

## A Study on the Lipid Lowering Effect of Coenzyme Q 10 in Dyslipidaemic Patients who Underwent Percutaneous Transluminal Coronary Angioplasty and receive Atorvastatin Therapy

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### ABSTRACT

The trial was conducted to study the lipid lowering effect of Coenzyme Q 10. It was a randomized controlled trial. Patients who underwent PTCA and receiving atorvastatin therapy were enrolled for the study. Totally 104 patients were enrolled. All the patients enrolled for the study were divided in to two groups at random and categorized as Group 1 and Group 2. The baseline serum lipid profile was measured for all the 104 patients and documented on the patient data sheet. Then Group 1 was given Atorvastatin 40 mg/day as they were already taking that along with drugs for diabetes and/or hypertension. Group 2 patients additionally received Coenzyme Q 10 30 mg/day orally. Both the groups of patients were monitored for compliance, and for ADRs and side effects. At the end of 3 months the lipid profile of the patients were measured again as the end point. Then the lipid profiles of Group 1 were compared with those of Group 2. The results showed that the percentage reduction in serum total cholesterol, LDL, VLDL and Triglycerides, were much higher in Group 2, compared to Group 1. The percentage increase in serum HDL level was much higher in Group 2, compared to Group 1. The study gives a strong evidence for the lipid lowering action of Coenzyme Q 10.

**Keywords:** Atorvastatin, cholesterol, coenzyme Q 10, HDL, lipid profile

Received 28 June 2013

Received in revised form 29 July 2013

Accepted 08 August 2013

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### INTRODUCTION

Atorvastatin is the lipid lowering drug which is widely used in dyslipidaemic patients. Every drug has its own pattern of causing ADRs and side effects. Likewise Atorvastatin also causes various ADRs and side effects. The most serious of them are myalgia and rhabdomyolysis. Atorvastatin has a number of pleiotropic effects on the body, but its ADRs and side effects make a situation such that, a drug or a food supplement which possesses lipid lowering effect in dyslipidaemic patients should be identified.

Coenzyme Q 10, a known antioxidant, is a bio-product which is synthesized in the body through the mevalonate pathway. Atorvastatin inhibits cholesterol synthesis in the body by blocking the mevalonate pathway at a particular point. This also results in Coenzyme Q 10 deficiency in the body [1].

Further, few pharmacological studies show that Coenzyme Q 10 has lipid lowering activity [2, 3]. So, it became necessary to perform this study to find whether actually Coenzyme Q 10 has lipid lowering effect.

A lot of studies have been performed on Coenzyme Q 10 alone, rather on the combination therapy with Atorvastatin, but very few are there.

In 2007, Giuseppe Caso and his colleagues performed a preliminary study on the effect of coenzyme Q 10 on statin induced myalgia [4]. In the year 2004, Flint Beal and his colleagues studied the effect of coenzyme Q 10 on the striatal lesions produced by the mitochondrial toxin, malonate [5]. Rozen-et-al, in the year 2002, studied the Migraine preventive effect of coenzyme Q 10 [6].

Yamagami, Langsjoen, and Singh-et-al studied the antihypertensive effect of coenzyme Q 10 [7]. Thibault-et-al, in the

year 1996, and Kim-et-al, in 2001, reported that patients taking lovastatin (Mevacor) at dosages to inhibit tumour growth achieved symptomatic relief of statin-induced musculoskeletal toxicity after coenzyme Q10 supplementation [8]. In 2007, Young-et-al studied the effect of coenzyme Q 10 on statin induced myalgia [9]. Folkers and his co-workers, in 1982, studied the effect of coenzyme Q 10 on the Immune function [10]. Folkers-et-al, in 1988, studied the effect of coenzyme Q 10 in AIDS patients, in the blood levels of CoQ10 were significantly lower in patients with AIDS related complex (ARC) than in a control group, and were significantly lower in patients with AIDS than in those with ARC [10]. Lockwood-et-al in 1994 studied the effect of coenzyme Q 10 in Breast cancer patients [11].

Wilkinson-et-al, in 1975, studied the effect of coenzyme Q 10 on periodontal disease [10]. Van Gaal and his colleagues, in 1984, studied the effect of coenzyme Q 10 on Obesity [12]. Vanfraecchem-et-al, in 1981, studied the effect of coenzyme Q 10 on Physical performance [12]. In 1985, Folkers-et-al studied the effect of coenzyme Q 10 on Muscular dystrophy [13].

