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Role of fractional CO_2 laser with intralesional steroid versus intralesional steroid alone in treatment of hypertrophic scar and keloids

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Abstract
Background: Hypertrophic scars and keloids are fibrous responses resulting from burns, surgery, inflammation, or trauma. Keloids are believed to form due to an imbalance between collagen synthesis and degradation in the extracellular matrix, leading to increased fibroblast density and proliferation. They commonly appear in individuals aged 10 to 30 and typically affect areas of high skin tension, including the upper back, shoulders, chest, and upper arms. Patients often experience not only cosmetic concerns but also pain, itching, limited mobility, and psychological issues. Various treatment options have been proposed, such as surgery, intralesional steroid injections, laser therapy, and cryosurgery, but the effectiveness of these methods can vary.
Materials and Methods: In this prospective randomised controlled study, 30 patients, Patients with keloids and hypertrophic scar are divided into two groups with 15 in each group, one group is receiving fractional co2 laser and intralesional triamcinolone acetonide and another group receiving intralesional triamcinolone acetonide alone. Pretreatment measurements and photographs will be documented and the Scar is assessed through Patient and observer scar assessment scale (PAOSAS). The treatment will be given at every 4 week interval until the keloids were resolved.
Conclusion: Intrathecal Bupivacaine with Buprenorphine 60 µg caused prolonged duration of postoperative analgesia when compared to intrathecal Bupivacaine with Nalbuphine 2 mg. (10).

Keywords: Keloid, hypertrophic scar, intralesional steroid, fractional CO_2 laser

Introduction
Keloid and Hypertrophic scars result from an abnormal wound healing process and can have a detrimental psychological effect on patients due to their unattractive appearance. Additionally, symptoms like itching, pain, and discomfort can negatively impact a patient's quality of life. Keloid formation is believed to stem from an imbalance in the synthesis and degradation of extracellular matrix collagen, leading to increased fibroblast density and proliferation.

Various treatments for keloids are currently available, including surgery, intralesional steroid injections, laser therapy, and cryosurgery. Intralesional steroid injection is often the first-line commonly used treatment. Corticosteroid inhibits alpha2-macroglobulin, which acts as an inhibitor of a collagenase. Once this pathway is blocked, collagenase is activated and collagen degeneration is enabled.

However, this method can cause significant pain during injection, which may lead patients to discontinue treatment and achieve unsatisfactory results. Other side effects, such as skin atrophy, hypopigmentation, and telangiectasia, can also result in cosmetic dissatisfaction.

Laser treatment, particularly with carbon dioxide (CO_2) lasers, is increasingly popular due to better patient tolerance, less pain, and improved aesthetics. This pattern of microscopic thermal damage stimulates epidermal turnover and dermal collagen remodelling. As the stratum corneum, which contains relatively less water, remains intact and epidermal function up on is preserved, while evidence shows that CO_2 laser therapy can effectively reduce keloids, it is associated with high recurrence rates.

Material and Methods

This prospective comparative study was carried out on patients of Department of Dermatology, Venereology and Leprosy at Great Eastern Medical School and Hospital, Ragolu, Srikakulam from April 2023 to September 2023. A total 30 adult subjects (both male and females) of aged ≥ 18, years were for in this study.

Study Design: Prospective open label observational study.

Study Location: This was a tertiary care teaching hospital based study done in Department of Dermatology, venereology and Leprosy, at Great Eastern Medical School and Hospital, Ragolu, Srikakulam, Andhra Pradesh.

Study Duration: April 2023 to September 2023.

Sample size: 30 patients.

Subjects & selection method: The study population was drawn from consecutive diabetic patients who presented to Dr. Ram Manohar Lohia Combined Hospital with dyslipidemia and were prescribed the indicated statins and underwent fasting blood test of lipid profile before statin treatment initiation between from November 2014 to November 2015. Patients were divided into three groups (Each group had 100 patients) according to doses of statins. The prescribed doses of statin in RMLH for diabetic patients With dyslipidemia were as follows:
Group A (N=15 patients)-Patients receiving intralesional triamcinolone acetonide.
Group B (N=15 patients) -Patients receiving intralesional triamcinolone acetonide and fractional co2 laser.

