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Severity of Pain on Injection of Propofol; Propofol LCT Versus Propofol MCT/LCT: A Randomised Double Blind Parallel Group Study

Dr. Ajeet Kumar, Dr. Ankesh, Dr. Ajit Gupta, Dr. Waquas Ahmed
Department of Anaesthesiology and Critical Care, Indira Gandhi Institute of Medical Sciences, Patna, Bihar
Corresponding Author - Dr. Ankesh

Abstract
Background- *Propofol has become a most popular intravenous agent. The most common problem with administration of i.v propofol is pain at the injection site. On an average, 70-85 % of patients report pain on injecting propofol.* ***Aim-*** *To study the incidence and severity of pain due to propofol injection.* ***Primary objective -*** *To compare pain between Propofol LCT and Propofol-MCT/LCT.* ***Secondary objective-*** *To compare heart rate and mean arterial pressure between Propofol LCT and Propofol-MCT/LCT.* ***Material and methods-*** *The study was conducted at Indira Gandhi Institute of Medical Sciences, Patna after approval by Institutional Ethical Committee. Drugs used for study- Inj.1% LCT Propofol and Inj.1% MCT/LCT Propofol. Intervention was done in the operation theatre under indoor hospital settings. Written Informed consent was obtained. Patients were randomly allocated to one of the groups using table of randomization, Group A (n = 100):Inj. I.V. Propofol 1%LCT and Group B (n = 100): Inj. I.V. Propofol1%MCT/LCT. Statistical analysis was done using SPSS version 20.0.* ***Results-*** *In Group A 85% of the patients felt pain, 31% patients had mild pain (score 1), 43% patients had moderate pain (score 2) and 11% patients felt severe pain (score 3). In Group B: 62 % patients did not feel any pain (score 0). 38% of patients felt pain. 32% patients complained of mild pain (score 1), 6% patients had moderate pain (score 2) and none of the patients had severe pain. We found reduction in incidence and severity of pain with Propofol MCT/ LCT versus Propofol LCT (38% Vs 85%); (p=0.0001).****Conclusion-*** *The study showed that propofol MCT/ LCT causes less incidence and severity of pain in comparison to propofol LCT.*

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I. Introduction

Propofol has become a most popular intravenous agent. It is a short acting, intravenously administered hypnotic agent. It is associated with pleasant sleep, rapid recovery and little postoperative nausea and minimal hemodynamic changes intra-operatively. Currently available preparation is 1% propofol, 10% soyabean oil and 1.2% purified egg phospholipid as an emulsifier with 2.25% of glycerol as a tonicity – adjusting agent and sodium hydroxide, disodium edetate (0.005%) was added as a retardant of bacterial growth. This formulation has a pH of 7 and appears as a slightly viscous, milky white substance. It's rate of onset of action is similar to that of the intravenous barbiturates but recovery is more rapid and patients are able to ambulate earlier after general anaesthesia. Propofol is used for both induction and maintenance of anaesthesia as a part of total intravenous or balanced anaesthesia techniques and is the agent of choice for ambulatory surgery.

The most common problem with administration of i.v propofol is pain at the injection site. On an average, 70-85 % of patients report pain on injecting propofol.

There are many factors which appear to affect the incidence of pain on propofol injection. These are size of the vein, speed of the injection, propofol concentration in the aqueous phase. Several methods have been used to reduce this pain; diluting the propofol solution, injection of propofol in large vein[1], adding lidocaine, pre-treatment with ephedrine, ketamine, metoclopramide, etc. [2,3] All have been tried with many different results. Despite these recommendations, the technique failed to gain widespread popularity, possibly because of the time needed to apply the tourniquet. As a result, pain associated with injection of propofol remains a challenge and more than 100 new studies have explored additional and alternative strategies. The most common method used in routine clinical practice is giving lignocaine before propofol or adding 10 to 40 mg of lignocaine to the propofol syringe immediately with or without the use of a tourniquet[4,5]. However, pain on injection still occurs by about 40% despite this treatment and lignocaine does not completely eliminate this type of pain [2,4]. It is reported that addition of lignocaine may destabilize the emulsion formulation of propofol with a potential risk of causing pulmonary fat embolism[5].

