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Original Research Article

Does non-protease inhibitor based anti-retroviral therapy modify peripheral arterial disease? A vision from eastern India

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ABSTRACT

Aim: Assess the effects of ART on PAD over a follow up period of 12 months.

Background: HIV induced endothelial dysfunction may manifest as peripheral arterial disease (PAD). Reports of follow up study showing the change of PAD in people living with HIV before and after initiation of non-protease inhibitor based ART (NPI-ART) are scarce.

Materials and methods: ART clinic based longitudinal study conducted at a tertiary care hospital in eastern India, 193 consecutive ART eligible HIV positive subjects of age between 18–49 years underwent ankle brachial pressure index (ABPI) measurement before ART initiation and after one year of receiving NPI-ART to examine the effect of ART on PAD. ABPI values of 0.90 or less were defined as PAD.

Results: Proportion of subjects with PAD among treatment naive subjects was 30.57%. It dropped to 12.95% after 6 months and to 3.62% after 1 year of NPI-ART. Not a single new case of PAD was diagnosed during the study period. Traits like normal BMI and no alcoholism were found to be independently associated with PAD in ART naive subjects. Interestingly significant improvement of PAD was also seen among normal BMI subjects and never alcoholics ($p < 0.05$). ABPI improvement was also significant among people who were asymptomatic, belonged to urban population and never used tobacco (p value < 0.05).

Conclusion: Prevalence of PAD decreased significantly after one year of ART. Routine ABPI measurement and early initiation of NPI-ART reduced PAD morbidity and improved quality of life.

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1. Introduction

Acquired Immune Deficiency Syndrome (AIDS) is one of the most devastating modern epidemics to have affected mankind. At the end of 2013, 35.0 million people were living with Human immunodeficiency virus (HIV) infection (PLH) all over the world [1]. India harbors almost 21 lakh PLH in 2013 [2]. HIV infection spares not a single system of the human body and the vascular system is no exception [3]. HIV infection causes direct endothelial dysfunction or damage and premature atherosclerosis which have

been established by molecular and radiological markers in good number of studies [4–6].

Studies have demonstrated that peripheral arterial disease (PAD) is a strong predictor of endothelial injury and increased vascular events among HIV infected persons [7]. Severity of HIV infection has been correlated with prevalence of PAD among them [7].

In the recent past, managing non-communicable diseases and improving quality of life among PLH has evolved as an important domain in HIV medicine. PAD among PLH can be attributed to conventional factors like old age, male sex, obesity, smoking, dyslipidaemia, hypertension, and diabetes mellitus as well as other factors like HIV induced endothelial damage or dysfunction, opportunistic infections which include tuberculosis (TB) and last but not the least antiretroviral therapy (ART), particularly protease inhibitors [7–10]. Reports of follow up study showing the change of

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PAD in PLH before and after initiation of non-protease inhibitor based ART (NPI-ART) are scarce. In this backdrop, our study was designed to assess the effects of ART on PAD over a follow up period of 12 months.

2. Methods

Specific objectives:

- To find out the proportion of subjects presenting with PAD at the time of initiation of ART.
- To study basic demographic, clinico-pathological parameters at the time of initiation of ART.
- To monitor the changes in PAD status and severity among the study subjects over period of 12 months.
- To assess the association, if any, with socio-demographic and clinico-pathological parameters and changing pattern of PAD among the study subjects.

This was undertaken as an institutional review board (IRB) approved longitudinal study. Subject recruitment process has been depicted in Fig. 1. The subjects were registered for ART as per Indian guidelines and the study in no way intervened or interfered with the standard treatment protocol [11]. All subjects were on Tenofovir, Lamivudine, Efavirenz regimen with compliance >95% in every month. All patients detected having PAD at initiation of ART were treated as per AHA/ACC guidelines [13]. The subjects were of age between 18–49 years who gave informed consent, were able to understand the questionnaire and who were willing to undergo investigations, were included in the study. A predesigned pretested semi structured case record form was used to obtain relevant information at the times of visit of the subject and also for self-recording of relevant information during the interim period.

Known cases of PAD previously established by abnormal ABPI or arterial Doppler study, known cases of diabetes mellitus, hypertension and dyslipidemia irrespective of treatment modalities and patients already on ART were excluded from study.