Inclusion criteria

1. All clinically diagnosed cases of hypertrophic scars and keloids.
2. Patients who have given their consent.
3. Aged ≥ 18 years.

Exclusion criteria

1. Patient with underlying diseases such as diabetes mellitus, because it hinder wound healing
2. Patients who refused steroid therapy.
3. Patients who lost follow-up within 6 months.

Procedure methodology

After written informed consent was obtained, a well-designed questionnaire was used to collect the data of the recruited patients retrospectively. The questionnaire included socio-demographic characteristics such as age, gender, nationality, height, weight, and consanguineous marriage, physical activity and lifestyle habits like smoking and alcohol and statin prescribed for at least 2 years continuously and dose, type of DM, its duration, and clinical and biochemistry laboratory investigations such as fasting blood glucose, glycated hemoglobin (HbA1C), total cholesterol, HDL and LDL cholesterol levels, and TGs.
All lipid parameters were quantified on samples collected in the fasting state. Cholesterol and TG quantization was determined by enzymatic assay. LDL-C was calculated using the Friedewald equation for patients with TG ≤ 400 mg/dl and measured by b-quantification for those with TG > 400 mg/dl. Levels of non-HDL-C were calculated by subtraction of HDL-C from total cholesterol.
Information about the type of statin (Rosuvastatin, atorvastatin) was taken from the pharmacy database. Baseline characteristics of the patients were collected from the database 1 week before the first use of statins. Height and weight were measured using standardized method. The body mass index (BMI) was calculated as the weight in kilograms (With 1 kg subtracted to allow for clothing) divided by height in meters squared.
Blood pressure was recorded using an electronic instrument (Model: HEM-7101, Omron Corporation, Tokyo, Japan) as the mean of two readings taken five minutes apart.

The prescribed doses of statin in RMLH for diabetic patients with dyslipidemia were as follows

- **Group A:** Atorvaststin 40 mg;
- **Group B:** Rosuvastatin 20 mg; and
- **Group C:** Rosuvastatin 20 mg at alternate days.

Fasting capillary blood glucose [CBG] was determined by using One Touch Ultra glucose meter (Johnson & Johnson, Milpitas, California) after eight hours of overnight fasting. A fasting venous sample was collected and lipids were measured.
All biochemical assays was carried out by the same team of laboratory technicians using the same method, throughout the study period. The samples were assayed for total cholesterol, triglycerides and HDL cholesterol.
Serum cholesterol (Cholesterol esterase oxidase-peroxidase-amidopyrine method), serum triglycerides (Glycerol phosphate oxidase-peroxidase-amidopyrine method), and high-density lipoprotein cholesterol (Direct method poly-ethylene-glycol-pretreated enzymes) was measured using the Beckman Coulter AU 2700/480 Autoanalyser (Beckman AU [Olympus], Ireland). The intra– and inter-assay coefficients of variants (CV) for the biochemical assays ranged from 3.1% to 7.6%. (10)
In every subject, a semi-quantitative food frequency questionnaire was administered to collect detailed information on dietary intake over the past year. Dietary fat and oil intake was assessed as the amount of fat/oil used during cooking and/or added at the table.

Statistical analysis

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Student's t-test was used to ascertain the significance of differences between mean values of two continuous variables and confirmed by nonparametric Mann-Whitney test. In addition, paired *t*-test was used to determine the difference between baseline and 2 years after regarding biochemistry parameters, and this was confirmed by the Wilcoxon test which was a nonparametric test that compares two paired groups. Chi-square and Fisher exact tests were performed to test for differences in proportions of categorical variables between two or more groups. The level $p < 0.05$ was considered as the cutoff value or significance.

Result

After 6 weeks of follow upmit was found that LDL-C, went down by -32.81% on regular dose of Atorvastatin 40 mg,-37.28% on Rosuvastatin 20 mg daily and -37.53% on Rosuvastatin 20 mg alternate day.