Safarinejad and coworkers, in the year 2009, studied the effect of coenzyme Q 10 on semen parameters, sperm function and reproductive hormones in infertile men [14]. Kocharian-et-al, in 2009, studied the effect of coenzyme Q 10 on diastolic function in children with idiopathic dilated cardiomyopathy [15]. Hamilton and colleagues, in 2009, studied the effect of coenzyme Q 10 on endothelial dysfunction in statin-treated type 2 diabetic patients [16].

Dr. Shultz and colleagues, in the year 2002, conducted a pilot study on the effect of coenzyme Q 10 on patients with Parkinson's disease [17].

#### **Objectives of the study:**

The objectives of this study were

1. To find whether Coenzyme Q 10 has lipid lowering effect in dyslipidaemic patients who underwent Percutaneous Transluminal Coronary Angioplasty (PTCA) and receive Atorvastatin therapy.
2. To compare the level of changes in the serum lipid levels between a group treated without Coenzyme Q 10 (Group

1) and a group treated with Coenzyme Q 10 (Group 2).

#### **MATERIALS AND METHODS**

This study was performed in the cardiology department of Meenakshi Mission Hospital and Research Centre (MMHRC), Madurai, under the co-guidance of Dr. S. Selvamani, M.D., DNB (internal medicine), DNB (cardiology) [interventional cardiologist]. Approval from the Ethics Committee and consent from the enrolled patients were obtained before the start of the study.

**Design of Study:** Randomized Controlled Study.

**Sample Size:** 104 patients

**Study Duration:** 3 months (90 days)

**No. of Groups:** 2

#### **Drugs Used:**

Group 1 (52 patients): Atorvastatin 40 mg/day (Storvas 40 mg tablets)

Group 2 (52 patients): Atorvastatin 40 mg/day + Coenzyme Q 10 30 mg/day (CoQ 30 soft gelatin capsules)

Parameter Measured: Serum Lipid Profile

#### **Inclusion Criteria:**

1. Patients who had serum lipid levels  
Total Cholesterol > 200 mg/dL  
LDL > 130 mg/dL  
HDL < 35 mg/dL  
Triglycerides > 170 mg/dL  
VLDL > 36 mg/dL
2. Patients who underwent PTCA within one year before the start of the study.
3. The patients who take Atorvastatin 40 mg/day.
4. Patients whose age was in the range 42 to 73 years.
5. Both Diabetic and Hypertensive patients were also included.

#### **Exclusion Criteria:**

1. Patients allergic to Atorvastatin.
2. Smokers
3. Pregnant and lactating women.
4. Patients who had any cardiac events after PTCA.
5. Patients with Arrhythmias and Congestive Heart Failure.
6. Patients taking any antioxidant like Vitamin E, omega-3 fatty acids...

#### **METHODOLOGY**

All the 104 patients enrolled for the study were divided in to two groups randomly. Group1 and Group2, 52 patients each. The patients were tested for all parameters of

blood; also they were subjected to Ultrasound Scanning to ensure that the patients were not having any infectious. Then the baseline lipid profile was taken for all the 104 patients and documented. Then Group 1 was given Atorvastatin 40 mg/day as they were already taking that along with drugs for diabetes and/or hypertension. Group 2 patients additionally received Coenzyme Q 10 30 mg/day orally. Both the groups of patients were monitored for compliance, and for ADRs and side effects. At the end of 3 months the lipid profile of the patients were taken again as the end point. Then the lipid profiles of Group 1 were compared with those of Group 2.

**Statistical Tool**

All the data were recorded in the Master Chart. The Data Analysis was done using

GraphPad InStat DTCG (GPI v 3.0). Mean, Standard Deviation, Student unpaired t-test and 'p' values were calculated for quantitative variables. The 'p' values were two-tailed and obtained by using the student's unpaired t-test, with the standard deviations of each value to be different. The 'p' value less than 0.05 was considered to imply a significant relationship.

The comparative charts were drawn using the mean of the values of different parameters.