In a newer formulation of propofol, MCT/LCT-propofol, the oil phase consists of medium-long chain triglyceride. Such a composition results in a smaller concentration of free propofol in the aqueous phase. An improved tolerability with MCT/LCT-propofol on injection compared with LCT-propofol has been claimed and reduced pain intensity with MCT/LCT-propofol [6,7]. The incidence of pain still ranges from 28% to 38%. [8, 9,10] Emulsion of MCT/LCT, although maintaining similar pharmacological properties as standard propofol [11] have similar concentrations in the aqueous phase. [12]

II. Aim & Objectives

To study the incidence and severity of pain due to propofol injection

Primary objective **-** To compare pain between Propofol LCT and Propofol-MCT/LCT

Secondary objective **-** To compare heart rate and mean arterial pressure between Propofol LCT and Propofol-MCT/LCT

III. Material And Methods

The study was conducted on patients for elective surgical procedures. Different surgical departments were selected for the study at Indira Gandhi Institute of Medical Sciences, Patna after approval by Institutional Ethical Committee.

Material: Drugs used for study

a) Inj.1% LCT Propofol

b) Inj.1% MCT/LCT Propofol

Method:

Patients were randomly allocated in one of the two groups. Group A received long chain triglyceride preparation [LCT-propofol]. Whereas Group B received medium chain/long chain propofol [MCT/LCT-propofol].

The speed of injection was controlled carefully. One quarter of total calculated dose was given in first 5 seconds. After this period injection was stopped for 5 seconds to allow assessment of pain by the method administered. Induction continued and second quarter of the total induction dose was administered over a further 5 seconds period. The pain was questioned again and assessment of pain was done. Finally remaining dose was given.

The pain score was obtained by asking the patient about any pain felt on injection and verbal response along with behavioral signs such as facial grimacing, arm withdrawal, tears. A score of 0-3 which consisted of no pain, mild pain, moderate and severe pain respectively was recorded.

Assessment of pain on Propofol injection according to the McCrirrick and Hunter Scale	
Degree of pain	**Response**
None (0)	No response to questioning
Mild (1)	Pain reported in response to questioning only, without any behavioral signs
Moderate (2)	Pain reported in response to questioning and accompanied by behavioral sign or pain reported spontaneously without questioning
Severe (3)	Strong vocal response or response accompanied by facial grimacing, arm withdrawal or tears

Study design

This study was an interventional, prospective, double blind, parallel group, randomized clinical study conducted on patient's different surgeries. Intervention was done in the operation theatre under indoor hospital settings. Written Informed consent was obtained from all the patients before the screening in the study.

Sample size

Patients were randomly allocated to one of the groups using table of randomization, Group A (n = 100):Inj. I.V. Propofol 1%LCT and Group B (n = 100): Inj. I.V. Propofol1%MCT/LCT.

Eligibility

Inclusion criteria:

- Age group of 18-60 years
- Patient of either sex
- ASA grade I and II undergoing various surgical procedures
- Body weight between 18-70 kg

Exclusion criteria:

- Patient refusal
- ASA grade III and IV
- History of allergy to study drugs

- Difficulty with communication
- Any history of cardiopulmonary, renal, neurological and psychiatric disorders
- Presence of infection on dorsum of hand
- Intake of any analgesic before surgery
- Vascular abnormalities

Randomization: Each patient fulfilling eligibility criteria was randomly allocated in two different groups (Group A & Group B) and was assigned a sequence number in increasing order. By the use of computer generated random numbers patients were allocated to one of the two groups.

In study **Group A** (n =100): Intravenous 1%LCT-Propofol 2 mg/kg body weight.

In study **Group B** (n = 100): Intravenous 1% MCT/LCT- Propofol 2 mg/kg body weight.

The procedure was explained to the patient in their language and informed consent was taken. Preparation included a fast of 8 hours before the surgery, premedication was given a night before and on the morning of the surgery with oral tab ranitidine 150 mg.

Procedure:

All patients were transferred to the operating room after premedication. On arrival to the operating room, an 18-gauge intravenous (IV) catheter was inserted in the vein of the forearm and 6 ml/kg/h crystalloid was infused intra-operatively, monitoring of electrocardiography, non-invasive blood pressure, oxygen saturation (SpO2) was started and baseline values were recorded. Pre- oxygenation with 100% oxygen. Intravenous 1%Propofol 2mg/kg body weight in controlled manner was given.