The total Cholestrol level reduced by -14.71%, 17.35%,-11.63%, respectively.
Trigyceride level reduced by -14.71%, 17.3%, 11.^3%, respectively.
Non HDL-C went down by -37.32%, 29.715% and -29.71% respectively.
HDL-C improved by +3.46%, +8.17% and 8.17%, respectively.
Table no 1 Shows metabolic parameters of patients of the three groups before treatment. Total cholesterol (TC), 224.3±30.8 mg/dl, 226.1±35.4 & 225.3±40.7 mg/dl, LDL-C, 158.3 ±22.6 mg/dl, 156.1 ±27.8&157.2±26.7 mg/dl, HDL-C, 37.5±2.70 mg/dl, 35.5±2.21 & 36.4±1.90 mg/dl, Triglyceride 165.8±30.8 mg/dl, 162.6±28.2 & 166.8±35.7 mg/dl, Non-HDL-C 180.6±31.2 mg/dl, 182.4±29.2 & 185.2±32.4 mg/dl, FBG, 142.5±25.7 mg/dl, 148.2±26.9 & 145.8±27. mg/dl 4, HbA1c, %, 5.82±0.2, 5.62±0.4 & 5.65±0.3 respectively of patients of the three groups. The difference in the values of all parameters in respect of three groups was not statistically significant (p>0.05) (10)

Table 1: Shows metabolic parameters of patients of the three groups before treatment. (10)

	Atorvastatin 40 mg	Rosuvastatin 20 mg	Rosuvastatin 20 mg alternate day	P value (I to II)	P value (I to III)	P value (II to III)
Lipids, mg/dL						
Total Cholesterol (TC)	224.3±30.8	226.1±35.4	225.3±40.7	0.7017	0.8449	0.8449
LDL-C	158.3±22.6	156.1±27.8	157.2±26.7	0.5399	0.7535	0.7757
HDL-C	37.5±8.70	35.5±9.21	36.4±7.90	0.357	0.487	0.389
Triglyceride	165.8±30.8	162.6±28.2	166.8±35.7	0.4444	0.8323	0.3570
Non-HDL-C	180.6±31.2	182.4±29.2	185.2±32.4	0.6740	0.3077	0.5216
Glucose and HbA1C						
FBG, mg/dL	142.5±25.7	148.2±26.9	145.8±27.4	0.1271	0.3808	0.5327
HbA1c, %	5.82±0.2	5.62±0.4	5.65±0.3	0.265	0.357	0.647

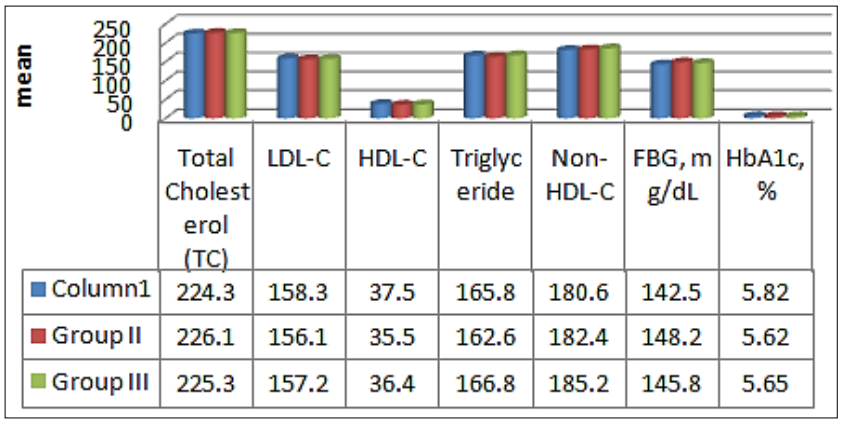


Fig 1: Comparison of lipid profile changes after six weeks of atorvastatin 40 mg therapy

Follow up after 6 weeks

Table no 2: Records the percent change in lipids, (mg/dL) on a regular dose of atorvastatin 40 mg. for 6weeks. (TC) level reduced by (-32.81%), low-density lipoproteins cholesterol (LDL-C) went down by (-46.99%), triglycerides reduced by (-14.71%), non-HDL-C went down by (-37.32%). While there had been a reduction in the undesirable Lipids, as above, due to the above medication, there was a positive upwards change in the desirable lipids like high-density lipoprotein cholesterol (HDL-C) which improved by (+3.46%). Further, Fasting blood glucose (FBG) mg/dL level were reduced by (-36.17%) and HbA1c, % hemoglobin A1C test which measures blood sugar control over the preceding three months had also gone down by (-1.89%). The desirable alterations in respect of all the above parameters after 6 weeks of medication which are attributable to the above medication, were highly statistically significant, $p<0.001$ except HbA1c.

