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IN SEARCH OF A CHEAPER ALTERNATIVE TO VIRAL LOAD TESTING FOR HIV TREATMENT MONITORING

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EXECUTIVE SUMMARY

HIV viral load testing after treatment initiation among People Living with HIV (PLHIV) is essential for monitoring effectiveness of the treatment. However, being a very expensive test, it creates a tremendous financial burden on the national programme considering the number of estimated PLHIV in India. Hence cheaper potential markers were searched to see if they can substitute HIV viral load testing.

A marker in blood samples of the HIV patients called 'Galectin-9' was found to be useful to screen patients with high viral load values indicating failure of the treatment. The test for this marker is cheaper and simpler and it reduces the cost per test by almost 24 times. This new marker has demonstrated a potential to be used as a screening test to lower budget spent on the current viral load testing.

National AIDS Control Programme (NACP) has **recently initiated annual viral load testing** for monitoring their treatment.

THE ISSUE

Currently, in India there are around 2.1 million PLHIV out of whom around 1.18 million are on treatment (1). National AIDS Control Programme (NACP) has recently initiated annual viral load testing for monitoring their treatment. The measurement of HIV copies (viral load) is essential to monitor success of the treatment. High viral load in any individual on treatment increases the risk of disease progression and development of drug resistance mutations. However, viral load is a costly test requiring sophisticated equipment, cold-chain dependent kits and skilled manpower. So, it is not feasible to have the viral load testing set-up at each Antiretroviral Therapy (ART) centre. As a result, many ART centres would require transportation of samples to the viral load testing laboratories. The estimated number of PLHIV is likely to increase in coming years because of increased life span of the patients taking medicines and more HIV infected patients will initiate treatment. Cost of viral load testing in current public-private partnership (PPP) model is Rs. 1200/- per test making annual cost for viral load testing Rs. 1,41,73,54,800/- for current patient burden. This cost is recurrent given no cure is available for HIV infection till date. Hence, cheaper potential markers are desired to save cost considering the tremendous financial burden of viral load testing on the programme.

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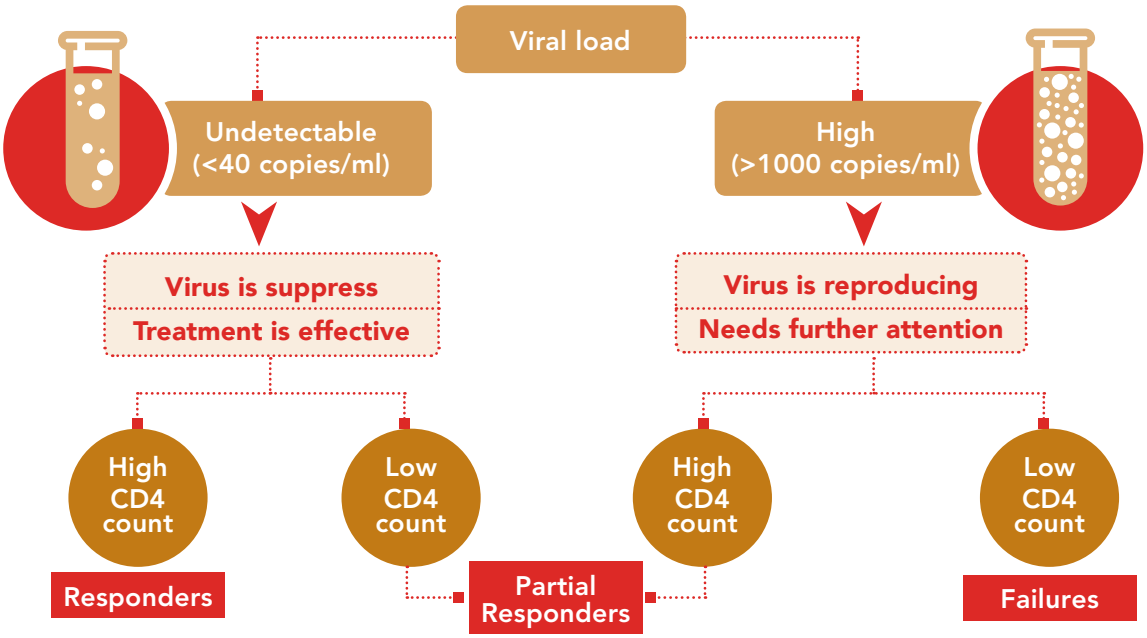
THE STUDY

A study was conducted to identify cheaper markers that could indicate presence of high viral load in PLHIV on treatment with the following objectives:

- To identify a marker which differs among PLHIV on treatment with and without high viral load
- To determine accuracy of the marker in identifying the patients with high viral load

THE METHODOLOGY

The PLHIV on treatment were recruited from two ART centres linked to tertiary care hospitals in Pune. Treatment for HIV infection causes viral load to reduce below the detection limit. Patients also experience increase in white blood cells (CD4) count, which is responsible for improved immunity. Non-adherence to the treatment leads to high viral load and low CD4 count among patients. Apart from these, few have undetectable viral load but still have low CD4 count. On the other hand, there are individuals who show increase in CD4 count but have high viral load. These partial responders are important, as they constitute about 15-20% of the PLHIV on treatment. Patients with HIV responding to the treatment, failing on the treatment and partially responding to the treatment were included in the study.