Monitoring

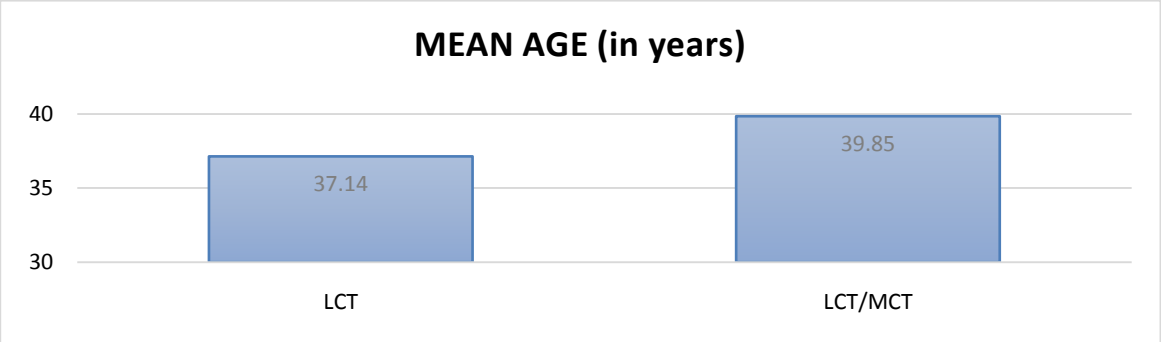
Monitoring was done with non-modular multipara monitor. It included Lead II Electrocardiography, Non invasive blood pressure (NIBP), Pulse rate, Respiration rate, EtCO2 and Oxygen saturation was monitored by pulse oximetry.

Statistical Analysis:

The statistical analysis was done using SPSS version 20.0. The values were represented in number, proportions (%) and mean ± SD.

IV. Results

Graph 1 and Table 1: Mean age of patient

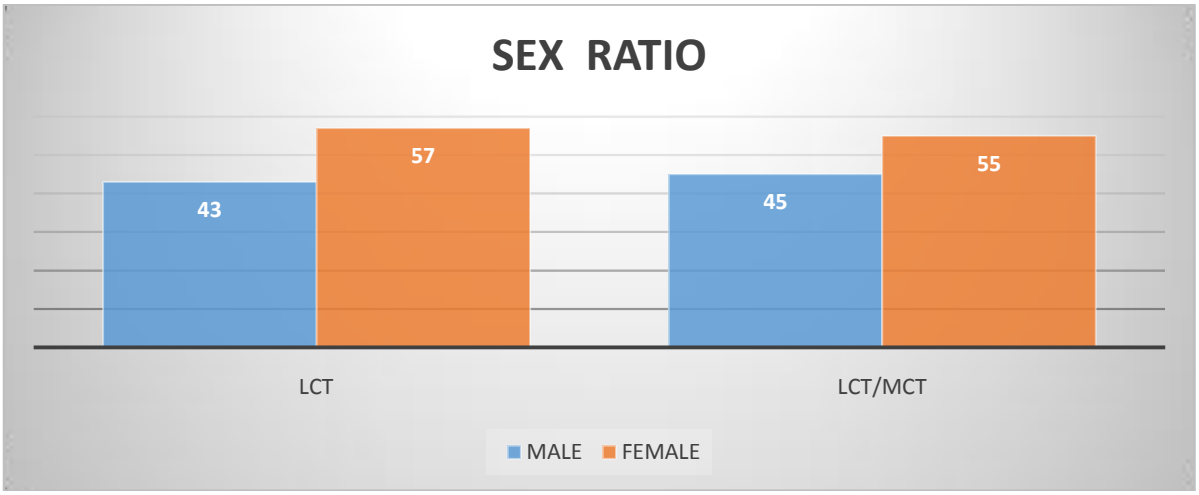


DRUG	MEAN AGE (YEARS)	STANDARD DEVIATION
LCT	37.1400	13.5729
MCT/LCT	39.8500	13.3714

t=1.422; p=0.156(>0.05); R=NS *paired t-test*

The mean age of patients in group A & group B was 37.1400 ± 13.5729 years and 39.8500 ± 13.3714 years respectively.