Table 2: (10 Bold): Records the Percent Change in Lipids profile after treatment given. (10)

	Atorvastatin 40 mg (Before)	Atorvastatin 40 mg (After)	Percentage Change	P value
Lipids, mg/dL				
Total Cholesterol (TC)	224.3±30.8	150.7±22.2	-32.81%	<0.001
LDL-C	158.3±22.6	83.9±15.1	-46.99%	<0.001
HDL-C	37.5±2.70	38.8±3.5	+3.46%	0.003
Triglyceride	165.8±30.8	141.4±22.6	-14.71%	<0.001
Non-HDL-C	180.6±31.2	113.2±18.1	-37.32%	<0.001
Glucose and HbA1C				
FBG, mg/dL	142.5±25.7	90.95±7.9	-36.17%	<0.001
HbA1c, %	5.82±0.2	5.71±0.3	-1.89%	0.198

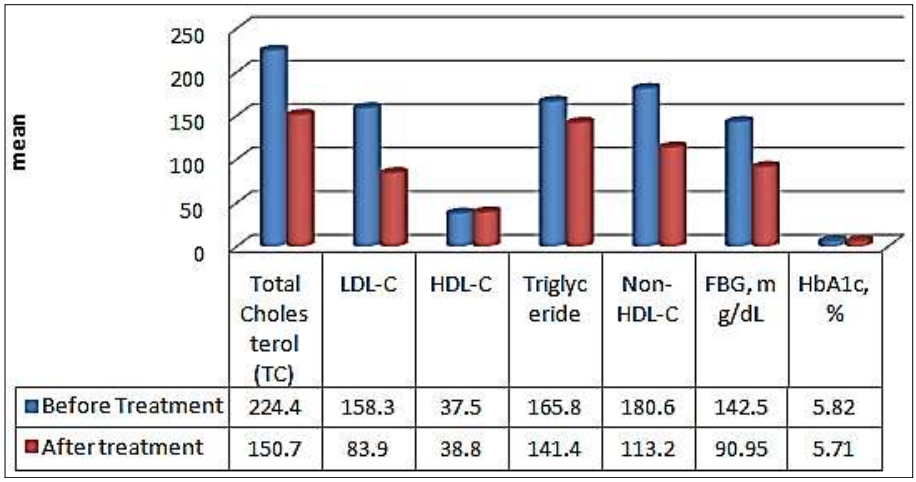


Fig 2: Percentage change in lipid parameters following six weeks of atorvastatin 40 mg treatment

Table no 3: Shows Percent Change in Lipids, (mg/dL) on a regular dose of Rosuvastatin 20 mg for 6weeks. Total Cholesterol (TC) level reduced by (-26.49%), Low-density lipoproteins cholesterol (LDL-C) went down by (-37.28%), Triglyceride reduced to (-17.3%), Non-HDL-C went down by (-29.71%), after 6 weeks of medication. While there had been a reduction in the undesirable Lipids due to the above medication, there was a positive upwards change in the desirable Lipids like high-density lipoprotein cholesterol (HDL-C) which improved by (+8.17%), Further, Fasting blood glucose, FBG, mg/dL level were reduced by (-37.95%). and HbA1c, % hemoglobin A1C test which measures blood sugar control over the preceding three months had also gone down by (-11.00%). The desirable alterations in respect of all the above parameters which were attributable to the above medication, were statistically significant, $p<0.001$---0.033.

