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Original Research Article Study of Lipid Profile in People Living With Human Immunodeficiency Virus In Relation To Antiretroviral Therapy.

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Abstract:-*Background – Lipid Abnormalities Are Common In Hiv Infected Patients Due To Hiv Infection Itself And Antiretroviral Therapy, So We Tries To Study Pattern Of Lipid Profile In People Living With Hiv Infection And Changes In Different Fraction Of Lipid Profile In These Patients After Six Months Of Initiation Of First Line Art Regimen As Per Naco In A Tertiary Care Centre.*
Methods- This Observational Prospective Study Was Conducted For A Period Of Eighteen Months, On 75 Newly Registered Hiv-1 Infected Art Naive Patients Who Were Normotensive, Non-Diabetic, Non-Smoker, Non-Alcoholic. Out Of Which 48 Patients Were Males And 27 Patients Were Females Of Age Group ≥ 15 Years With Appropriate Inclusion And Exclusion Criteria, Attending Art Centre In A Tertiary Care Hospital. Patients Were Started On First Line Art Regimen I.E. Tle Regimen As Per Current Naco Guidelines. 12 Hours Fasting Lipid Profile Were Analysed Enzymatically Before Initiation Of Art And Then Reviewed After 6 Months Of Art.
Results – Study Concluded That There Was Significant Change In Different Fraction Of Lipid Profile In Hiv-1 Infected Patients After 6 Months Of Art. There Was Significant Rise In Tc From (139.0933 ± 25.57462 To 173.1200 ± 49.9846), Tg From (121.8600 ± 20.83492 To 144.3467 ± 35.2096), Ldl-C From (70.880 ± 28.0759 To 100.5840 ± 50.0037) With P-Value < 0.001 After 6 Months Of Art In Hiv-1 Infected Patients. Art Had No Significant Effect On Hdl-C At The End Of 6 Months. There Was Change In Hdl-C From (43.8360 ± 13.6018 To 43.2480 ± 13.0469) With P-Value 0.7874 I.E. > 0.05.
Conclusion – Based On This Study We Conclude That Art Therapy Including Nnrti Based Regimen Caused Significant Lipid Abnormality I.E. Raised Tc, Tg, Ldlc In Art Receiving Patients After 6 Months. Thus Laying Emphasis On Need To Assess Lipid Profile At Beginning, Before Initiation Of Art And Monitor Any Rising Trend In Lipid Profile After 6 Months. These Lipid Abnormalities Predisposes These Patients To Development Of Cardiovascular Complications And Therefore Should Be Monitored.
Keywords*- Art, Hdl Cholesterol, Ldl Cholesterol, Total Cholesterol, Triglyceride.*

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I. Introduction

Patients With Advanced Hiv Disease Frequently Present Alteration In Lipid Metabolism Due To Infection With Hiv Itself. Hiv Infection Causes A Specific Pattern Of Dyslipidemia, Resulting From Combination Of Increased Production And Decreased Clearance Of Lipoproteins[1]. The Introduction Of Antiretroviral Therapy [Art] In The Mid 1990s Led To Substantial Improvement In The Prognosis Of Hiv/Aids Patients, With A Reduction In Morbidity And Mortality Due To Opportunistic Infections And Consequent Improvement Of The Patient's Quality Of Life[2-7] .In Addition To Reduction In Aids Related Deaths, Art Treatment Has Also Been Recognized To Prevent Hiv Transmission By Reducing Viral Load. However, There Is Evidence That Art Is Associated With Lipodystrophy Syndrome ,A Disturbance Of Lipid Metabolism Characterized By Insulin Resistance, Dyslipidemia, Fat Maldistribution Usually Presenting As Visceral Abdominal Obesity And Cervical Fat Pad Accumulation[Buffalo Hump][2,5,7,8],Metabolic Bone Disease And Lactic Acidosis. Art Associated Dyslipidemia Is Characterized By Elevated Serum Concentrations Of Total Cholesterol, Triglycerides, Low Density Lipoprotein[Ldl-C],Very Low Density Lipoprotein[Vldl] And Low Levels Of High Density Lipoprotein[Hdl-C], Constituting Atherogenic Lipid Profile[9,10].These Art Induced Lipid Derangements Are Potentially Atherogenic And Can Increase Cardiovascular Risk, Representing A Challenge In Treatment Of Hiv Infection[11,12]. Moreover, Lipodystrophic Body Changes Can Jeopardize The Quality Of Life Of These Patients, Leading To Low Adherence To Art And Subsequent Virologic And Clinical Failure. During The Last Decade, An Increasing Frequency Of Dyslipidemia Has Been Observed Among Art Treated Hiv Positive Patients.