**RESULTS**

**Changes in Lipid Profile:**

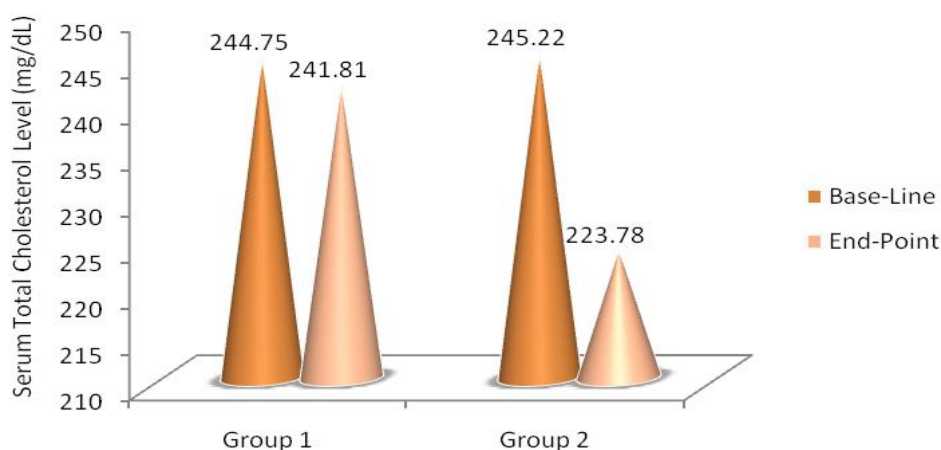
**Changes in Serum Total Cholesterol Level:**

(Fig.1) and (Table 1) imply that the Mean change in serum total cholesterol level in Group 1 was insignificant and that of Group 2 was significant.

**Table 1: Changes in Serum Total Cholesterol Level**

Study Groups	Serum Total Cholesterol (mg/dL) [mean]		'p' value
	Base-line	End-point	
Group 1: Atorvastatin 40 mg/day	244.75 ± 22.97	241.81 ± 22.39	0.7168
Group 2: Atorvastatin 40 mg/day + Coenzyme Q 10	245.22 ± 30.49	223.78 ± 29.29	0.0388

**Figure 1: Statistical Representation of Changes in Serum Total Cholesterol Level**



**Changes in Serum LDL Level**

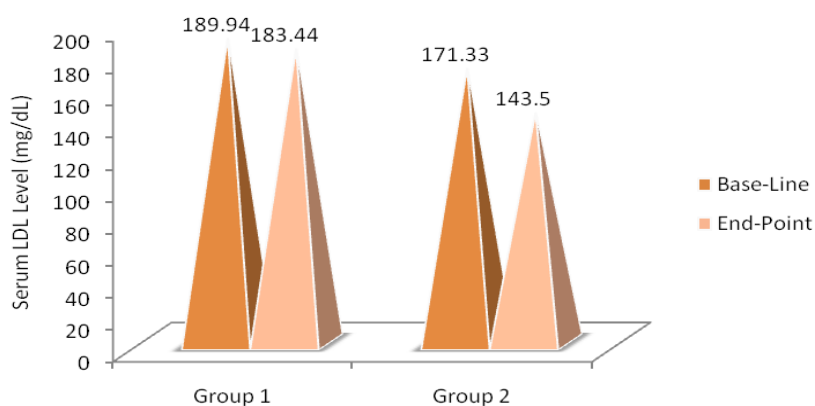
There was decrease in serum LDL level in both Group 1 and 2. Fig.2 and Table 2 imply

that the Mean change in serum LDL level in Group 1 was insignificant and that of Group 2 was significant.

**Table 2: Changes in Serum LDL Level**

Study Groups	Serum LDL (mg/dL) [mean]		'p' value
	Base-line	End-point	
Group 1: Atorvastatin 40 mg/day	189.94 ± 19.93	183.44 ± 20.19	0.3670
Group 2: Atorvastatin 40 mg/day + Coenzyme Q 10	171.33 ± 25.56	143.5 ± 24.61	0.0022

**Figure 2: Statistical Representation of Changes in Serum LDL Level**



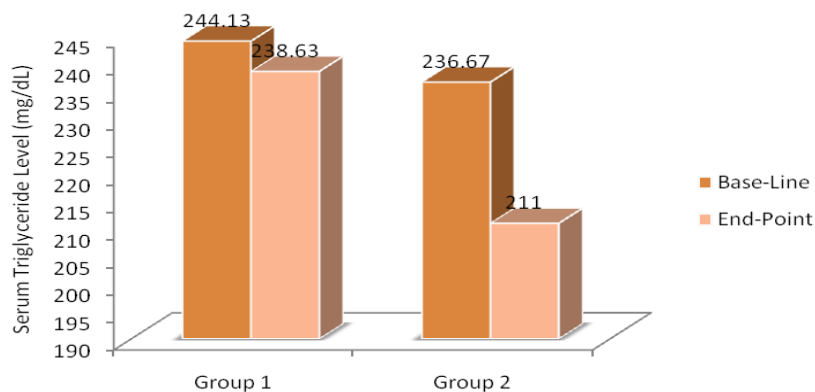
**Changes in Serum Triglyceride Level (Fig.3) and (Table 3)** imply that the Mean

change in serum triglyceride levels in Group 1 and Group 2 were insignificant.