Table 3: Shows Percent Change in Lipids, (mg/dL) on a regular dose of Rosuvastatin 20mg for 6 weeks. (10)

	Rosuvastatin 20 mg (before)	Rosuvastatin 20 mg (After)	Percentage Change	P value
Lipids, mg/dL				
Total Cholesterol (TC)	226.1±35.4	166.2±25.7	-26.49%	<0.001
LDL-C	156.1±27.8	97.9±14.7	-37.28%	<0.001
HDL-C	35.5±2.21	38.4±3.6	+8.17%	<0.001
Triglyceride	164.6±28.2	136.2±23.4	-17.3%	<0.001
Non-HDL-C	182.4±29.2	128.2±20.5	-29.71%	<0.001
Glucose and HbA1C				
FBG, mg/dL	148.2±26.9	91.95±8.8	-37.95%	<0.001
HbA1c, %	5.62±0.4	5.5±0.2	-2.13%	0.187

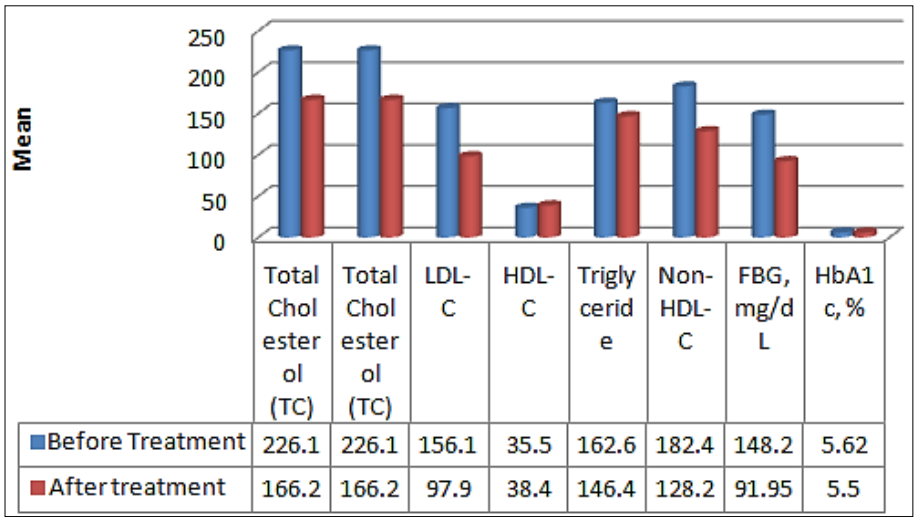


Fig 3: Percent reduction in lipid levels after six weeks of rosuvastatin 20 mg therapy

Table no4 Shows Percent Change in Lipids, (mg/dL) on a dose of Rosuvastatin 20 mg on alternate Days for 6weeks. Total Cholesterol (TC) level reduced by (-26.36%), Low-density lipoproteins cholesterol (LDL-C) went down by (-37.53%), Triglyceride reduced by (-11.63%), Non-HDL-C went down by (-29.71%). While there had been a reduction in the undesirable Lipids due to the above medication, there was a positive upwards change in the desirable Lipids like high-density lipoprotein cholesterol (HDL-C) which improved by (+8.17%), Further, Fasting blood glucose,

FBG, mg/dL level were reduced by (-36.65%). and HbA1c, % hemoglobin A1C test which measures blood sugar control over the preceding three months had also gone down by (+4.07%). The desirable changes in respect of all the above parameters attributable to the above medication, were statistically highly significant, p<0.001---0.033 except HbA1c.

Table 4: Compares the effects of Rosuvastatin 20 mg alternate day (Before vs. after) on various lipid and glucose parameters, including Total Cholesterol (TC), LDL-C, HDL-C, Triglycerides, Non-HDL-C, Fasting Blood Glucose (FBG), and HbA1c, with respective percentage changes and p-values

	Rosuvastatin 20 mg alternate day (Before)	Rosuvastatin 20 mg alternate day (After)	Percentage Change	P value
Lipids, mg/dL				
Total Cholesterol (TC)	225.3±40.7	165.9±23.1	-26.36%	<0.001
LDL-C	157.2±26.7	98.2±16.3	-37.53%	<0.001
HDL-C	36.4±1.90	38.5±2.9	+5.76%	< 0.001
Triglyceride	166.8±35.7	140.4±21.9	-15.83%	<0.001
Non-HDL-C	185.2±32.4	127.2±19.9	-31.31%	<0.001
Glucose and HbA1C				
FBG, mg/dL	145.8±27.4	92.35±9.6	-36.65%	<0.001
HbA1c, %	5.65±0.3	5.66±0.4	+0.17%	0.287