It Is Well Known That Protease Inhibitors Induce Derangement Of Lipid Profile During Art[13-15]. Among Nucleoside Reverse Transcriptase Inhibitors [Nrti], Zidovudine And Stavudine Is Associated With Lipodystrophy Syndrome[16,17]. However Evidence In Support Of Adverse Effect Of Nnrti [Like Efavirenz And Nevirapine] On Lipid Profile In Hiv Patients On Art Is Limited. First Line Haart Regimens As Defined By Who Are Largely Used In Resource Constrained Countries And Do Not Include Protease Inhibitors[18].

Patients In Resource Limited Settings Are More Likely To Have Advanced Hiv Disease And Poor Nutritional Status And To Begin Treatment With Non Protease Inhibitor Based Regimen. Evidence In Support Of Dyslipidemia Associated With First Line Haart In Our Area Is Scarce[19,20]. Thus, Aim Of The Present Study Is To Study Lipid Profile In Hiv Patients In Our Tertiary Care Centre, Started On First Line Art Regimen I.E. Tenofovir, Lamivudine, Efavirenz[Tle] As Per Current Naco Recommendation[21] . And Also To Determine Changes In Its Different Fractions Due To Tle After Six Months Of Therapy.

II. Methods

We Conducted A Prospective Study On 75 Newly Registered Art Naive Hiv-1 Infected Patients Of Age ≥ 15yrs Attending Art Clinic In Our Tertiary Care Centre For A Period Of 18 Months From February 2016 To August 2017. Out Of These 75 Patients, 48 Patients Were Male And 27 Were Females. Patients With Age < 15 Years, Hiv-2 Infection, Pre-Existing Hepatobiliary Disease, Renal Disease, Coronary Heart Disease, Dyslipidemia, History Of Diabetes, Hypertension, Smoking, Alcohol Intake Were Excluded From The Study. Also The Patients Who Were Already On Lipid Lowering Drugs, Oral Contraceptive Pills And Who Had Poor Adherence To Art Were Not Included In The Study. All These Patients Were Started On Fixed Drug Combination Of Tenofovir 300mg, Lamivudine 300mg, Efavirenz 600mg In A Single Pill As Per Current Naco Guidelines. All Patients Underwent Detailed History, Clinical Examination, Routine Blood Investigations,Anthropometric Measurements,Cd4 Count And Lipid Profile Estimation Before And After Six Months Of Initiation Of Art. Patients Were Also Screened For Presence And Type Of Opportunistic Infections. Hiv Was Diagnosed By Elisa. 12 Hours Fasting Lipid Profile Was Analysed Enzymatically By Biosystem Reagents And Kit. Total Cholesterol Was Determined Using Calorimetric Enzymatic Techniques Based On Successive Action Of Cholesterol Oxidase And Peroxidase. Hdl Cholesterol Concentration In The Serum Supernatant Was Determined By The Same Process After Precipitation Of Very Low Density Lipoprotein Cholesterol, Ldl And Chylomicrons. Ldl Cholesterol Concentration Was Determined Using The Formula Of Fridewald Etal[22] (Ldl Cholesterol = Total Cholesterol - Triglyceride/5 - Hdl-C). Dysilipidemia Is Defined As Per Ncep-Atp Iii[23] Guidelines (National Cholesterol Education Programme-Adult Treatment Panel -Iii) As Total Cholesterol ≥ 200mg/Dl, Ldl -C ≥ 130 Mg/Dl, Hdl- C < 40 Mg/Dl ,Triglyceride ≥ 150 Mg/Dl .