**Table 3: Changes in Serum Triglyceride Level**

Study Groups	Serum Triglycerides (mg/dL) [mean]		'p' value
	Base-line	End-point	
Group 1: Atorvastatin 40 mg/day	244.13 ± 73.36	238.63 ± 72.62	0.8327
Group 2: Atorvastatin 40 mg/day + Coenzyme Q 10	236.67 ± 105.94	211 ± 105.43	0.4714

**Figure 3: Statistical Representation of Changes in Serum Triglyceride Level**



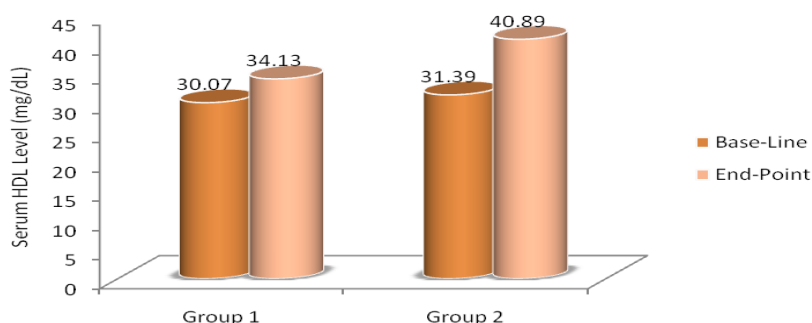
**Changes in Serum HDL Level**  
(Fig. 4) and (Table 4) imply that the Mean change in serum HDL level in Group 1 was

insignificant and that of Group 2 was very significant.

**Table 4: Changes in Serum HDL Level**

Study Groups	Serum HDL (mg/dL) [mean]		'p' value
	Base-line	End-point	
Group 1: Atorvastatin 40 mg/day	30.07 ± 7.01	34.13 ± 7.59	0.1391
Group 2: Atorvastatin 40 mg/day + Coenzyme Q 10	31.39 ± 5.84	40.89 ± 5.22	0.0001

**Figure 4: Statistical Representation of Changes in Serum HDL Level**



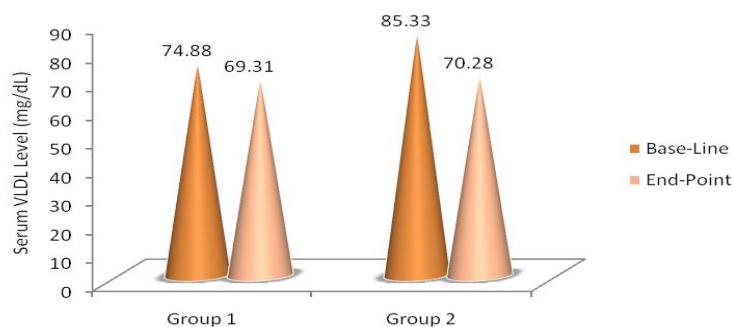
**Changes in Serum VLDL Level**  
VLDL levels decreased in both the groups. Fig.5 and Table 5 imply that the Mean

change in serum VLDL levels in Group 1 and Group 2 were insignificant.