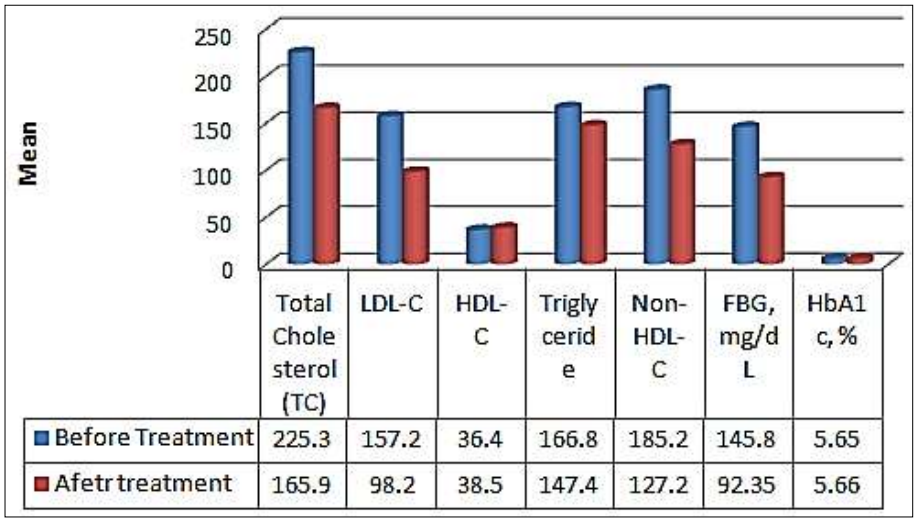
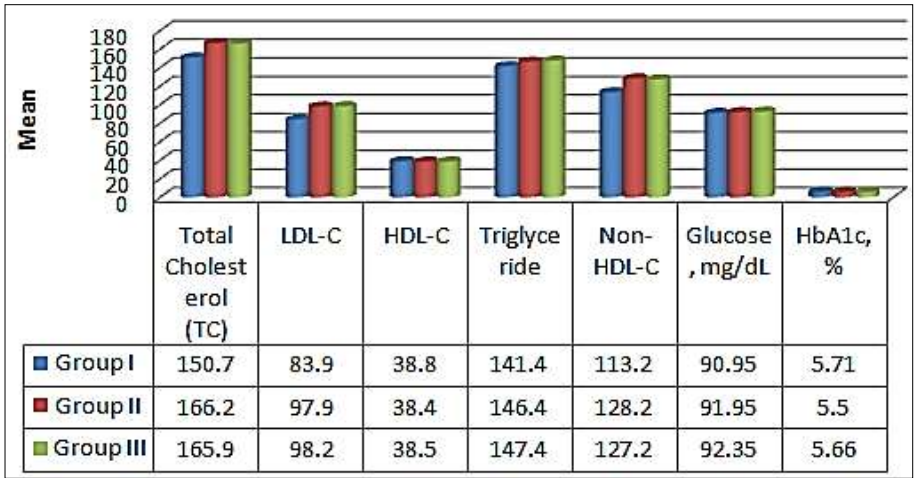


Fig 4: Effect of rosuvastatin 20 mg alternate-day therapy on lipid levels after six weeks

Table no 5 Shows metabolic parameters of patients of each of the three groups after 6 weeks of treatment. Metabolic parameters of patients of the three groups after 6 weeks of medication reveal that not only maximum quantities of harmful lipids like total cholesterol, LDL-C, Triglyceride, Non-HDL-C, Glucose, mg/dL, have gone down, there was an increase in the useful lipids like HDL-C and in the patients treated with a regular dose of Atorvastatin 40 mg. In that group of patients the HbA1c, % level was also well within the normal range of 4% to 5.6%. The variation in the quantities of Total Cholesterol, LDL-C and HbA1c, % among the patients of the three groups was statistically significant as p<0.001.

Table 5: Shows metabolic parameters of patients of each of the three groups after 6 weeks of treatment.