For Statistics, Openepi Software Was Used. P Value Was Calculated By Applying Paired Student's T Test And Value < 0.05 Considered As Significant And <0.001 As Highly Significant.

III. Results

We Studied 75 Hiv-1 Positive Patients Who Were Started On Art Regimen, Majority Of The Patients Belonged To The Age Group 30-39 Yrs(40%), Mean Age Of The Sample Was 37.5733±9.73 Yrs.Most Common Occupation Was Housewifery (28%), Most Of The Patients(78.66%) Belonged To Low Socioeconomic Class (66.66% Class Iv And 12% Class V).Most Common Risk Factor Was Heterosexual Contact (80%), Followed By Unsafe Blood Transfusion (6.66%).Majority Of The Subjects Were Either Married Or Widowed And Belonged To Cdc Grade A2.Opportunistic Infections Were Present In 18.6% Of The Patients, Of Which Tuberculosis Was The Most Frequent Accounting For 17.33% Of All Infections. Mean Bmi Of Study Population At Baseline Was 18.9707±2.5547 Kg/M2 With Majority Of Patients(53.33%) Having Normal Bmi(18.5-23). Following 6 Months Of Art, Bmi Changes To 19.43+2.27 Kg/M^2 Showing No Significance(P Value- 0.2433). Majority Of Patients At Baseline Has Cd4 Count <200, Mean Cd4 Count Being 252.7733±161.3364, Following 6 Months Of Art, Mean Cd4 Count Was 377.88± 199.6141 (P Value < 0.001) I.E. Highly Significant. Thus Indicating That Art Led To Significant Improvement In Cd4 Count.Art Therapy(Tle Regimen) Caused Significant Rise In Total Cholesterol From 139.0933± 25.5746 To 173.1200± 49.9846 (P Value < 0.001),Triglycerides From 121.8600 ± 20.8349 To 144.3467±35.2096 (P Value <0.001), Ldl-Cholesterol From 70.8880 ± 28.0759 To 100.5840 ± 50.0037 (P Value < 0.001) After Six Months In Hiv Infected Patients. Mean Hdl-C Before Art Was 43.8360 ± 13.6018(48% Pt Has Hdl-C < 40) , After Art Mean Hdl-C Was 43.2480 ± 13.0469 (44% Pt Has Hdl-C < 40) With P Value Being 0.7874. Thus ,Art Had No Significant Effect On Hdl-C Level (P Value > 0.05).

Table 1 :Distribution Of Study Subjects As Per The Total Cholesterol Before Start Of Art(N = 75)

Cholesterol Level	Frequency	Percent
<200	75	100%

>200	0	0%
Total	75	100%
Mean-139.0933, Sd-25.5746, Range- 91-199		

Table 2 :Distribution Of Study Subjects As Per The Total Cholesterol After Six Months Of Art (N = 75)

Cholesterol Level	Frequency	Percent
<200	44	58.66%
>200	31	41.33%
Total	75	100%
Mean-173.1200, Sd-49.9846, Range- 94-251		

Table 3 : Distribution Of Study Subjects As Per The Triglyceride Before Start Of Art(N = 75)

Triglyceride Level	Frequency	Percent
<150	75	100%
>150	0	0%
Total	75	100%
Mean-121.8600, Sd-20.8349, Range- 61.5-148		

Table 4 : Distribution Of Study Subjects As Per The Triglyceride Level After Six Months Of Art (N = 75)

Triglyceride Level	Frequency	Percent
<150	48	64%
>150	27	36%
Total	75	100%
Mean-144.3467, Sd-35.2096, Range- 92-206		

Table 5 : Distribution Of Study Subjects As Per The Hdl Cholesterol Before Start Of Art(N = 75)

Hdl Cholesterol Level	Frequency	Percent
<40	36	48%
>40	39	52%
Total	75	100%
Mean-43.8360, Sd-13.6018, Range- 18-75		

