

COMPARISON OF ELEVATION IN SERUM TRIGLYCERIDE LEVEL AND ALLERGIC REACTIONS WITH PROPOFOL MEDIUM CHAIN TRIGLYCERIDE AND LONGCHAIN TRIGLYCERIDE PREPARATION (MCT/LCT) VERSUS PROPOFOL LONGCHAIN TRIGLYCERIDE PREPARATION(LCT) – AN OBSERVATIONAL STUDY

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Abstract

Background: To study the elevation in serum triglyceride levels and incidence of allergic reactions both local and systemic between Propofol MCT/LCT preparation and Propofol LCT preparation. **Materials and Methods:** The study was an Observational study in finding elevation in serum triglyceride levels among 50 ASA 1 and 2 patients. Preoperatively serum triglycerides were estimated in all the patients. They were divided into 2 groups of 25 each Group MCT and Group LCT, each receiving propofol injection at 2mg/kg for induction of general anaesthesia. After 4 hours postinduction blood was drawn and serum triglyceride levels were estimated. Any features of all ergicreactions intraoperatively were monitored and local injection site was examined after 6 hours post-induction for allergic reactions. **Result:** Statistical Analysis was done with SPSS. The Mean difference of Triglyceride values between two groups showed a decrease in serum triglyceride level in Group MCT and an increase in Group LCT. Intraoperatively no allergic reactions were noted for both the groups. There were no local allergic reactions noted. **Conclusion:** Elevation in serum triglyceride was noted with Propofol LCT group. Both groups never showed any allergic reaction systemically or locally.

INTRODUCTION

Propofol is the most common intravenous induction agent for used for induction and maintenance of Anaesthesia. Propofol being an insoluble drug requires a lipid vehicle for emulsification. The current formulations use soybean oil as the oil phase and egg lecithin as emulsifying agent. The objective of the study was to find the elevation in serum triglyceride levels in both the formulations of propofol and to find any allergic reactions to the same.^[1,2]

The pharmacodynamics of Propofol MCT_LCT and found that medium chain triglycerides forming the lipid emulsion are more rapidly metabolized compared to the long - chain triglycerides of the current soybean oil - based formulations.^[2,3] compared pain of injection of propofol in 64 children aged 2- 6 years by comparing 0.5% or 1% Propofol MCT/LCT and found out that 23.3% in 0.5% propofol showed pain on injection and 70% in

the 1% propofol showed pain on injection and serum triglyceride elevation was higher with 0.5% propofol. Hence concluded that Propofol of 0.5% Propofol MCT reduced pain on injection. Serum Triglyceride levels increased abruptly due to cumulative doses.^[4,5]

MATERIALS AND METHODS

It was an Observational Study with Comparison Group. Study was formulated after obtaining approval from the Institutional Research and Ethical committee and Informed consent from the patient. Patients were secured from Pushpagiri Institute of Medical Science and Research centre, Tiruvalla between March 2016- March 2017.

The study was designed in a way that 2 groups would receive:

- GRP LCT receive Propofol LCT 1% (2mg/kg)
- GRP MCT – receive Propofol MCT/LCT 1%(2mg/kg)

Sample Size Estimation

$$N = 2pq / (Z\alpha + Z\beta)^2$$

P1- P2

$$= 2 * 0.7 * 0.3 / (1.96 + 2.84)^2$$

$$0.7 - 0.3$$

N= 25 Total: 50 patients (25 in each group)

Assuming a significance level of 5 %,

Assuming a significance level of 5 %, power of 80 % and the sample size was calculated to be 25.

Hence 25 patients in each group.

Sampling Technique

Consecutive sampling with those patients satisfying with written informed consent satisfying the inclusion and exclusion criteria was formulated till the desired sample size was achieved.

Inclusion Criteria

Aged 20-60years, ASA 1 and 2 (American Society of Anaesthesiologists) undergoing General anaesthesia.

Exclusion Criteria

Known Hypersensitivity to egg or any study drugs, Impaired cognition, Pre existing neurological disorders, BMI>25, Pregnant patient, Emergency surgeries, Unwilling patient

Methodology

Patients were assigned into two different groups of 25 each. Pre anaesthetic checkup was done the day before surgery. Routine NPO Protocols were followed and Anti aspiration prophylaxis was given with T. Ranitidine 150mg and T. Metoclopramide 10mg HS and 6am on the morning of surgery. 20G Cannula placed on the largest vein on the dorsum of hand. Before induction the patient was reminded that he or she would receive amedication which may or may not cause pain on injection on forearm. Routine baseline Hemodynamic parameters and oxygen saturation were recorded after administration of Inj Ondansetron 4mg.