Demographical, clinical and laboratory parameters were documented for all the subjects. CD4 testing was done using Multiset V2.2 FACSCalibur (#E97300192) software and expressed in counts/dl. Blood glucose levels were measured using hexokinase method. Hyperglycaemia and Dyslipidameia was defined as per ADA guideline and ACC/AHA guideline respectively [14,15]. HBsAg, anti-HCV antibody and Venereal disease research laboratory (VDRL) tests were done with ELISA kit.

All the cases were studied as per the Edinburg claudication questionnaire and ankle brachial pressure index (ABPI) measurement for screening of PAD (at start of ART, at 6 months and after one year of ART initiation). ABPI was measured for all patients as per standard protocol [16,17]. ABPI threshold of 0.90, measured at rest, has 79% sensitivity and 96% specificity to detect >50% reduction in arterial luminal diameter [12] and this information was used for interpreting the results in this study. ABPI results were uniformly reported with noncompressible values defined as greater than 1.40, normal values 1.00 to 1.40, borderline 0.91 to 0.99, and abnormal 0.90 or less which was defined as PAD [13].

Data were keyed into the computer and have been double checked to avoid any error in data entry. Epi-info 7 software, downloaded from WHO site, was used to manage and analyze the demographical, clinical and laboratory parameters preliminarily. The data was described by tabular, graphical and statistical means with help of Stata software, version 9.2 (Stata). Statistical significance was tested by chi square or t-test as relevant and *p*-values have been approximated to the nearest two decimal places and all other decimals in the text have been approximated to one decimal. *p*-Value <0.05 was taken to be significant at 95% CI.

3. Results

193 subjects were recruited of which 21 patients did not attend our clinic for follow up as per the study protocol. Of all those recruited 98 (50.8%) were male, 89 (46.1%) were from urban background, 110 (57%) were illiterate, 59 (30.6%) were educated up to primary school, 16 (8.3%) up to secondary level, rest (4.1%) had higher education. 18 (9.3%) of the subjects were single, 60 (31.1%)

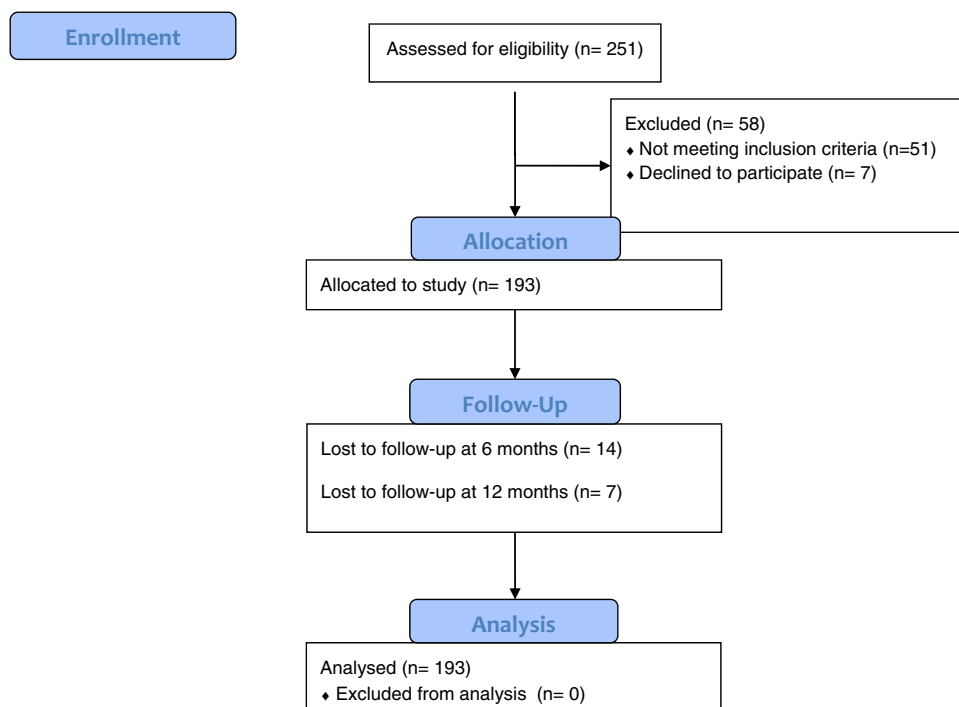


Fig. 1. Flow chart showing subject recruitment pattern.

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