	Atorvastatin 40 mg	Rosuvastatin 20 mg	Rosuvastatin 20 mg alternate day	P value (I to II)	P value (I to III)	P value (II to III)
Lipids, mg/dL						
Total Cholesterol	150.7±22.2	166.2±25.7	165.9±23.1	<0.001	<0.001	0.9309
LDL-C	83.9±15.1	97.9±14.7	98.2±16.3	< 0.001	< 0.001	0.8914
HDL-C	38.8±3.5	38.4±3.6	38.5±2.9	0.4266	0.5100	0.8290
Triglyceride	141.4±22.6	146.4±23.4	147.4±21.9	0.1259	0.0580	0.7554
Non-HDL-C	113.2±18.1	128.2±20.5	127.2±19.9	< 0.001	< 0.001	0.7267
Glucose and HbA1C						
Glucose, mg/dL	90.95±7.9	91.95±8.8	92.35±9.6	0.398	0.261	0.759
HbA1c, %	5.71±0.3	5.5±0.2	5.66±0.4	0.013	0.010	0.056



	Total Cholesterol (TC)	LDL-C	HDL-C	Triglyceride	Non-HDL-C	Glucose, mg/dL	HbA1c, %
Group I	150.7	83.9	38.8	141.4	113.2	90.95	5.71
Group II	166.2	97.9	38.4	146.4	128.2	91.95	5.5
Group III	165.9	98.2	38.5	147.4	127.2	92.35	5.66

Fig 5: Comparison of metabolic parameters in patients treated with atorvastatin and rosuvastatin after six weeks

Table no 6 National Cholesterol Education Program NCEP ATP III goal. Figures show that while NCEP ATP III goal was achieved by 40 (40%) patient treated with a regular dose of Rosuvastatin 20 mg, 39 (39%) patient could achieve the goal with an alternate dose of Rosuvastatin 20 mg. As for treatment with Atorvastatin 40 mg was concerned only 37 (37%) patient achieved the goal as stipulated by National Cholesterol Education Program NCEP ATP III goal.

Table 6: National Cholesterol Education Program NCEP ATP III goal.

Number of patients (%) achieving NCEP ATP III goal		
Statin therapy	**Achieved (%)**	**Total**
Atorvastatin 40 mg	37 (37)	100
Rosuvastatin 20 mg	40 (40)	100
Rosuvastatin 20 mg alternate days	39 (39)	100
Total	116(38.66)	300

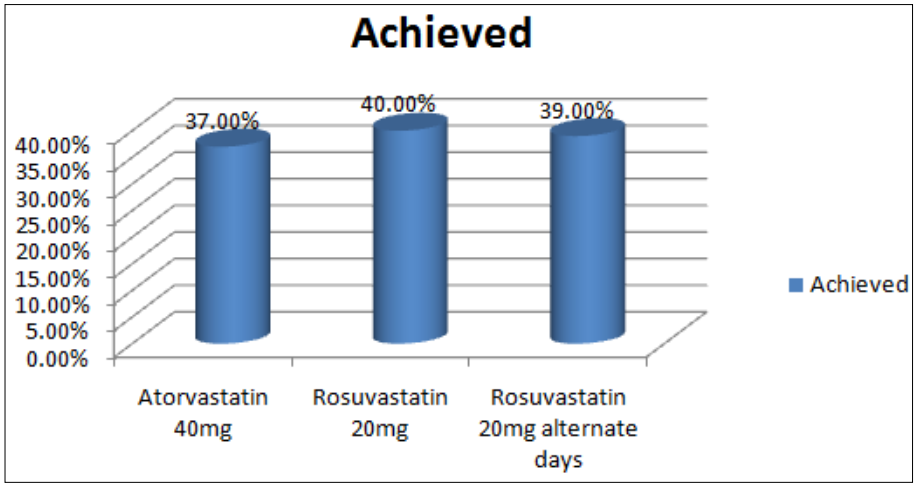


Fig 6: Number of patients achieving NCEP ATP III goals with different statin regimens

Discussion

Dyslipidemia in patients with diabetes plays an important role in development of atherogenesis. The standarded of treatment for dyslipidemia have been statins. For the treatment of dyslipidemia the most commonly used statins are atorvastatin and rosuvastatin.

