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EFFECTS AND EFFICACY OF 1ST LINE AND 2ND LINE ART: A COMPARATIVE STUDY

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ABSTRACT: INTRODUCTION: The role of ART in the HIV/AIDS patients is to be protecting the patient from opportunistic infections and there by improve the quality of life, in individuals whose CD4 count is less than 350 cells/c.mm. **OBJECTIVES:** To study the effects and efficacy of the ART including assessment of CD4 count those who are receiving 2nd line and reasons for failure for 1st line. **METHODOLOGY:** A hospital based cohort study at Rajiv Gandhi Institute of Medical Sciences, Kadapa among ART centre attenders during period 2013 – 2014 A total no. of 30 patients who are receiving 2nd line were selected. The data thus obtained was subjected to analysis and results are presented. Out of 30 HIV patients about 30% are between the age of 40-50yrs, 63.3% patients are between 20-40yrs, 3.3% below 18yrs & 3.3% more than 50yrs of age Out of 30 HIV patient's 20 patients are having below 200cells/c.mm. After 6months only 60 patients are below 200cells/c.mm with 2nd line antiretroviral therapy 14 patients CD4 count shows more than 350cells/c.mm. Conclusion: Majority of patients improved after 2nd line therapy who fails to respond 1st line Bacterial infections are significantly control after initiation of 2nd line drugs. Incidence of superficial fungal infections reduced. Absolutely no adverse effects observed except skin rash in 2 patients among the study group.

KEYWORDS: Anti-retroviral therapy, CD4 count, Viral Load.

BACKGROUND: WHO guidelines are consistent in recommending antiretroviral therapy. For an individual with symptomatic HIV/AIDS or with CD4 cell count < 200cells/c.mm in fact waiting to initiate <200cells/c.mm results in substantially inferior clinical outcomes (AIDS events & death) in the analysis of multiple clinical cohort studies even when controlling for lead time and other bias.

Individuals who initiate HAART at higher CD4 cell count are more likely to survive longer with AIDS Free State.

For individuals with CD4 cell count between 201-350cells/c.mm current guide lines favor therapy initiation.⁽¹⁾

Monotherapies can lead to resistance, so combination of ART drugs are preferred two from NRTIs, one from NNRTIs or from PIs.⁽²⁾ This type of treatment is known as HAART (Highly active antiretroviral therapy). If the patient fails to respond to 1st line we prefer 2nd line ART drugs.

The failure of regimen may be due to virological failure immunological failure are or due to recurrent infections (Opportunistic infections) The purpose of HAART is to control OIs and thereby improving quality of life due to enhanced CD4 count and reducing viral load. The efficacy of anti-retroviral drugs depends on how they are combined.^(3,4 5)

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MATERIALS AND METHODS:

Study Design: A hospital based cohort study.

Subjects: HIV positive individuals visiting to RIMS kadapa who are on second line.

Sample Size: All the HIV positive individuals total 30 nos. visiting to ART centre during 2013-2014 who are on second line.

Inclusion Criteria: All HIV positive adults both male & female who have registered at ART centre.

Exclusion Criteria: Pregnancy & paediatric age group.

Ethical considerations: Confidentiality regarding to HIV status and other issues are strictly observed.

METHODOLOGY: Selected patients who are receiving 2nd line at ART centre RIMS, Kadapa information regarding adverse effects and other parameters were collected With the help of questionnaire HIV positive patients are selected for study who are not responded to first line ART may be due to virilological failure or immunological failure or clinical failure CD4 testing and blood for biochemical parameters and performed every 6 months. The data thus obtained was subjected to analysis and results are presented.