Table 6 :Distribution Of Study Subjects As Per The Hdl Cholesterol After Six Months Of Art(N = 75)

Hdl Cholesterol Level	Frequency	Percent
<40	33	44%
>40	42	56%
Total	75	100%
Mean-43.2480, Sd-13.0469, Range- 12.6-74		

Table 7 : Distribution Of Study Subjects As Per The Ldl Cholesterol Before Start Of Art (N = 75)

Ldl Cholesterol Level	Frequency	Percent
<130	74	98.66%
>130	1	1.33%
Total	75	100%
Mean-70.8880, Sd-28.0759, Range- 16.4 – 148.9		

Table 8 : Distribution Of Study Subjects As Per The Ldl Cholesterol After Six Months Of Art (N = 75)

Ldl Cholesterol Level	Frequency	Percent
<130	47	62.66%
>130	28	37.33%
Total	75	100%
Mean-100.5840, Sd-54.0037, Range- 7.2 – 202.3000		

Table 9 : Effect Of Art On Total Cholesterol

Total Cholesterol	**Sample Size**	**Mean**	**Standard Deviation**
Before Start Of Art	75	139.0933	25.5746
After Art	75	173.1200	49.9846
T-Statistics – 5.24833, Df – 110, P Value – 0.000000754 (P Value- <0.001 Highly Significant)			

Table 10 : Effect Of Art On Triglyceride

Triglyceride Level	**Sample Size**	**Mean**	**Standard Deviation**
Before Start Of Art	75	121.8600	20.8349
After Art	75	144.3467	35.2096
T-Statistics – 4.75996, Df – 120, P Value – 0.000005458 (P Value- <0.001, Highly Significant)			

Table 11: Effect Of Art On Hdl Cholesterol

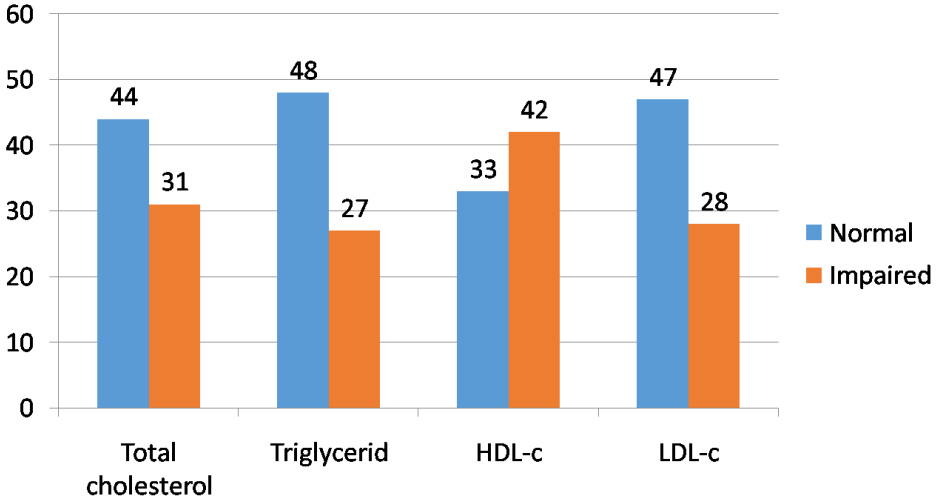
Hdl Cholesterol	**Sample Size**	**Mean**	**Standard Deviation**
Before Start Of Art	75	43.8360	13.6018
After Art	75	43.2480	13.0469
T-Statistics – 0.27018, Df – 148, P Value- 0.7874			

Table 12 : Effect Of Art On Ldl Cholesterol

Ldl Cholesterol	**Sample Size**	**Mean**	**Standard Deviation**
Before Start Of Art	75	70.8880	28.0759

After Art	75	100.5840	54.0037
T-Statistics – 4.22527, Df – 111, P Value- 0.00004913(P Value- <0.001, Highly Significant)			