Graph 2 and Table 2: Sex distribution of patients

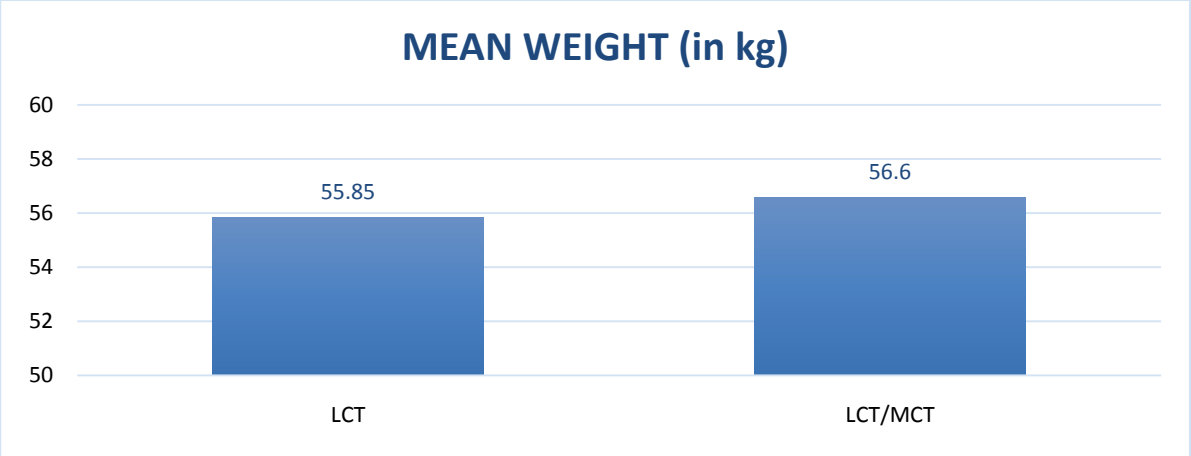


SEX	DRUG		
	LCT	MCT/LCT	TOTAL
FEMALE	57	55	112
MALE	43	45	88

$\chi 2=0.081$; $p=0.776$ (> 0.05); df=1; R=NS *Chi- square Test*

In group A 43% were males and 57% were females. In group B, 45% were males and 55% were females.