Age	No. of HIV pt	% of HIV pt
>50 yr	1	3.3
40-50yr	9	30
20-40yrs	19	63.3
<18yr	1	3.3
Sex		
Male	24	80
Female	6	20
Age and sex wise distribution of HIV patients		

CD4 status initially and after 6 Months:

1st line & 2nd line:

CD4count	initially	>6m	initially	>6m
>50	30%	10%	20%	3.3%
50-100	20%	3.3%	16.6%	3.3%
100-150	23.3%	13.3%	20%	3.3%
150-200	16.6%	13.3%	10%	10%
200-250	6.6%	20%	10%	6.6%
250-300	3.3%	16.6%	10%	6.6%
300-350	0%	3.3%	13.3%	20%
>350	0%	20%	0%	46.6%

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Biochemical & pathological parameters Analysis:

Hemoglobin	1 st line	2 nd line
Decreased	83.3%	70%
Normal	16.6%	30%
Increased	0	0

Decreased	0	0
Normal	100	96.6%
Increased	0	3.3%
Total count		

Decreased	96.6%	93.3%
Normal	0	0
Increased	3.3%	6.6
Blood urea		

Decreased	0	0
Normal	100%	96.6%
Increased	0	3.3%
Serum creatinine		

Decreased	0	3.3%
Normal	93.3%	86.6%
Increased	6.6%	10%
Total bilirubin		

1 st line	No of HIV pt	% of HIV pt
ZLN	30	100
ZLE	0	0
1 st line ART regimens received at ART centre		

Z-Zidovudine, L-Lamivudine, N-Nevirapine, E-Efavirenz

TLAR	29	96.6%
TLLR	1	3.3%
2 nd line from the same group		

T-Tenofovir, L-Lamivudine, L-Lopinavir R-Ritonavir A-Atazanavir

DISCUSSION: The present study was conducted at outpatient department of ART centre of RIMS kadapa during the period of april 2013 – april 2014 by random sampling method.

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The main purpose of this study is to know the effectiveness of ART for the HIV individuals. We followed this group for a period of 01 year.

ART 2nd line regimens are preferred, who are not improving with 1st line regimens due to virological failure or opportunistic infection.

In few patients 2nd line therapy was initiated even CD4 counts are slightly more than 350 cells/c.mm those who are suffering from recurrent infections or viral load is not reaching undetectable levels.

If we analyze age group among patients in our study, we observed 30% are between 40-50yrs 3% more than 50yrs. 63% is between 20-40yrs and 3% are below 18yrs.

All patients who received ART their CD4 count was below 350cells/c.mm. Most of the patients count is between 50-100cells/c.mm. Few patients count is between 100-150 cells/c.mm. Very less no. of patients between 150-350 cells/c.mm.

Our patients received ZLN, ZLE as 1st line regimens of ART and TLAR, TLLR as 2ND line regimens of ART.

Hemoglobin decreased in 83% of patients who were on 1st line and 70% of pts who were on 2nd line.

Total count was normal in patients who are receiving 1st line whereas increase in 3% patients those receiving 2nd line.

Blood urea increased in 3% patients those receiving 1st and 6% in patients receiving 2nd line drug.

Regarding serum creatinine increased in 3% pts those receiving 2nd line drugs was observed.⁽¹⁾

Total bilirubin decreased in 3% pts those receiving 2nd line where 6% increase in patients those receiving 1st line and 10% in patient receiving 2nd line drugs.

During our study we found that 36% pts develop mycobacterial infection with 1st line and none after initiating 2nd line. Patients suffered from other bacterial infections were 30% with 1st line and 10% with 2nd line.

On the other hand superficial fungal infections were seen in 10% patients with 1st line and 6% patients with 2nd line. No deep fungal infection seen during period of study.

We observed viral infection in 6% patients with 1st line and 10% pts with 2nd line.

No protozoal infections noticed during our study from April-2013 to april-2014.

Patients complaining of various untoward effects during our study period. None of our patients suffered from headache, insomnia and diarrhoea.

But 16% of patients developed anaemia with first line.

Skin rash observed in 13% of pts with 1st line & 6% with 2nd line.

Other findings include myalgia, fatigue & vomiting in 10% of pt with 2nd line.

CONCLUSION: During our study we found improvement in CD4 count with 2nd line, who fails to respond to 1st line antiretroviral therapy. Incidence of infections is greatly reduced. No significant adverse effects noticed but there is slight increase in biochemical parameters in few patients. So close follow up needed for the renal and liver parameters in patients those who are on 2nd line regimen.

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