Changes In Different Fraction Of Lipid Profile After 6 Months Of Art



IV. Discussion

Several Studies Have Suggested That Antiretroviral Therapy(Art) Causes Derangement In Lipid Profile. This Hospital Based Observational Prospective Study Was Conducted In Our Institute Jah Group Of Hospitals, G.R.M.C, Gwalior During The Period Between February 2016 And August 2017. A Total Of 75 Hiv-1 Patients Started On First Line Art(Tle Regimen) Attending Art Clinic Were Studied. Mean Cd4 Count Of Study Population At The Start Of Study Was 252.7733 ± 161.3364. After Six Months Of Art The Cd4 Count Improved Such That Mean Cd4 Count Of The Study Population Is 377.88 ± 199.6141 Indicating That Art Led To Significant Improvement In Cd4 Count Of Hiv Patients(P-Value < 0.001). At The Baseline Total Cholesterol, Triglyceride Were Within Normal Limits. Ldl Cholesterol Level Was Within Normal Limits In Majority Of Patients (98.67%) Except 1.33% Patients Who Already Had Abnormal Ldl Cholesterol Level Before Initiation Of Art. 48% Patients Had Abnormal Hdl Cholesterol Level (Ie.<40 Mg/Dl) At Baseline. At Baseline, Mean Cholesterol Level Was 139.0933 ± 25.5746, Mean Triglyceride Level Was 121.8600 ± 20.8349, Mean Hdl Cholesterol Level Was 43.8360 ± 13.6018, Mean Ldl Cholesterol Level Was 70.8880 ± 28.0759. Following Six Months Of Art, Mean Cholesterol Level Was 173.1200 ± 49.9846, Mean Triglyceride Level Was 144.3467 ± 35.2096, Mean Hdl Cholesterol Level Was 43.2480 ± 13.0469, Mean Ldl Cholesterol Level Was 100.5840 ± 54.0037. There Is Significant Increase In Total Cholesterol Level (41.33% Patients, P-Value < 0.001), Triglyceride Level (36% Patients, P-Value<0.001), Ldl Cholesterol Level (37.33% Patients, P-Value<0.001). Art Doesn't Caused Significant Rise In Hdl Cholesterol Level(P-Value = 0.7874, Ie >0.05).

These Findings Were Similar To Previous Studies Such As Conducted By Bekelo Et Al[24] Who Found That Patients Who Received Nnrti Based Regimen For Atleast Six Months Has Significantly Raised Cholesterol, Triglycerides, Ldl Cholesterol(P Value <0.05), Decreased Hdl- Cholesterol In Cameroon. One Study Conducted By Indumati Et Al[25] In Patients Who Received First Line Art Regimen(Stavudine/Zidovudine+ Lamivudine+ Nevirapine) For !2 Months Found No Changes In Hdl-C After Art.But Significant Rise In Serum Cholesterol, Triglycerides, Ldl Cholesterol When Patient Was Receiving Art Regimen Where One Of Drug Belong To Nnrti Class. Priyadarshini C Et Al[26] Found Raised Hdl-C In Tuberculosis Patients On Nnrti Containing Regimen. Other Lipid Abnormality Like Raised Total Cholesterol, Triglycerides, Ldl-Cholesterol Were Same As Other Studies. Bapilal Et Al[19] Found That Lipid Abnormalities Such As Elevated Total Cholesterol, Triglyceride, Ldl Cholesterol And Hdl Cholesterol Level Occur In Patients On Art As Early As 6 Months And That Too Significant Where One Of Class Of Patients Received Nnrti Based Regimen.

V. Conclusion

Based On This Study, We Conclude That Art Therapy Including Nnrti Based Regimen Caused Significant Lipid Abnormalities I.E. Raised Total Cholesterol, Triglycerides, Ldl-Cholesterol In Hiv Infected Patients After 6 Months Of Therapy. Thus Laying Emphasis On Need To Assess Lipid Profile At Beginning, Before Initiation Of Art And Monitor Any Rising Trend In Lipid Profile After 6 Months. These Lipid Abnormalities Predisposes These Patients To Development Of Cardiovascular Complications And Therefore Should Be Monitored For Allowing Early Intervention.

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