**Table 5: Changes in Serum VLDL Level**

Study Groups	Serum VLDL (mg/dL) [mean]		'p' value
	Base-line	End-point	
Group 1: Atorvastatin 40 mg/day	74.88 ± 34.08	69.31 ± 32.28	0.6391
Group 2: Atorvastatin 40 mg/day + Coenzyme Q 10	85.33 ± 38.67	70.28 ± 38.13	0.2480

**Figure 5: Statistical Representation of Changes in Serum VLDL Level**



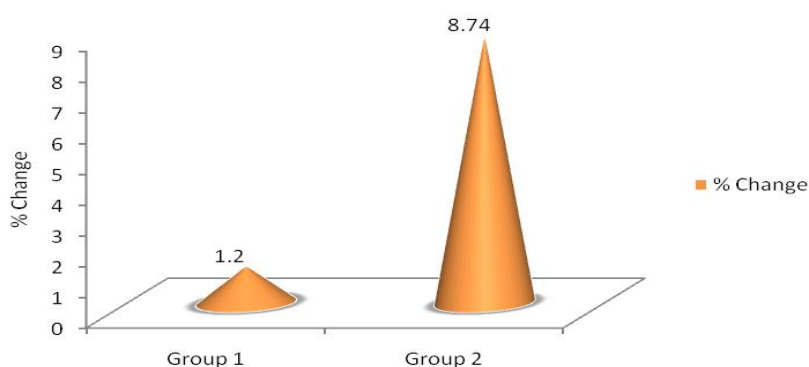
**Comparison of % Changes in Lipid Profile % Changes in serum total cholesterol level** Even though the % reduction in serum total cholesterol level is

much higher in Group 2, compared to Group 1, statistically it was not significant. (Table 6) and (Fig.6) show that.

**Table 6: Comparison of % Changes In Serum Total Cholesterol Level**

Study Groups	Change In Serum Total Cholesterol Level (- ve)		'p' value
	mg/dL (mean)	% change	
Group 1: Atorvastatin 40 mg/day	2.94	1.20	0.0859
Group 2: Atorvastatin 40 mg/day + Coenzyme Q 10 30 mg/day	21.44	8.74	

**Figure 6: Statistical Representation of Comparison of % Changes In Serum Total Cholesterol Level**



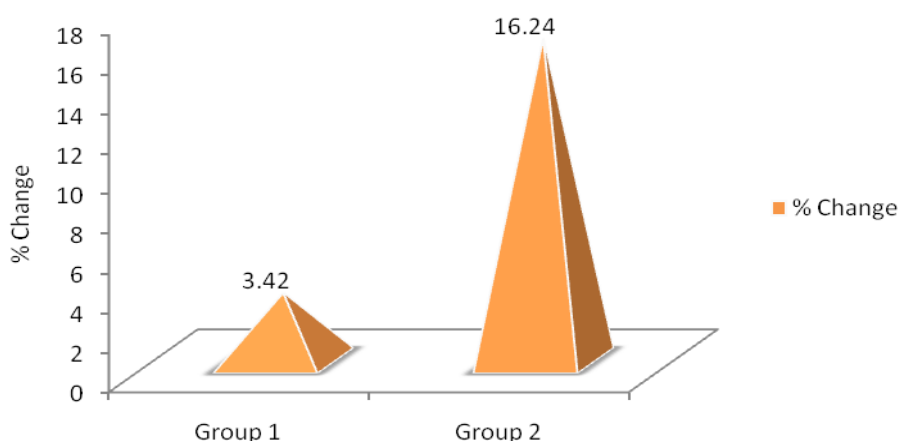
**% Change in serum LDL level**  
The % reduction in serum LDL level is much higher in Group 2, compared to Group 1, but

statistically it was not quite significant. Table 7 and Fig.7 represent that.

**Table 7. Comparison of % Changes In Serum LDL Level**

Study Groups	Change In Serum (- ve)		'p' value
	mg/dL (mean)	% change	
Group 1: Atorvastatin 40 mg/day	6.5	3.42	0.0667
Group 2: Atorvastatin 40 mg/day + Coenzyme Q 10 30 mg/day	27.83	16.24	

**Fig. 7. Statistical Representation of Comparison of % Changes In Serum LDL Level**



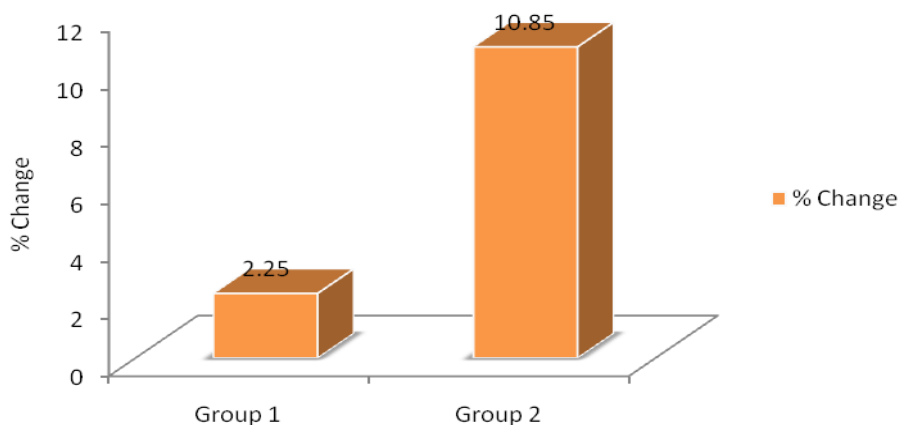
**% Changes in serum triglycerides level**  
 Although the % change in serum triglyceride level is much higher in Group 2,