Graph 3 and Table 3: Mean weight of patient

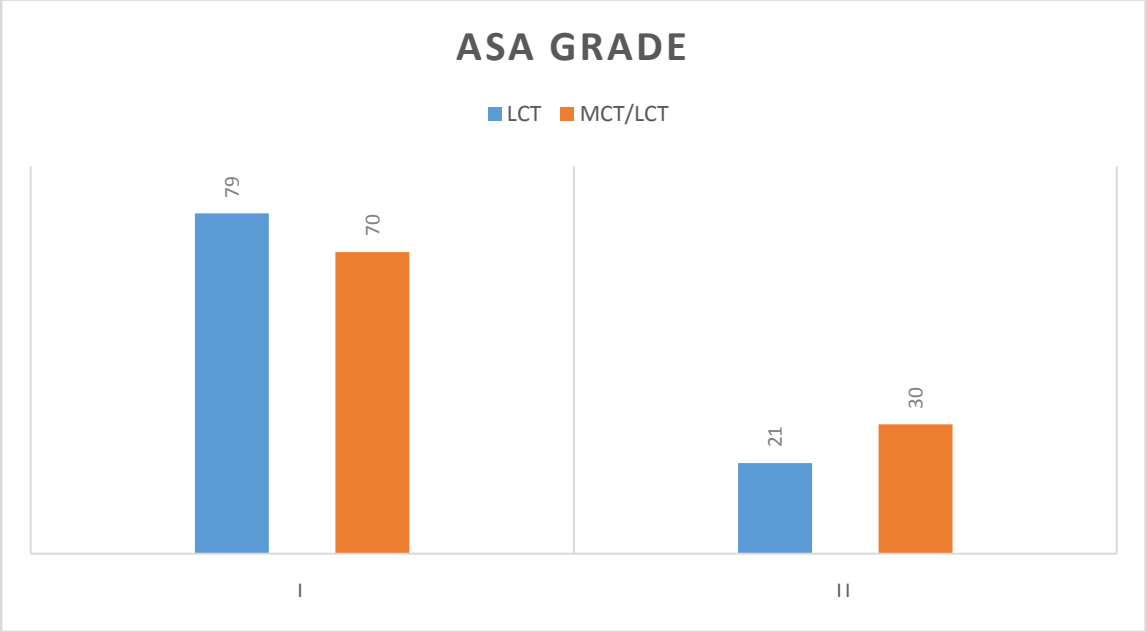


DRUG	MEAN WEIGHT (Kg)	STANDARD DEVIATION
LCT	55.8500	10.8128
MCT/LCT	56.6000	9.1574

t=0.529; p=0.597; R=NS

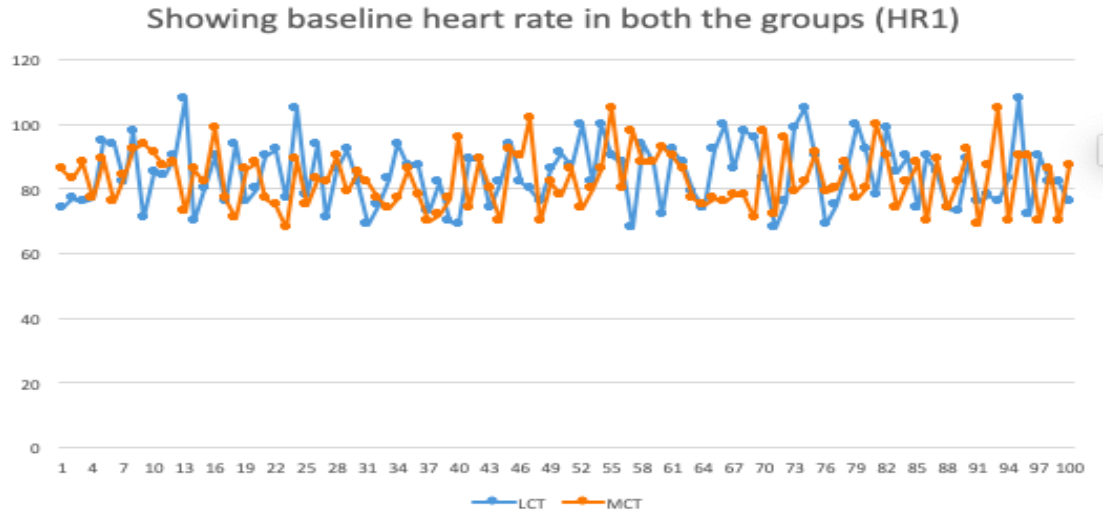
Mean weight of group A & group B was 55.8500 ± 10.8128 kg and 56.6000 ± 9.1574 kg respectively.

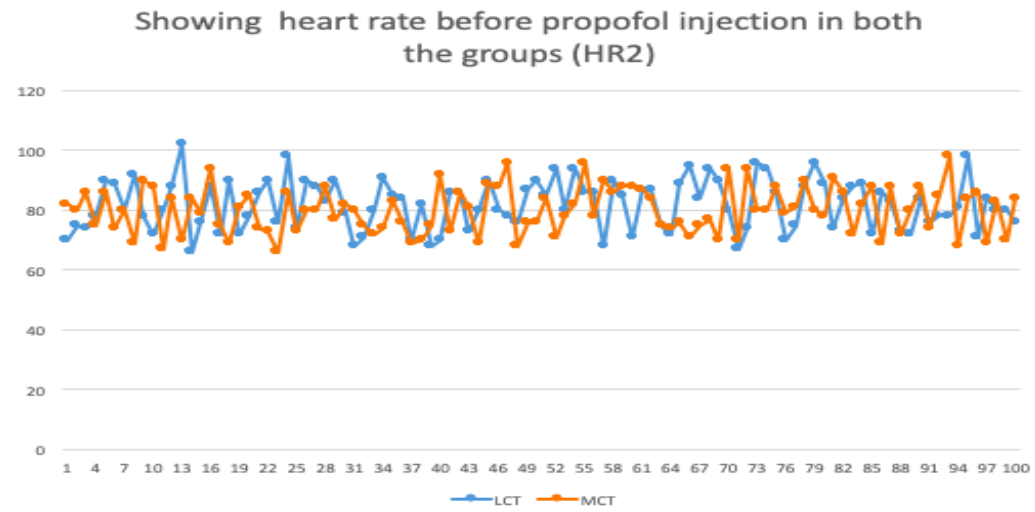
Graph 4 and Table 4: Distribution of patients according to ASA grade I and II

