Section: General Medicine

Original Research Article

A COMPARISON OF FASTING LIPID PROFILE IN LIVING DONOR RENAL TRANSPLANT RECIPIENTS WITH THEIR PRE TRANSPLANT VALUES

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Abstract

Background: Dyslipidemia has been a major problem in Renal Transplant Recipients. The association of dyslipidemia with atherosclerotic cardiovascular diseases are well known, which are actually the major cause of death post-transplant. Dying with an intact graft can be prevented by screening for dyslipidemia and timely therapeutic intervention. The objectives of the study were to compare the lipid profile post transplantation with pre transplant values and to assess the factors contributing to the dyslipidemia post-transplant. **Materials and Methods:** The study was conducted as a cross-sectional analysis with review of old records. All the renal transplant recipients attending the Nephrology Department, Govt. Medical College, Kottayam for a time period of 10 months duration, who satisfied the inclusion criteria and the exclusion criteria were enrolled in the study. Participants were interviewed and data entered in pre structured proforma. Fasting lipid profile was done and compared with the pre transplant values. **Result & Conclusion:** 27 patients were available for the comparison of which 8 were on lipid lowering drugs. The analysis was initially done in the non-statin group. The variables showing significant differences were studied in the total study population also. Statistically significant increase was found in the total cholesterol, LDL-C, VLDL-C and Non-HDL-C values post-transplant. HDL-C, Triglyceride, LDL/HDL ratio and TC/HDL ratio failed to show any statistically significant change between the 2 groups. The triglyceride, VLDL-C, LDL/HDL and TC/HDL levels showed significant correlation between the pre transplant and post renal transplantation values which point to the existence of host factors that play a significant role in determining lipid levels. When the statin group was also included, the comparison showed significant increases in total cholesterol, LDL-C and Non-HDL-C post-transplant compared to the pre transplant state. The comparison of lipid profile post-transplant with the pre transplant state in the NODAT group showed significant differences in Total Cholesterol, LDL-C and Non-HDL-C. When the comparison was done in the other group, ie, after excluding NODAT and in the presence of all other risk factors, it failed to show any significant difference in the lipid profile. The VLDL-C which showed significant difference earlier turned insignificant in the absence of NODAT.As NODAT was showing such significant association with dyslipidemia, the comparison was extended into the population taking statins too which also showed significant increases in total cholesterol, LDL-C and Non-HDL-C post renal transplantation when compared to the pre transplant state. Other factors like Body Mass Index and graft dysfunction were also taken into account, but there was no significant change in the lipid values. All of them were on Hemodialysis prior to transplant and the duration of dialysis did not show any influence on the lipid profile. There was significant dyslipidemia post renal transplantation when compared to the pre transplant state even when patients on statins were included for the analysis. New Onset Diabetes After Transplant was the transplant specific risk factor associated with dyslipidemia in our study population. The host specific factors were also responsible in part for the dyslipidemia. Immunosuppressives did not play a significant role in our population for the development of dyslipidemia probably because of the low doses used. The duration post renal transplantation did not show any correlation with dyslipidemia.

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INTRODUCTION

Kidney transplantation is the treatment of choice for end stage renal disease.[1] A successful transplant improves the quality of life and decreases the morbidity and mortality risk for most patients when compared to maintenance hemodialysis.[2-4] However, the patients need closer follow up after surgery because they are on multiple immunosuppressives and are at increased risk of malignancy, infection and cardiovascular disease. In addition they may be having multiple co-morbidities contributing to or associated with end stage renal disease.

Here we focus on the cardiovascular co-morbidity, a major chunk of which can be attributed to dyslipidemia, diabetes mellitus, hypertension and consequent atherosclerosis. Although dyslipidemia and cardiovascular disease are common complications of kidney transplantation, a causal association of lipid abnormalities with cardiovascular risk has not been proven in this patient population.

However, extrapolation from general population studies and some data in kidney transplant patients recognize the need to assess and treat dyslipidemias as part of routine post renal transplant care. Also the risk of rejection and cardiovascular risk must be balanced by the careful titration of immunosuppressive medications.

