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A PROSPECTIVE COMPARATIVE STUDY OF PAIN ON INJECTION OF PROPOFOL MCT WITH PROPOFOL LCT IN A TERTIARY CARE HOSPITAL

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Abstract

Introduction: Propofol is the most popular intravenous (IV) anesthetic induction agent nowadays. It provides rapid, smooth induction and early clear headed recovery and used for variety of purposes like induction of general anaesthesia, sedation, total intravenous anaesthesia, anticonvulsant and as an antiemetic. Conventionally, propofol formulation contains long chain triglycerides (LCT). But, the side effect of this formulation is a severe pain on intravenous injection.

Materials and Methods: This Prospective comparative study was carried out in the Department of Anaesthesia, Shaheed Nirmal Mahto Medical College (SNMMC), Dhanbad, Jharkhand. Assuming VAS score of Propofol MCT 2.089 and SD of 0.896, keeping power at 80% and confidence interval at 95% (alpha error at 0.05) a sample of 60 patients would be required to detect a minimum of 25% of pain on IV Propofol MCT and LCT. We include 150 patients in each group to compensate for possible drop out. A total of 300 patients aged between 18-65 years willing to give written informed consent fitting into the inclusion criteria were included in this prospective comparative study scheduled for various elective surgeries under general anaesthesia.

Results: The VAS pain score is compared between Group L 6.37 ± 2.49 (Propofol LCT) and Group M 4.15 ± 1.90 (Propofol MCT), Group M reported significantly reduced pain after IV propofol injection ($p < 0.001$) compared to Group L. There is an overall less incidence of pain in Group M (54%) compared to Group L (65%). Induction time in seconds when compared between Group L (34.07 ± 2.68) to Group M (33.61± 2.72) was similar, and had no difference.

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When comparison of serum triglycerides was done preoperatively and postoperatively showed no difference.

Conclusion: Propofol MCT was associated with less incidence of pain on injection, compared to Propofol LCT, and does not need addition of any other drug to reduce this pain of injection. Also, the formulation did not increase serum triglyceride levels after single bolus dose.

Key Words: Propofol, general anaesthesia, sedation, triglyceride.

INTRODUCTION

Propofol is the most popular intravenous (IV) anesthetic induction agent nowadays. It provides rapid, smooth induction and early clear headed recovery and used for variety of purposes like induction of general anaesthesia, sedation, total intravenous anaesthesia, anticonvulsant and as an antiemetic.[1] Conventionally, propofol formulation contains long chain triglycerides (LCT). But, the side effect of this formulation is a severe pain on intravenous injection. Newer formulation of propofol containing combination of medium and long chain triglycerides (MCT/LCT; 50:50) have significantly less concentration of free propofol.[2] Also, changes in the formulation may have an impact on the pharmacokinetics, pharmacodynamics or safety characteristics of a drug and hence can alter induction time.[3]

The results of this study showing that the concentration of free propofol is significantly smaller in propofol MCT/LCT than in propofol LCT are consistent with previously reported suggestions that the use of propofol MCT/LCT reduces the incidence and intensity of pain on injection.[4] Adding to the additional note regarding potential risks related to propofol however, an increase in serum triglyceride levels has been described repeatedly, particularly after long-lasting infusions. In critically ill patients presenting with deranged metabolic or enzymatic systems, prolonged propofol administration might result in an excessive fat load with ensuing pancreatitis, which is a well-known complication of hyper triglyceridemia.[5] So we considered to compare the pain on injection and if the single bolus dose of propofol do elevate serum triglycerides levels or not.

We wanted to study the efficacy of Propofol MCT over routinely use Propofol LCT in attenuating the pain on injection & any change of serum triglyceride levels after single bolus induction dose.

MATERIALS AND METHODS

Study design: A Prospective comparative study

Study Location: Department of Anaesthesia, Shaheed Nirmal Mahto Medical College (SNMMC), Dhanbad, Jharkhand.

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This Prospective comparative study was carried out in the Department of Anaesthesia, Shaheed Nirmal Mahto Medical College (SNMMC), Dhanbad, Jharkhand. Assuming VAS score of Propofol MCT 2.089 and SD of 0.896, keeping power at 80% and confidence interval at 95% (alpha error at 0.05) a sample of 60 patients would be required to detect a minimum of 25% of pain on IV Propofol MCT and LCT. We include 150 patients in each group to compensate for possible drop out. A total of 300 patients aged between 18-65 years willing to give written informed consent fitting into the inclusion criteria were included in this prospective comparative study scheduled for various elective surgeries under general anaesthesia. Patients are divided into groups into 150 each. Group MCT received 25% of Propofol MCT induction dose. Group LCT received 25% of propofol LCT. Pre anaesthetic evaluation was done a day before the surgery. Patients were asked to be nil by mouth by 8 hours.

All the necessary routine investigations were noted along with preoperative triglycerides. Patients with chronic pain disorder, known allergy to the study drug, pregnancy, abnormal renal and liver function were excluded from the study.