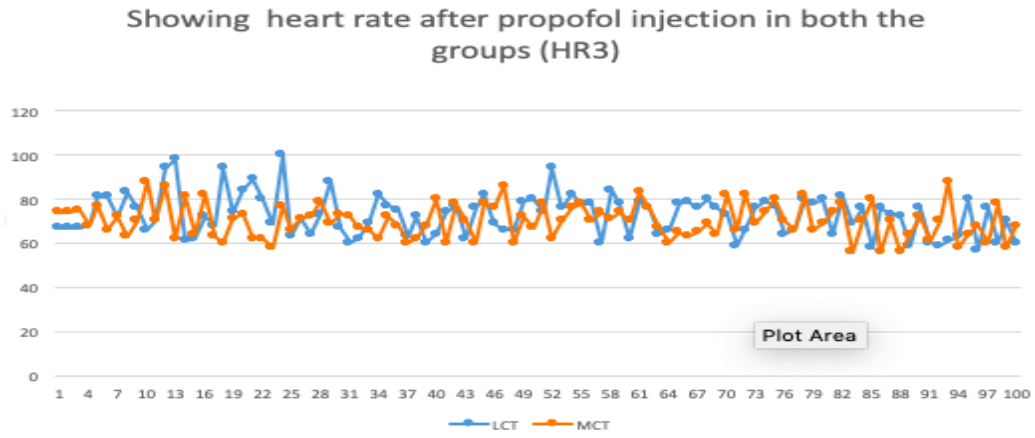


ASA GRADE	DRUG		TOTAL
	LCT	MCT/LCT	
1	79	70	149
2	21	30	51

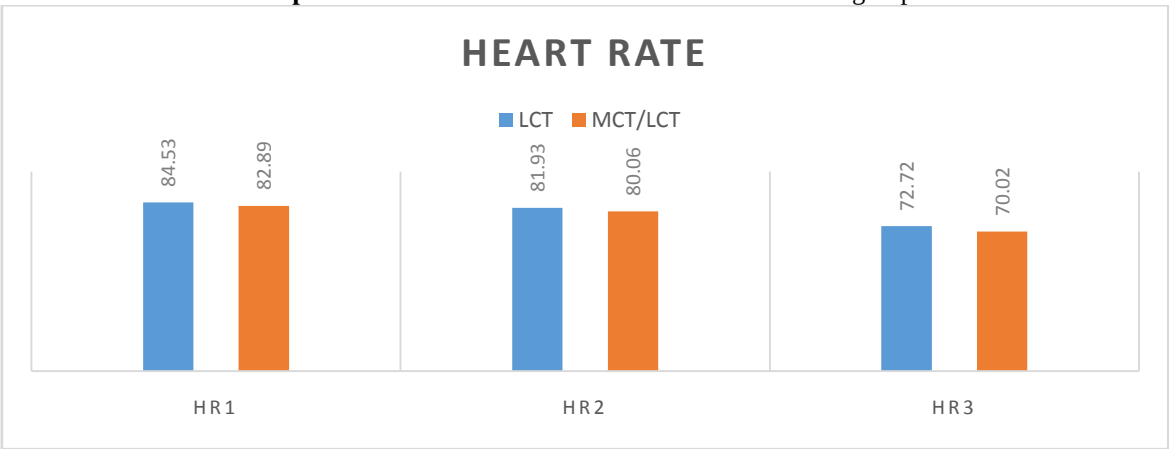
$\chi 2=2.132$; $p=0.144$ (>0.05); df=1; R=NS *Chi- square Test*







Graph 5 and Table 5:- Shows the heart rate in both the groups



HR1 (Baseline heart rate in both the Groups)		
DRUG	**MEAN**	**STANDARD DEVIATION**
LCT	84.5300	9.8201
MCT/LCT	82.8900	8.6712