Due to the high incidence of atherosclerotic disease events in the renal transplant population, several national groups suggest that patients with renal transplants should be considered to be in the highest cardiovascular disease risk group with respect to risk factor management.[5] Kidney transplantation should therefore be considered a coronary heart disease equivalent risk. The prevalence and ability to modify dyslipidemias therefore render lipid modification a potentially important intervention for improving outcomes after kidney transplantation.[6,7]

Acute graft rejection is another complication of hyperlipidemia; it can increase the risk of graft loss 2-fold. Hyperlipidemia also may contribute to chronic allograft nephropathy.

If we critically analyze the death of patients with transplanted kidney, majority of them have had intact grafts. The cause of death is usually ischemic heart disease which is preventable if the risk factors are identified early. Currently there is no definite recommendation for the management of dyslipidemia in this group. We still follow the guidelines for general population. Renal transplantation is a multidisciplinary effort involving the hard work and team work of many people which is futile if we do not have enough precautionary measures to prevent death due to non renal causes.

Dyslipidemia occurs in 45% to 78% of renal transplant recipients, depending on the patient population and the time point after transplant when serum lipids are examined. However, there is a paucity of literature concerning the prevalence and type of lipoprotein abnormality in renal transplant recipients from the Indian sub continent. So this study was a sincere attempt to study the lipid profile in post renal transplant patients and to assess the factors influencing the changes in lipid profile.

Objectives

To compare the fasting lipid profile in patients post renal transplantation with their pre transplant values and to study the factors influencing the change such as

- Immunosuppressive drugs.
- New Onset Diabetes After Transplant.
- Duration Post Transplant.
- Mode of renal replacement therapy pre transplant.
- Graft dysfunction
- Obesity

Hypothesis

There is significant dyslipidemia post renal transplantation compared to the pre transplant state.

MATERIALS AND METHODS

Study Design: Cross sectional analytical study

Study Setting: Out-patient department, Department of Nephrology, Government Medical College, Kottayam.

Sample Size: 27 All patients post renal transplantation who satisfied the inclusion criteria and exclusion criteria were included in the study.

Study Duration: January 2014 to October 2014.

Inclusion Criteria

Living donor renal transplant recipients with a minimum of 3 months duration post-transplant.

Exclusion Criteria

Renal Transplant Recipients who are

- Dialysis dependant after 3 months post transplant.
- Diagnosed to have hereditary dyslipidemia.

Method of Study

Study population was the renal transplant recipients under the regular follow up of Nephrology department,Govt. Medical College Kottayam attending the out patient department within a period of 10 months from January 2014 to October 2014. Written, informed consent were obtained from all subjects after explaining the study procedure in detail. The following details were noted at the time of interview

- Demographic data
- Basic Kidney disease
- Duration and mode of renal replacement therapy before transplant
- Antihypertensives used
- Lipid lowering medications used
- Immunosuppressives used and their dose
- Body mass index
- Fasting lipid profile
- Fasting blood sugar
- Serum creatinine

27 living donor renal transplant recipients were enrolled in the study. They were analysed as 2 groups

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based on lipid lowering drug intake. Those on statins constituted 8 and the remaining 19 were not on any lipid lowering drugs. The effect of immunosuppressive drugs, NODAT, duration post-transplant, mode of renal replacement therapy pre transplant, graft dysfunction and obesity were analyzed for the change in lipid profile post transplantation. Those variables which were significant in the non-statin group were studied for their significance in the total 27 patients selected for the comparison.

The pre transplant fasting lipid profile, fasting blood sugar, Serum creatinine, usage of lipid lowering drugs, usage of antihypertensives and diabetic status were obtained from the registries kept in the nephrology department. The main outcome variables included the change in the lipid profile and the risk factors associated with development of lipid abnormalities.

A proforma was filled after interviewing the study sample to assess their life style, basic kidney disease, duration and mode of renal replacement therapy before transplant, medications prescribed, body mass index, fasting lipid profile before and after transplant, fasting blood sugar before and after transplant, other diseases contributing to dyslipidemia and GFR before and after transplant. A measuring tape was used to measure the height of the subjects and a weighing machine was used to measure the body weight. The Fasting lipid profile was done after a 12 hour fast. The triglycerides, total cholesterol and HDL cholesterol were measured by enzymatic techniques. VLDL was calculated as triglyceride/5. LDL-C was calculated using the Friedewald's formula.[8] The Fasting Blood sugar was measured by glucose oxidase peroxidase method and serum creatinine was measured by Jaffe's method from the Biochemistry lab of Govt. Medical College, Kottayam.