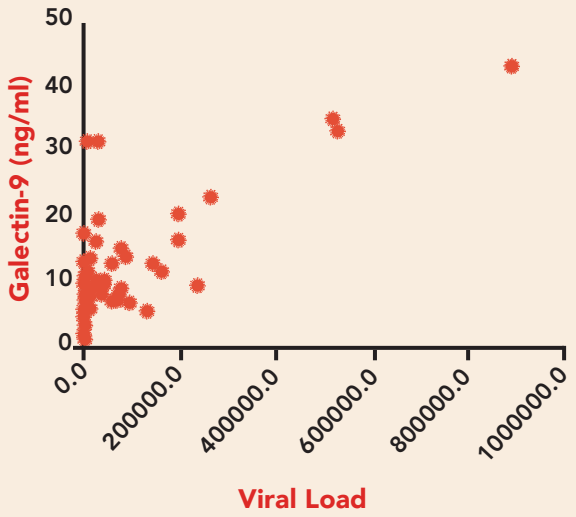


A total of 63 HIV positive individuals with undetectable viral load were recruited. Their age ranged from 23 to 62 years. There were 31 males and 32 females. HIV positive individuals with high viral load were 43. Male and female patients were 21 and 22, respectively. Their age ranged from 18 to 55 years.

The patients were tested for a panel of markers selected on the basis of previous studies showing their association with HIV viral load. The panel included markers like Galectin-9 (2), C-reactive protein (3), soluble CD14 (4), IL-6 (5), Lipopolysaccharide (6) and CD38 expressing CD8 cells (7). Levels of the markers were compared in these PLHIV to find out if they show any association with viral load and also if they can be used to differentiate PLHIV with undetectable viral load from those with high viral load. These markers are known to be influenced by immune status as well as presence of other infections. Hence inclusion of partial responders was essential to find out if they fail in this differentiation in the presence of other infections or in individuals with differing immune status as reflected by their CD4 counts.

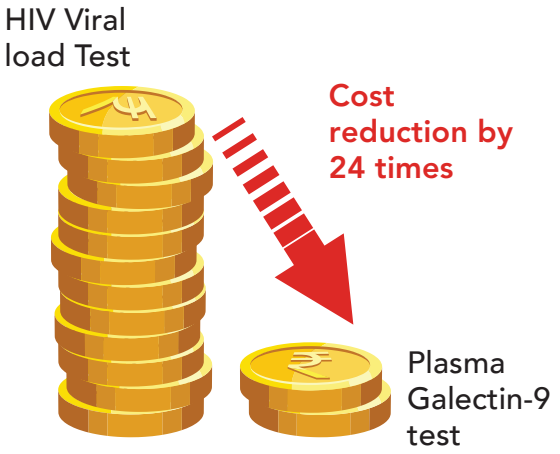
FINDINGS

- 40 individuals of those testing positive for HIV showed rise in CD4 count due to treatment. However, 23 were partial responders who did not show increase in CD4 count despite treatment.
- 18 patients with high viral load did not experience increased CD4 count as expected, against 25 partial responders showing increased CD4 count.
- Only two markers namely Galectin-9 and CD38 expressing CD8 cells differed significantly between the patients with undetectable viral load and those with high viral load irrespective of CD4 count and presence of other infections.
- Galectin-9 levels went hand in hand with the viral load values among these patients.
- A cut-off value of 5.79 ng/ml was identified for differentiating the individuals with higher viral load values from those with undetectable viral load.
- More than 90% of the patients with higher viral load values could be identified correctly using this cut off.



LEARNINGS

- Galectin-9 measurement is a simple to perform and cheaper alternative to viral load test.
- It can be used to identify HIV infected individuals on treatment with high viral load values with the accuracy of more than 90%.



RECOMMENDATIONS

- The study underlined the role of Galectin-9 as a marker for identifying PLHIV with high viral load.
- It can be used as a screening test to identify PLHIV with high viral load based on the cut-off value of Galectin-9. Only patients with Galectin-9 levels more than 5.79 ng/ml need to be further tested for viral load, cutting down expenses on the viral load testing done under the programme.
- The test can serve as an alternative to finding viral load in hard to reach areas where transportation of samples to viral load testing laboratories is very challenging.
- The test can also serve as an alternative to viral load in case of machine breakdown or other topical problems hindering conduct of the viral load testing.

Cost of viral load testing in current **public-private partnership (PPP) model is Rs. 1200/- per test** making annual cost for viral load testing Rs. 1,41,73,54,800/- for current patient burden.

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