compared to Group 1, statistically it was not significant. (Table 8) and (Fig.8) show that.

**Table 8: Comparison of % Changes In Serum Triglyceride Level**

Study Groups	Change In Serum (- ve)		'p' value
	mg/dL (mean)	% change	
Group 1: Atorvastatin 40 mg/day	5.5	2.25	0.0737
Group 2: Atorvastatin 40 mg/day + Coenzyme Q 10 30 mg/day	25.67	10.85	

**Figure 8. Statistical Representation of Comparison of % Changes In Serum Triglyceride Level**



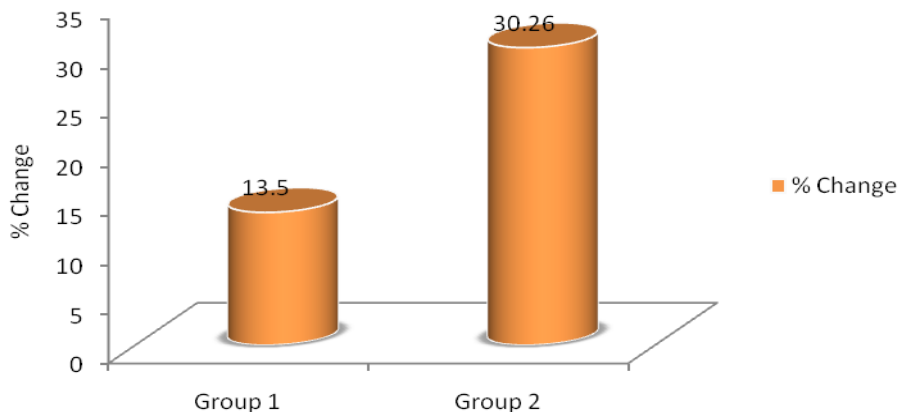
**% Changes in serum HDL level**  
 There was a high increase in serum HDL level in Group 2, compared to Group 1. So,

statistically it was extremely significant. Table 9 and Fig.9 represent that.

**Table 9: Comparison of % Changes In Serum HDL Level**

Study Groups	Change In Serum (+ ve)		'p' value
	mg/dL (mean)	% change	
Group 1: Atorvastatin 40 mg/day	4.06	13.50	0.0026
Group 2: Atorvastatin 40 mg/day + Coenzyme Q 10 30 mg/day	9.5	30.26	

**Fig. 9. Statistical Representation of Comparison of % Changes In Serum HDL Level**



**% Changes in serum VLDL level**

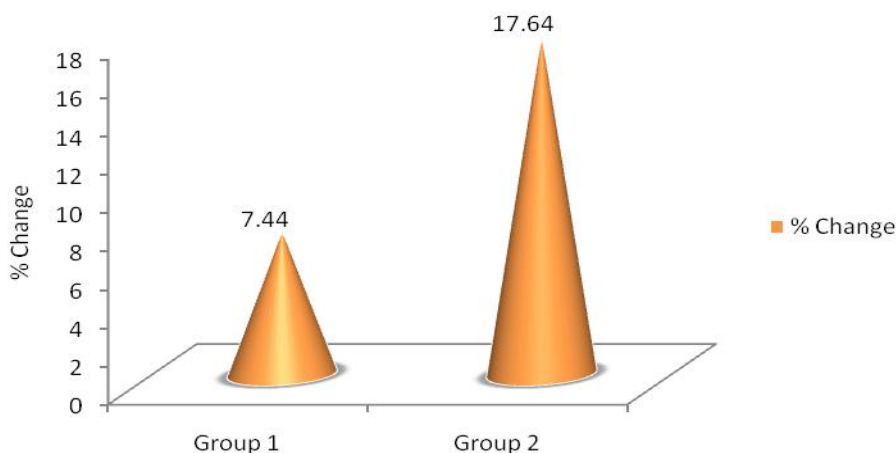
There was a considerable decrease in serum VLDL level in Group 2, compared to Group