Definitions: Hypercholesterolemia is defined as total cholesterol ≥200 mg/dL or low-density lipoproteins ≥100 mg/dL, and hypertriglyceridemia as triglycerides ≥150 mg/dL. A low high-density lipoprotein is defined on values <40 mg/dL for men and <50 mg/dL for women. A high non HDL cholesterol is defined on values ≥130mg/dL. The low-density lipoprotein/high-density lipoprotein ratio (abnormal > 3.0) and the total cholesterol/high-density lipoprotein ratio (abnormal > 4.0) are also defined based on the Adult Treatment Panel- III guidelines.[9]

BODY MASS INDEX(BMI)

The WHO guidelines for South Asian population classifies BMI as follows:

- <17.5 kg/m2-under weight
- 17.5-22.99-normal weight
- 23-27.99-over weight
- ≥28 kg/m2-obese

New Onset Diabetes After Transplant

Fasting Blood Sugar ≥126mg/dl was taken as NODAT

Estimated Glomerular Filtration Rate(eGFR)

It was calculated using the Modification of Diet in Renal Disease (MDRD) equation.

eGFR = 186 x serum creatinine-1.154 x age-0.203 x [1.210 if black] x [0.742 if female]

Statistical Analysis

Data were entered in Microsoft excel spread sheet and analyzed statistically using SPSS (Statistical Program for Social Science, Version 16) software for windows.

Quantitative data were analysed using Independent T test, Anova test, Pearson Correlation test and Paired Samples T test.

Significance of association was analyzed by calculating 'p' value which was considered significant when less than .05.

RESULTS

The objective of the study was to compare the fasting lipid profile post renal transplantation with the pre transplant state and to study the factors influencing the change.27 patients were available for the comparison of which 8 were on lipid lowering drugs(statins). The analysis was initially done in the non-statin group. The variables showing significant differences were studied in the total study population also.

Statistically significant increase was found in the total cholesterol values post-transplant in the non-statin group.The mean TC value pre transplant was 162.05 (SD=25.7) and post-transplant mean was 199.53(SD=49.7). The mean difference was 37.47(SD=53.5) with a p value of .007.

Comparison of LDL-C also revealed statistically significant increase in the post transplant state. The mean value pre transplant was 98.95(SD=37.3) and post transplant mean was 124.53 mg/dl (SD=22.1). The mean difference was 25.58(SD=39.3) with a p value of .011.

The VLDL-C values also showed statistically significant increase post transplant.The mean pre transplant value was 19.84mg/dl(SD=8.33) and post transplant mean was 25.74(SD=13.15).The mean difference was 5.89(SD=11.39) with a p value of .037.

There was also significant increase in the Non HDL-C values post transplant compared to the pre transplant state. The mean value was 118.26(SD=24.23) pre transplant and 150.26(SD=47.58) post transplant. The mean difference was 32(SD=44.79) with a p value of .006.[Table 1]

HDL-C,Triglyceride,LDL/HDL ratio and TC/HDL ratio failed to show any statistically significant change between the 2 groups.

Another interesting finding was that triglyceride, VLDL-C, LDL/HDL and TC/HDL showed significant correlation between the pre transplant and post renal transplantation values in patients who were