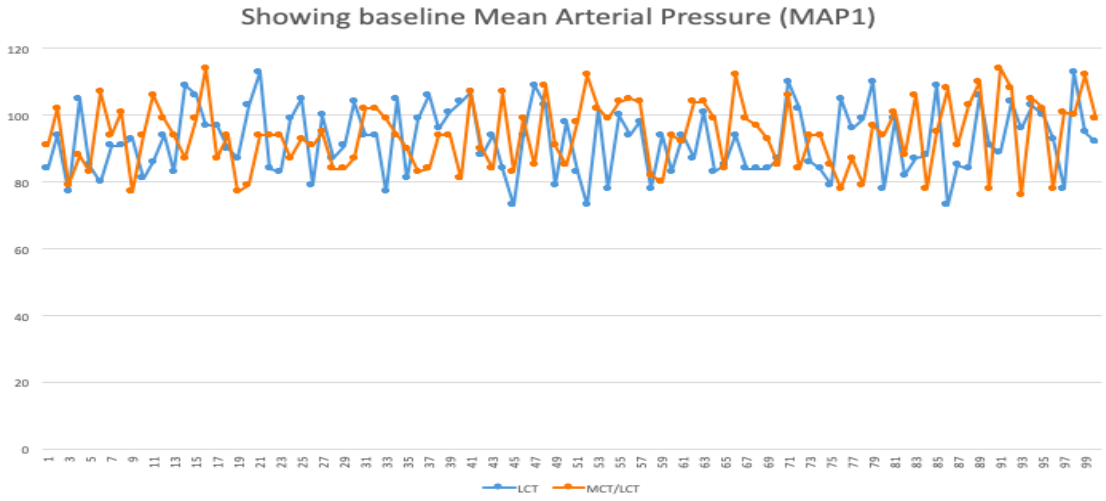
t=1.252, p=0.212, R=NS

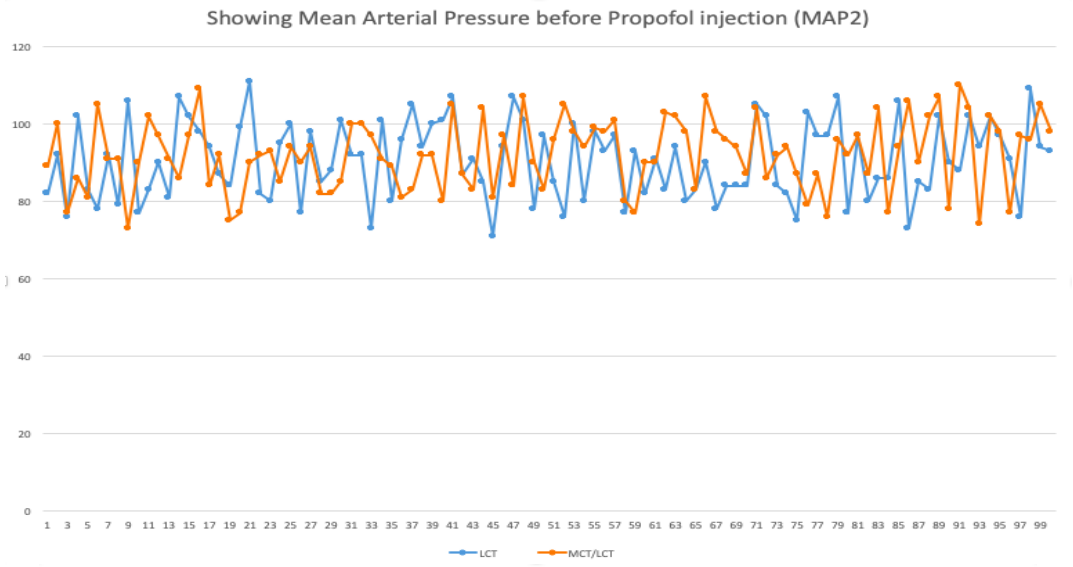
HR2 (Heart rate before Propofol Injection)		
DRUG	**MEAN**	**STANDARD DEVIATION**
LCT	81.9300	8.3560
MCT/LCT	80.0600	7.7431

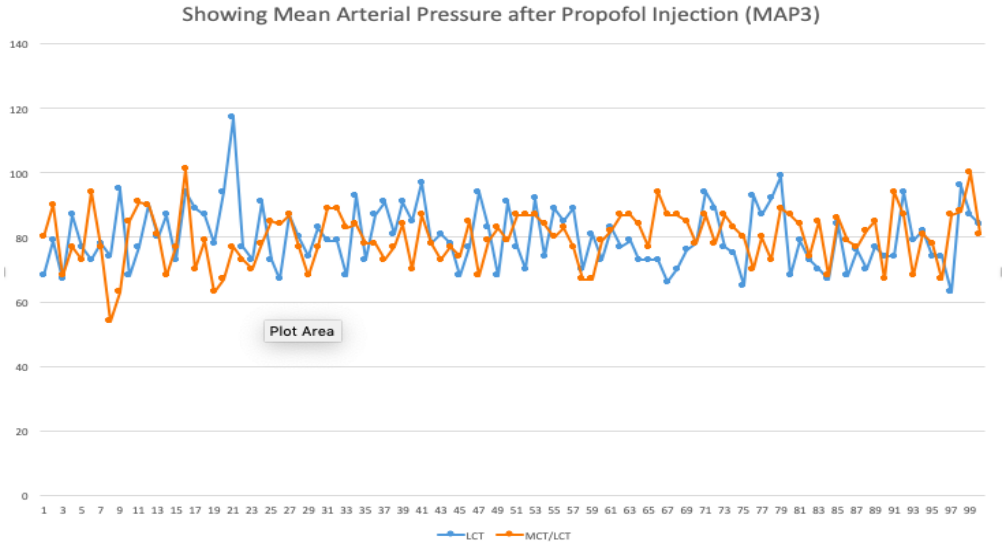
t=1.641, p=0.102, R=NS

HR3 (Heart rate after Propofol Injection)		
DRUG	**MEAN**	**STANDARD DEVIATION**
LCT	72.7200	9.4185
MCT/LCT	70.0200	7.6778