The four major statin beneficiary groups have already been defined by NCEP 2013 report.

There is a wealth of evidence suggesting that lowering low density lipoprotein cholesterol (LDL-C) reduces the risk of cardiovascular disease (CVD). Both European and US guidelines for CVD prevention recommend the use statins as first-line therapy for dyslipidemia and specify target LDL-C levels. Previously, a National Cholesterol Education Program (NCEP) report had proposed to lower target levels to even more aggressive LDL-C goals for very high-risk patients.

Despite the proven benefits of LDL-C reduction, lipid management is suboptimal and many patients fail to achieve recommended LDL-C goals [11, 12]. The most likely reasons for this are the use of agents with poor efficacy for LDL-C lowering and suboptimal dose titration.

Such aggressive LDL-C goals, however are harder to achieve. The most effective statin at the lowest dose would represent a simple, effective treatment strategy, enabling more patients to achieve goals without the need for dose titration.

Rosuvastatin, at a dose of 20 mg, has demonstrated high efficacy for LDL-C lowering, enabling patients with hypercholesterolemia to achieve their lipid goals [10, 11].

Currently no Indian study is available for treating diabetic patients with dyslipidemia or dyslipidemia alone with statin on alternate day and no previous study has documented the efficacy, safety and cost effectiveness of various statins prescribed to diabetic patients. Thus the present study aimed to build on this growing awareness of atherosclerosis-specific care of diabetes patients, by examining efficacy and safety of the two most commonly prescribed statins in India.

The present study was an open label prospective comparative study done in Department of General Medicine, at Dr. Ram Manohar Lohia Combined Hospital a tertiary care teaching hospital, Lucknow, Uttar Pradesh in the time interval of November 2014 to November 2015.

The study shows that rosuvastatin (20 mg daily and 20 mg on alternarnate days) was found to be the most effective statin at reducing LDL-C when compared with atorvastatin (40 mg) daily. In other words, rosuvastatin at its lowest dose in this study (20 mg) on alternate days was more effective at reducing LDL-C levels than atorvastatin at their higher dose (40 mg) daily. Our results are consistent with STELLAR trial which is one of the major open-label, randomized, and multicenter trials to compare rosuvastatin (10, 20, 40, or 80 mg) with atorvastatin (10, 20, 40, or 80 mg), pravastatin (10, 20, or 40 mg), and simvastatin (10, 20, 40, or 80 mg) across dose ranges for reduction of LDL-C [13]. The results of the STELLAR trial revealed that rosuvastatin was consistently, across all doses, the most effective at reducing LDL-C levels in comparison to all of the other statins.

Brunzell JD *et al*. reported the lowering of triglycerides is another important goal in reducing CVD risk among diabetic patients [5]. In the present study, the greatest reduction in triglycerides was (−17.3%, $p< 0.01$) and was achieved by patients taking rosuvastatin (20 mg daily). This was the case, even in comparison with rosuvastatin 20 mg on alternate days and to higher doses of atorvastatin (40 mg). However, it is important to note that rosuvastatin (20 mg on alternate day) and atorvastatin (40 mg) both achieved the second highest reduction in triglycerides (−15.83%, $p< 0.05$, and −14.71%, $p<0.05$), respectively. These findings are similar to the majority of studies in the literature, which have shown a slightly higher reduction in triglycerides in patients taking rosuvastatin in comparison to atorvastatin as reported by Clearfield MB *et al*. [14]. It thus appears that, reduction in triglyceride levels is equal with rozuvastatin and atorvastatin in relation to this factor (Triglycerides), and that both rosuvastatin and atorvastatin are effective in reducing it.

Raising HDL-C levels is another major factor known to reduce CVD risk. In the present study, all of the statins were found to increase HDL-C levels as has been shown in previous studies. Rosuvastatin (20 mg daily) lead to maximal increase (+8.17%).

Conclusion

Rosuvastatin 20 mg on every other regimen had equal effect when compared to daily dose regimen of atorvastatin 40 mg &rosuvastatin 20 mg.

Conflict of Interest: Not available

Financial Support: Not available

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