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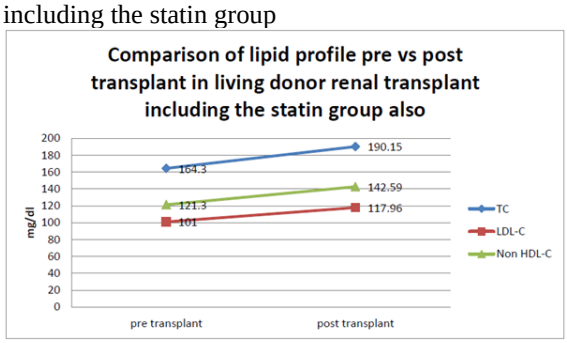
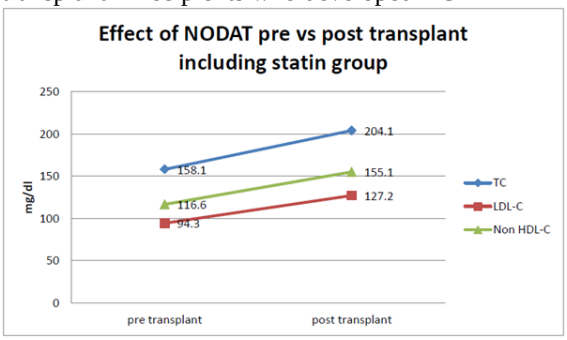
not on statins, which point to the existence of host factors (environmental or genetic predisposition) that play a significant role in determining lipid levels. This was assessed using the Pearson correlation test.
When the statin group was also included,the comparison showed significant increases in total cholesterol,LDL-C and Non HDL-C post transplant compared to the pre transplant state[Table 2, Figure 1]

Figure 1 : Comparison of lipid profile pre vs post transplant in living donor renal transplant recipients including the statin group



Our next aim was to study the factors responsible for the dyslipidemia post renal transplant. Among the transplant specific risk factors, immunosuppressive drugs, new onset diabetes after transplant and duration post transplant were the comparable ones in our study population.
The comparison was not possible in immunosuppressive usage because most of them were on prednisolone, tacrolimus and mycophenolic acid and thus there was not a comparable group.
The comparison of lipid profile in the NODAT group was done in those patients who were not on lipid lowering drug [Table 3-5]. The comparison of lipid profile post transplant with the pre transplant state in the NODAT group showed significant differences in Total Cholesterol, LDL-C and Non HDL-C.
When the comparison was done in the other group, ie, after excluding NODAT and in the presence of all other risk factors, it failed to show any significant difference in the lipid profile. The VLDL-C which showed significant difference earlier turned insignificant in the absence of NODAT [Table 6].
As NODAT was showing such significant association with dyslipidemia, the comparison was extended into the population taking statins too which also showed significant increases in total cholesterol, LDL-C and Non HDL-C post renal transplantation when compared to the pre transplant state [Table 7][Figure 2]

Figure 2 : Comparison of lipid profile pre vs post transplant in recipients who developed NODAT



Similar comparison was made after excluding those with NODAT to assess the influence of other factors, which showed no significant difference [Table 8]
Here, the TC,LDL-C and Non HDL-C which were previously having significant difference had turned insignificant when NODAT was excluded. This also shows the impact of NODAT on the increase in TC, LDL-C and Non HDL- C post living donor renal transplantation compared to the pre transplant state.
Other factors like Body Mass Index and graft dysfunction were also taken into account. The comparison was done in those with BMI $\geq$ 23kg/m2 and also in those with eGFR $\leq$ 60 ml/min/1.73m2 but there was no significant change in the lipid values. All of them were on Hemodialysis prior to transplant and the duration of dialysis did not show any influence on the lipid profile.

Table 1: Table showing the correlation of lipid values pre and post renal transplant in the non statin group.

Lipid type	Sample size	Correlation	Significance (p value)
Triglyceride	19	.469	.043
VLDL	19	.514	.024
LDL/HDL	19	.532	.019
TC/HDL	19	.585	.009

Table 2: Table comparing the lipid profile in living donor renal transplant after including the statin group also.

Lipid profile	Mean(mg/dl)	SD	N	Mean difference	p-value
TC	190.15	46.06	27	25.85	.018
Pre TC	164.30	29.76			
LDL-C	117.96	35.05		16.96	.039
Pre LDL-C	101.00	22.94			
Non HDL-C	142.59	43.85		21.29	.023
Pre Non HDL-C	121.30	25.58			

Table 3: Comparison of total cholesterol in the NODAT group in patients who were not on lipid lowering drug

TC	Mean	N	Std. Deviation	Mean difference	Significance
TC	220.29	7	53.38	67.28	.011
Pre TC	153.00	7	17.08		

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Table 4: Comparison of LDL cholesterol in the NODAT group in patients who were not on lipid lowering drug

LDL-C	Mean	N	Std. Deviation	Mean difference	Significance
LDL-C	141.00	7	42.91	50.42	.011
Pre LDL-C	90.57	7	11.83		

Table 5: Comparison of non HDLcholesterol in the NODAT group in patients who were not on lipid lowering drug

