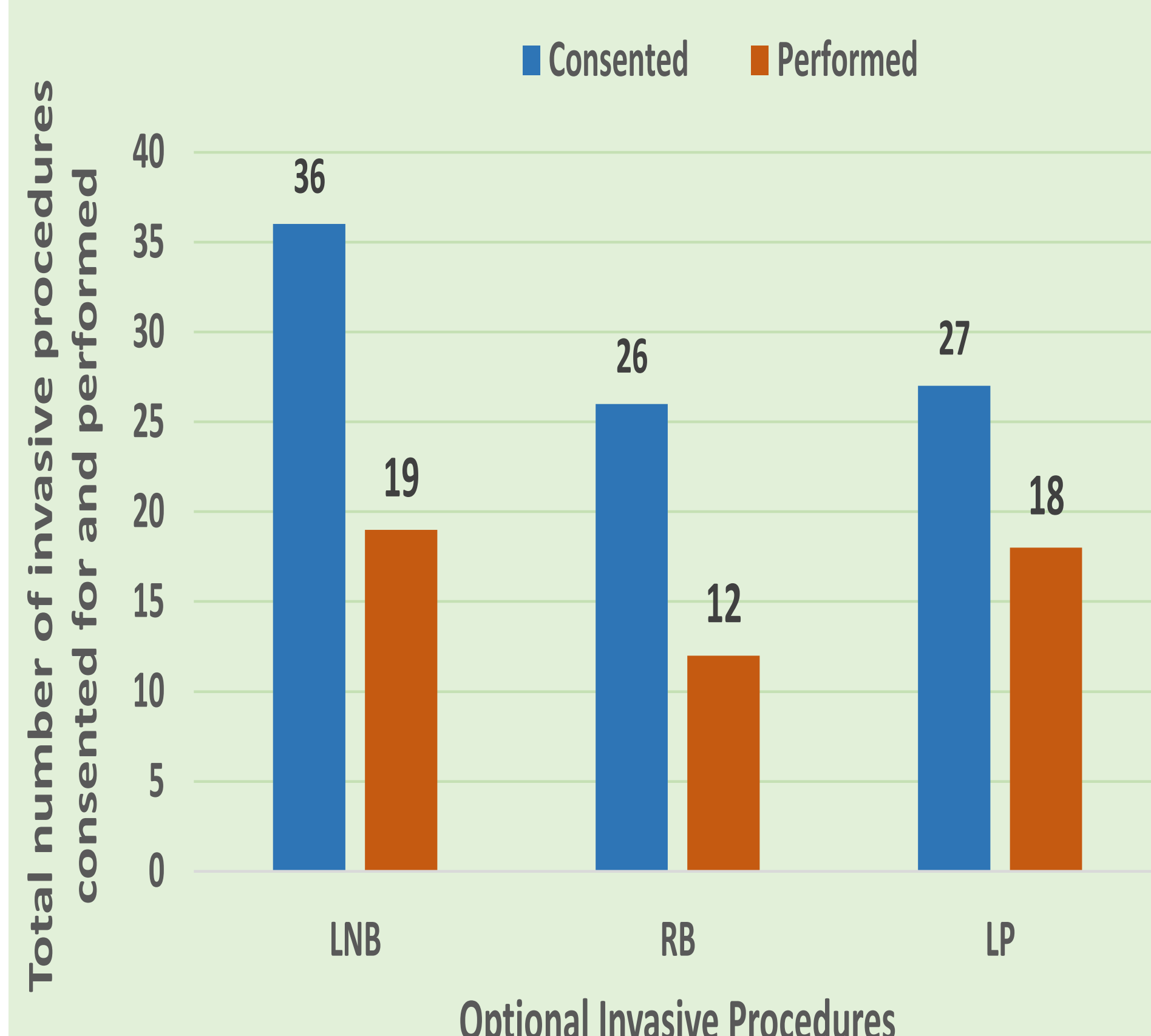
- Across sites, a total of 56 participants were screened and 38 enrolled, 52.6% (n=20/38) HIV infected.
- The median age of enrolled participants was 28; and more than three quarters were female (n=29/38).
- At time of analysis, participants had consented to a total of 89 invasive procedures (27 lumbar puncture, 36 lymph node biopsy, 26 rectal biopsy).

Figure 1: Venn diagram illustrating the acceptability of the different invasive procedures



- Overall, 100% (n=56) of participants consented for at least one invasive procedure; 51.8% (n=29) consented for only one procedure; 48.2% (n=27) consented for at least two procedures; and 10.7% (n=6) consented for all three procedures.