1. So, statistically it was extremely significant. (Table 10) and (Fig.10) represent that.

**Table 10: Comparison of % Changes In Serum VLDL Level**

Study Groups	Change In Serum (- ve)		'p' value
	mg/dL (mean)	% change	
Group 1: Atorvastatin 40 mg/day	5.57	7.44	0.0003
Group 2: Atorvastatin 40 mg/day + Coenzyme Q 10 30 mg/day	15.05	17.64	

**Fig. 10: Statistical Representation of Comparison of % Changes In Serum VLDL Level**



**Final Results**

**Changes in lipid profile**

1. The reduction in serum total cholesterol level in Group 2 (Coenzyme Q 10 given) was higher than that of Group 1 (Coenzyme Q 10 not given) and the reduction was found to be statistically significant (Table 1).
2. The reduction in serum LDL level in Group 2 was higher than that of Group 1 and the reduction was found to be statistically significant (Table 2).
3. The reduction in serum triglyceride level in Group 2 was higher than that of Group 1, but the reduction was found to be statistically insignificant (Table 3).
4. The increase in serum HDL level in Group 2 was higher than that of Group 1 and the reduction was found to be statistically very significant (Table 4).
5. The reduction in serum VLDL level in Group 2 was higher than that of Group 1 but the reduction was found to be statistically insignificant (Table 5).

**Comparison of % Changes in Lipid Profile**

1. The % reduction in serum total cholesterol, LDL, and Triglyceride were much higher in Group 2, compared to Group 1, but statistically they were not significant (Table 6, 7 & 8).
2. The % increase in serum HDL level was much higher in Group 2, compared to Group 1 and statistically it was significant (Table 9).
3. The % reduction in serum VLDL level was much higher in Group 2, compared to Group 1, and statistically it was significant (Table 10).

**DISCUSSION**

Coenzyme Q 10 is a known antioxidant which prevents lipid peroxidation in the body. Currently it is being prescribed for increasing the sperm count in infertile men. Coenzyme Q 10 in single or in combination with certain minerals like Selenium is prescribed in these cases up to 300 mg/day. Safety assessment studies in healthy volunteers state that Coenzyme Q 10 is safe up to the dose of 900 mg/day.



As per the observations and results of this study we can conclude that Coenzyme Q 10 possesses lipid lowering effect in dyslipidaemic patients who underwent PTCA and receive Atorvastatin therapy.

Coenzyme Q 10 reduces serum total cholesterol and serum LDL, and increases serum HDL when given in combination with Atorvastatin.

On the whole, the comparison of reduction in lipid parameters shows that Atorvastatin - Coenzyme Q 10 combination has a powerful lipid lowering effect, when compared to Atorvastatin alone.

When comparing the % changes in lipid profile between Group 1 and Group 2, it is clearly visible that the lipid lowering effect of Atorvastatin - Coenzyme Q 10 combination is more effective than that of Atorvastatin alone.

Currently Coenzyme Q 10 is not prescribed by physicians for lowering serum lipid levels, because of inadequate studies on the lipid lowering effect of Coenzyme Q 10, and the cost of the medication. Each 30 mg capsule of Coenzyme Q 10 is Rs.19.

But, considering its therapeutic efficacy, safety, and other beneficial effects, Coenzyme Q 10 can be recommended for prescription to dyslipidaemic patients.

#### **ACKNOWLEDGEMENT**

I wish to acknowledge the cooperation and the guidance from the chairman of our college and the Head of the department of Pharmacy Practice, Prof. M. Nagarajan, M. Pharm., DMS (BM), and DMS (IM).

I would be thankful to Dr. S. Selvamani, M.D., DNB (internal medicine), DNB (cardiology) [interventional cardiologist], in Meenakshi Mission Hospital and Research Centre (MMHRC), Madurai, for his guidance on the field. He guided me all the way from enrolling the patients till the end of the study.

Thanks to the Medical records department of MMHRC for providing me the medical records and helping me with full mind.

I thank all my department-mates, friends and well wishers for cooperating me throughout.

Above all I should remember the part the members of my family had in making all the situations peaceful and allowing me to spend my whole mind and time to my study.

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