Non-HDL-C	Mean	N	Std. Deviation	Mean difference	Significance
Non-HDL-C	170.00	7	54.55	56.71	.013
Pre-Non HDL- C	113.29	7	20.12		

Table 6: Comparison of lipid profile in patients without NODAT who were not on lipid lowering drug

LIPID PROFILE	Mean	SD	N	Mean difference	p-value
TC	187.42	45.4	12	20.08	.188
Pre TC	167.33	28.9			
LDL-C	114.92	31.6		11.08	.287
Pre LDL-C	103.83	25.5			
VLDL-C	23.83	11.6		5.67	.158
Pre VLDL-C	18.17	6.6			
Non HDL-C	138.75	41.1		17.58	.164
Pre Non HDL-C	121.17	26.7			

Table 7: Comparison of lipid profile in patients with NODAT including those who were on lipid lowering drug

NODAT	Mean(mg/dl)	SD	N	Mean difference	P value
Pre TC Post TC	158.1	32.28	10	45.2	.038
	204.1	53.47			
Pre LDL-C Post LDL-C	94.3	18.64		32.9	.037
	127.2	42.5			
Pre Non HDLC Post Non HDLC	116.6	22.8		38.5	.028
	155.1	53.03			

Table 8: Comparison of lipid profile in patients without NODAT including those who were on lipid lowering drug

Lipid profile	Mean	SD	N	Mean difference	p-value
TC	181.94	40.58	17	14.47	.233
Pre TC	167.47	28.71			
LDL-C	112.53	29.88		7.58	.414
Pre LDL-C	104.94	24.79			
Non HDL-C	135.24	37.25		11.17	.309
Pre Non HDL-C	124.06	27.37			

DISCUSSION

The objective of the study was to compare the fasting lipid profile post renal transplantation with the pre transplant values. The comparison was done in 27 living donor renal transplant recipients. The group was again sub divided into those on statin and those not on any lipid lowering drug. The statin group constituted 8 and 19 belonged to the other.

There were significant increases in the total cholesterol values post renal transplantation compared to the pre transplant state even when the statin group was also included. There were also statistically significant increases in LDL-C and Non HDL-C in our study population. These were above the recommended levels in patients not on statins. So there is significant dyslipidemia in the form of elevated LDL-C and Non HDL-C. The triglyceride, VLDL-C, LDL/HDL ratio and TC/HDL ratio showed significant positive correlation between the 2 groups in the non statin population. The differences in HDL and triglycerides were insignificant. The HDL value actually showed an increase.

A study conducted by Razeghi et al,[10] comparing the lipid profile pre and post transplant also supports this finding. One interesting finding was that even though the total cholesterol value showed significant increase post transplantation, the mean value post transplant was normal. All of our living donor transplant patients were on hemodialysis prior to transplant. ESRD on dialysis is a malnourished state and this can lead to decrease in total cholesterol values. This finding is supported by a study by Appel G et al,[15] named "Lipid abnormalities in renal disease" published in Kidney International in 1991, which states that there is significant decrease in the total cholesterol values in ESRD patients on dialysis due to malnutririon.

Another study named "Lipid disturbances in a 2 year follow up after a successful kidney transplantation"

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published in Transplantation proceedings in 2000 by E.Kisielnicka et al,[16] found that hypercholesterolemia was sustained for 2 years post renal transplantation with a peak at month 3 with a tendency to decline after that. Differences between the transplanted and healthy control groups were significant. The triglyceride and LDL-C did not show any significant difference in their comparison between pre transplant and post transplant lipid profile. The peak values of LDL was observed at the end of third month post transplantation.

The HDL levels were significantly higher when compared to the pre transplant state and this was due to low HDL levels pre transplant. The patients were on cyclosporine, prednisolone and azathioprine, while majority of our study population were on tacrolimus and mycophenolic acid along with prednisolone. Tacrolimus is a less dyslipidemic drug compared to cyclosporine. This might also have contributed to the changes in our study.

We excluded patients less than 3 months post transplant. This might be the reason why total cholesterol still fell within the recommended level. The triglyceride levels showed a significant positive correlation because ESRD itself is a hyper triglyceridemic state. This may have been the reason why triglyceride levels showed no significant difference between the 2 groups.