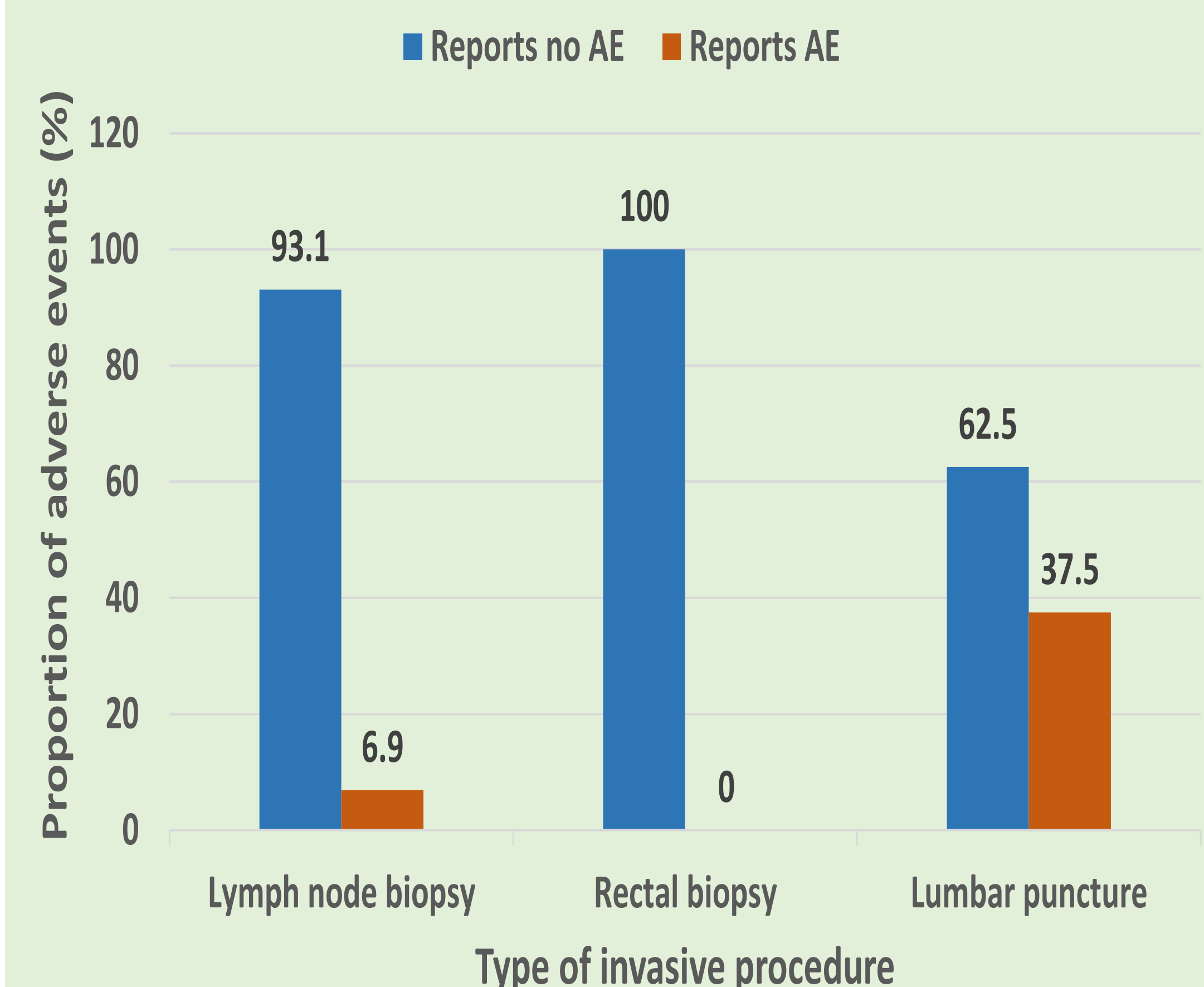
Figure 2: Comparisons of invasive procedures consented with procedure actually performed



Although participants could have consented for more than one procedure, one procedure, of their choice, could be performed per visit.

- Eight adverse events related to the study invasive procedures were reported; 2 related to lymph node biopsy and 6 post lumbar puncture headache.
- Seven of the 8 adverse events were generally mild and resolved with simple analgesia and counseling. One participant with post lumbar puncture headache required hospitalization.

Figure 3: Proportion of participants experiencing adverse events by type of invasive procedure



Conclusions

- Invasive procedures among a small subset of both HIV infected and uninfected individuals living in East Africa is generally well accepted and well tolerated.

Acknowledgements

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