On arrival of patient to operation theatre, all routine monitors are attached to the patient and baseline parameters such as HR, SBP, DBP, MAP, and SPO2 were recorded. Intra-venous cannulation was done using wide bore cannula (18 G or 20 G) on the dorsum of the hand or forearm. Pre-medications were deliberately avoided to avoid influence on study results. With a tourniquet in place distal to venous cannulation. 2.5 ml of total 10 ml propofol i.e. 25% of the induction dose is given to according to the groups divided. Patients are asked to indicate the severity of pain on injection using VAS Score, at 25 seconds. This is the end point of the study and further procedure was carried out in conventional manner depending on the type of surgery. Awareness of the pain due to propofol after general anaesthesia is not considered. Postoperative serum triglyceride levels were measured. Statistical Analysis Descriptive and analytical statistics were done. The normality of continuous data was analysed by the Shapiro-Wilk test. As the data followed normal distribution, parametric test was used to analyse the data. The independent sample t-test and paired sample t-test were used to check mean differences wherever appropriate. The chi-square test was used to check differences in proportions. The level of significance was kept at $p<0.05$.

RESULTS

In all the patients' demographic details in table 1, such as age, sex, weight and ASA status were comparable between both groups. The VAS pain score is compared between Group L 6.37 ± 2.49 (Propofol LCT) and Group M 4.15 ± 1.90 (Propofol MCT), Group M reported significantly reduced pain after IV propofol injection ($p < 0.001$) compared to Group L. There is an overall less incidence of pain in Group M (54%) compared to Group L (65%). Induction time in seconds when compared between Group L (34.07 ± 2.68) to Group M (33.61± 2.72) was similar, and had

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no difference. When comparison of serum triglycerides was done preoperatively and postoperatively showed no difference.

Parameter	N	Group LCT	Group MCT
Age (Mean±SD)	150	44.30 ± 11.20	41.76 ± 101.8
Gender			
Male	150	80 (53.3%)	82 (54.7)
Female		70 (46.5%)	68 (45.3)
Weight (Mean ± SD)	150	59.67±9.53	61.92±12.51
ASA Grade			
ASA 1, n (%)	150	114 (76%)	118 (78.7%)
ASA 1, n (%)		36 (24%)	32 (22.3%)

Table 1: Patient demographics

Parameter	N	Group LCT	Group MCT	P Value
SVAS Pain Score (Mean ± SD)	150	6.37 ± 2.49	4.15 ± 1.90	<0.001
Induction time in seconds (Mean ± SD)	150	34.07 ± 2.68	33.61 ± 2.72	0.306
Pain Present n (%)	150	130 (86.7%)	108 (72%)	0.027

Table 2: Comparison of Mean VAS Pain Score, Induction Time and Presence of Pain between the Two Groups

Triglycerides	N	Group LCT	Group MCT
Pre-Op Triglycerides	150	128.94±21.60	128.62±21.59
Post-Op Triglycerides	150	134.41±20.44	132.44±12.76
P-Value		0.099	0.174

Table 3: Comparison of Pre and Post Triglycerides Values of Group Propofol LCT and Propofol MCT

DISCUSSION

In our study we compare the efficacy of Propofol MCT with Propofol LCT. Table 1 shows Patient characterstics pertaining to demographic details and ASA grade, did not differ between

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both the groups. Table 2 shows The VAS score in Propofol LCT (6.37±2.49) is more compared to Propofol MCT (4.15±1.90). Similarly, Rau et al reported less injection pain with Propofol MCT/LCT (p=0.0007). Table 2 shows that incidence of pain in more in Propofol LCT (86.7 %) compared to Propofol MCT (72.0%). Larsen et al reported Propofol MCT/LCT had significantly lower incidence of pain on injection in comparison with standard propofol group LCT (37% vs 65 %). (12) Table 2 compared the Induction time in Group L 2.72), was found to be ±2.68) and Group M (33.61±(34.07 similar.[6] Table 3 Compared the pre-operative and postoperative triglycerides which showed no significant difference between both the groups, similar to Manjula et al failed to increase triglyceride levels to a significant level, despite the difference in the lipid content, single dose of MCT/LCT or LCT propofol did not increase serum triglyceride levels significantly to cause any adverse effects but Bhukal et al demonstrated that both LCT and MCT-LCT propofol cause significant rise in triglyceride levels in children when used for induction and maintenance of anaesthesia.[7] However, children in MCT-LCT group had lower triglyceride levels than children in LCT group at the end of propofol infusion and 4 hours after termination.[8]

Adding on to details Ali et al stated that increased serum triglyceride level after propofol infusion is associated with increased risk of pancreatitis, coronary artery disease. It occurs in ICU patients who receive long term propofol infusion (>24 hrs.).[9] But this propofol infusions are not now routinely used as newer and better drugs like dexmedetomidine and others have taken over propofol. No studies have cited that there was increase in serum triglycerides after single bolus dose of propofol except a case of 21-year-old patient operated for Bartholin duct excision developing pancreatitis after single dose of propofol.[10]

CONCLUSION

Propofol MCT was associated with less incidence of pain on injection, compared to Propofol LCT, and does not need addition of any other drug to reduce this pain of injection. Also, the formulation did not increase serum triglyceride levels after single bolus dose.

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