Our study also showed an increase in HDL levels, but it was not significant. The increase may have been due to the decrease in HDL-C in ESRD. The mean HDL-C pre transplant in our study was less than 40 mg/dl. This may be the same reason for no significant increase in LDL/HDL and TC/HDL even though TC and LDL showed a significant increase post transplantation. A study by Lo JC,Chandra M et al published in American journal of kidney disease reports a low HDL-C in CKD patients on dialysis.[17]

Our study also showed that new onset diabetes after transplant(NODAT) was the transplant specific risk factor associated with the increase in TC,LDL-C and Non HDL-C.The study by E.Kisielnicka et al also found that the corticosteroids and cyclosporine were the major cuprit. Their study sample included the immediate 3 months post transplant patients also. The peak cholesterol and LDL-C values were observed during this period which subsequently diminished. Here we excluded the above said population from our study. So the influence of immunosuppressive medications were less in our population. Also tacrolimus is known to cause NODAT and NODAT was seen in 37% of the living donor transplant group compared.

The new diabetes might have played its role in altering the lipid profile. Diabetes is well known to increase the atherogenic small dense LDL and triglycerides and decrease the HDL fraction. Due to the ESRD prior to transplant, the triglycerides were elevated and HDL was decreased. So during the comparison study, there were no significant differences between the 2 groups. Our study population had elevated LDL-C and Non HDL-C,which is concurrent with the pattern in diabetes. Mathew JT et al,[12] Phuong Thu T Pham et al,[13] studied NODAT and its risk
factors and consequences which proposes corticosteroids, calcineurin inhibitors, Hepatitis C infection, Cytomegalovirus infection and weight gain as the major factors responsible for diabetes post transplant and there was elevation in Total cholesterol, LDL-C, triglycerides, Non HDL-C and decrease in HDL-C.

In a study published in British Medical Journal in 1999 named “Lipid abnormalities after renal transplantation” by Daniel C Brennan, Mohamed H Sayegh et al, they observed that the hyperlipidemia was clearly correlating with cyclosporine use more than tacrolimus. Also cyclosporine was associated with hypomagnesemia which can lead onto diabetes, hypertension and dyslipidemia. There was also significant association of cyclosporine use with cardiovascular complications.

Another study conducted at Armed Forces Medical College Pune by Lt Col KV Baligaet al,[11] published in 2002 in MJAFI named “Lipid profile in transplant patients: A Clinical Study” reported that the transplant group had significantly higher LDL and Total cholesterol values. They also found a significant inverse correlation between duration post transplant and triglyceride and total cholesterol levels.

“Lipid profile before and after renal transplantation-a longitudinal study” by Pannu HS et al,[14] conducted at Dayanand medical college and hospital, Ludhiana published in Renal Failure 2003 showed significant elevation in the lipids and lipoproteins after renal transplantation and immunosuppressive drugs seemed to be the culprit.

“Association between pre kidney transplant risk factors and post transplant cardiovascular events and death” a study by Aalten J et al published in Renal Failure 2003 also showed significant association of dyslipidemia with cardiovascular complications and graft dysfunction.

So in general almost all the available studies were showing significant increase in TC,LDL-C and Non HDL-C post transplantation compared to the pre transplant state and was going hand in hand with our study.

CONCLUSION

There was significant dyslipidemia post renal transplantation when compared to the pre transplant state in living donor renal transplant recipients even when patients on statins were included for the analysis.

New Onset Diabetes After Transplant was the transplant specific risk factor associated with dyslipidemia in our study population.

The host specific factors were also responsible in part for the dyslipidemia.

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Immunosuppressives did not play a significant role in our population for the development of dyslipidemia probably because of the low doses used.
The duration post renal transplantation did not show any correlation with dyslipidemia.

Limitations

- The most important limitation of the study was the sample size. The surgery was not a day to day affair in our hospital. So including 27 patients itself was a hectic task considering the duration of study.
- A longitudinal study would have been better for comparison of lipid profile pre and post transplant.The lipid profile post transplant was not studied after a fixed period post transplant.
- Scarcity of studies from South India for a genuine comparison.
- The influence of diet and exercise on the lipid profile could not be studied because most of the patients were leading a sedentary life.

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