GRP M – received Propofol MCT/LCT (2mg/kg), GRP L – received Propofol LCT(2mg/kg)

All injection were given at 0.5ml/sec All patients post induction received General Anaesthesia Standardized with Morphine 0.1mg/kg, Vecuronium for adequate muscle relaxation and Sevoflurane as maintenance inhalational agent. Routine intra-operative monitoring protocols with hemodynamic monitoring with Heart Rate, Blood Pressure and Oxygen Saturation recorded at 1min, 3 min 5 min, 10 min, 20 min and 30 minutes. All patients were reversed from General Anaesthesia using

Neostigmine 2.5mg and Glycopyrrolate 0.4mg. Serum triglyceride levels were taken 4 hours post induction in all patients irrespective of the duration of surgery. Local site reaction was assessed 6 hours post induction.

Statistical Analysis

Data was entered using Microsoft Excel software and Analysed using SPSS (Statistical Package for Social Sciences) Software 20.0. Baseline clinical and demographic correlates were tabulated and frequency/percentage were found out. Possible cofounders were adjusted using Multiple Logistic Regression Analysis. Comparison of elevation in serum triglyceride was analysed using paired T test. Comparison of hemodynamic parameters (HR, SBP, DBP, Spo2) were analysed using test of means / proportions whichever was applicable P value pf < 0.05 was taken statistically significant.

RESULTS

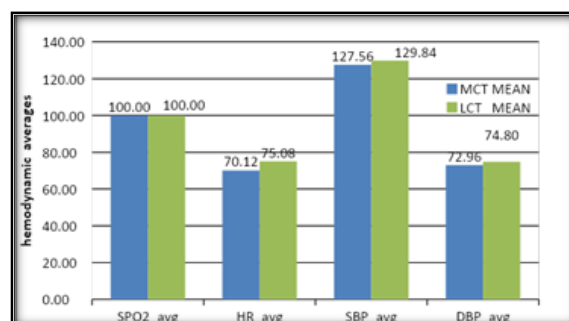


Figure 1: Hemodynamic Variability

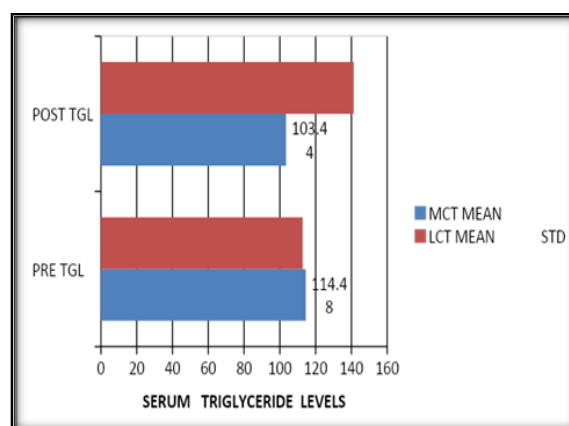


Figure 2: pre and post triglyceride elevation between group MCT and group LCT

Table 1: ASA distribution of study participants

ASA	MCT (N=25)	LCT (N=25)
I	11 (44%)	17 (68%)
II	14 (56%)	8 (32%)

As per [Table 1] ASA distribution shows out of 50 participants 28 (56%) belonged to class I ASA and 44% belonged to class II ASA.

Table 2: Comparison of Hemodynamic parameters between the groups

	MCT (N=25)		LCT (N=25)		P- value
Parameters	Mean	SD	Mean	SD	

SSPO2_avg	00.00	.000	00.00	.000	.000
RHR_avg	0.12	.622	5.08	.639	.006*
SSBP_avg	27.56	1.303	29.84	.636	.58
DDBP_avg	2.96	.734	4.80	.930	.49

As per [Table 2] hemodynamic variability was comparable in SBP, DBP and SpO2 except with Heart rate which was not comparable with a p value of 0.006.

Table 3: Comparison of pre and post triglyceride elevation between group MCT and group LCT

Triglycerides	MCT (N=25)	LCT (N=25)
Pre induction TGL	114.48±36.039	112.76±32.427
Post induction TGL	103.44±35.008	141.28±36.531
p-value	0.01*	0.01*

As per [Table 3] in Group MCT Mean difference between the post and pretriglyceride values are statistically significant with paired T Test with the significance level p value <0.01 which is less than 0.05 with a correlation coefficient of 0.911 and with a 95% confidence interval of lower difference Of 4.829 with upper interval of 17.251. In Group LCT paired T test was used in determining the elevation in triglycerides and was statistically significant with p value of 0.000 which is less than <0.05 with a correlation coefficient of 0.869 and a 95% confidence interval of difference with upper case of -21.042 and lower case of -35.998 the test of Means there was an increase of 28.52±1.104. in triglyceride level in Group LCT and there was a decrease in triglyceride levels by 11.04±1.031. in Group MCT between the pre and post triglyceride levels. Hence there was an increase in serum triglyceride levels with Propofol LCT than with Propofol MC.

DISCUSSION

Propofol is the most commonly used intravenous induction agent despite its pain on injection. Various methods were introduced to decrease its pain on injection and one popular method was to increase the lipid formulation and forming Propofol MCT LCT preparation. Patients with impaired cognition, pregnant patients and patients with BMI >25 were excluded from the study as it may affect the outcome of the study. Hence 50 patients were divided into two and recruited to two groups – Group MCT and Group LCT having 25 patients each. The sex distribution in the study were males 11 (22%) and females 39 (78%). In Group MCT the number of males were 5 (20%) and females 20 (80%).

In Group LCT the males were 6 (24%) and females were 19 (76%). Even though male to female ratio is not equal but it is statistically insignificant since in both control and study group's male to female ratio is comparable. There were no significant differences in other demographic variables between the two groups. The Mean oxygen saturation (SpO2) between the two groups was comparable, Group MCT and Group LCT each were 100±0.000 respectively with a P value of 1 and is not

statistically significant. There was no apnoea in any of the patients in both groups and none desaturated. The Mean value of Heart rate: in Group MCT 70.12 ±5.622 mmHg and in Group LCT 75.08±6.639 which were not comparable and was statistically significant with a P value of 0.006. This showed heart rate was increased with the administration of Propofol LCT. In Group MCT the heart rate showed a decrease at 1, 3 and 5 minutes when compared with the baseline when compared to the GRP LCT. At 1 min for the MCT group mean was 70.32±8.36 vs 86.16± 9.564 for Group LCT. At 3 min MCT mean was 67.08±8.524 vs 75.48±8.856 for LCT. At 5 min MCT mean was 64.2±7.303 vs 71.36±7.599 for LCT. There was significant Heart rate variability in Group MCT and Group LCT at 1 min, 3 min and 5 min with a p value of 0.000, 0.002 and 0.002 respectively

Sun et al, Mallick et al proposed that propofol anaesthesia decreases parasympathetic tone to a lesser extent than sympathetic tone and this predisposed the patients to bradycardia in response to noxious stimuli.^[7,8] The mean value for Systolic blood pressure in Group MCT was 127.56± 1.303 vs 129.84±7.633 in Group LCT which were comparable and insignificant statistically with a P value of 0.580. The Mean value for Diastolic Blood Pressure for Group LCT was 72.96±5.734 vs 74.80±5.930 and was comparable statistically and was insignificant with a P value of 0.496. The Mean values for Preoperative triglyceride in Group MCT were 114.48±36.039 vs 112.76±32.427 in Group LCT. The Mean value for postoperative triglyceride in Group MCT was 103.44±35.008 vs 141.28±36.531 in Group LCT.

Sarkar et al conducted RCTS on Propofol MCT and Propofol LCT, Group MCT showed no statistically significant difference were found in preoperative and 24 hours postoperative serum triglyceride levels in both groups. Hemodynamics were similar in both groups and were stable.^[6] Regarding Triglyceride level we estimated Serum triglyceride levels after 4 hours postinduction. The maximum rise in serum rise in serum triglycerides occurs within 6 hours.^[9,10] Sarkar et al have done serum triglyceride estimation at 24 hours postoperatively by which time the serum triglyceride levels will have. Ward et al studied the pharmacodynamics and concluded that Propofol MCT_LCT resulted in rapid metabolism than the

Propofol LCT. There is less elevation of serum triglycerides with Propofol MCT_LCT but there were increased ketone bodies and octanoate (metabolite of incomplete oxidation of fatty acids).^[5] This study supports our study.

Theilen et al studied elevation of serum triglycerides and concluded that plasma triglyceride concentrations during sedation did not differ between the groups, whereas there was a more rapid triglyceride elimination in Propofol MCT_LCT after termination of the propofol administration.^[2] This also supports our finding of lower. Triglyceride levels with Propofol MCT_LCT at 4 hours postinduction. Bhukal et al,^[3] compared elevation of serum triglycerides with both 1% Propofol MCT_LCT and 1% Propofol LCT in 40 children and concluded that there was elevation in serum triglyceride in both the groups although less with MCT and decrease in levels was also rapid with termination of Propofol MCT.^[11,12] Their finding is also correlating with our study showing lower serum triglyceride level 4 hours postinduction with Propofol MCT_LCT.

CONCLUSION

Serum Triglyceride decreased for Propofol MCT_LCT by 11.04 ± 1.031 and increased with Propofol LCT by 28.52 ± 1.104 . There were no significant hemodynamic changes contributing to allergic reactions. There were no local site reactions for both the groups. Hence 1% Propofol MCT_LCT preparation is a better choice for the induction of anaesthesia with regard Serum triglyceride level maintenance with no significant allergic reactions.

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