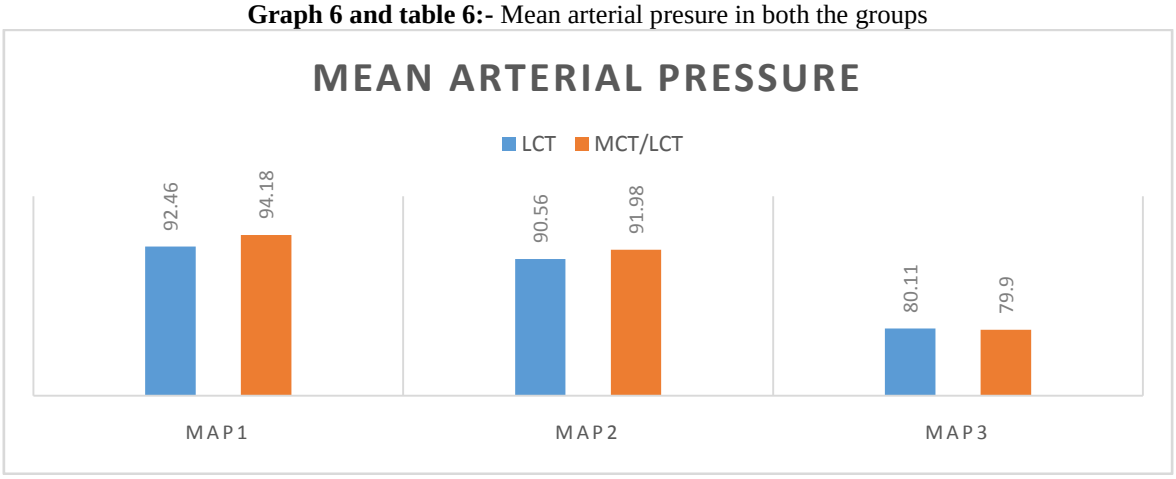
t=2.222, p=0.101, R=NS







Graph 6 and table 6:- Mean arterial presure in both the groups



MAP1 (Baseline Mean Arterial Pressure)		
DRUG	**MEAN**	**STANDARD DEVIATION**
LCT	92.4600	10.1756
MCT/LCT	94.1800	9.9650

t=1.208, p=0.229, R=NS

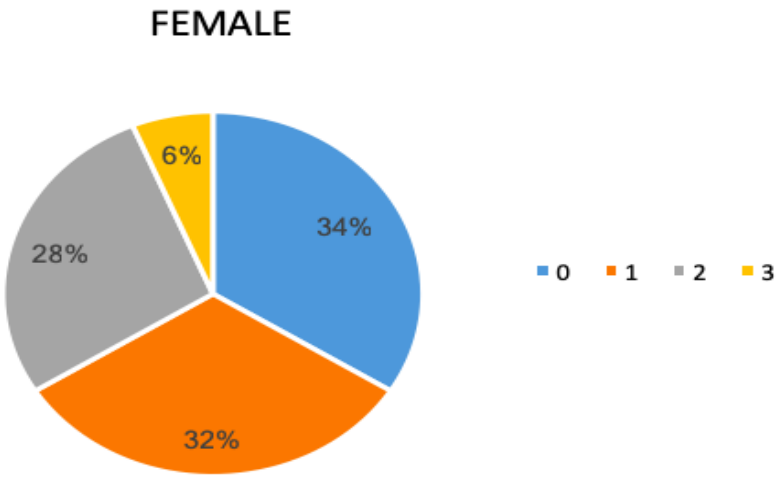
MAP2 (Mean Arterial Pressure before Propofol Injection)		
DRUG	**MEAN**	**STANDARD DEVIATION**
LCT	90.5600	9.9882
MCT/LCT	91.9800	9.2321

t=1.044, p=0.298, R=NS

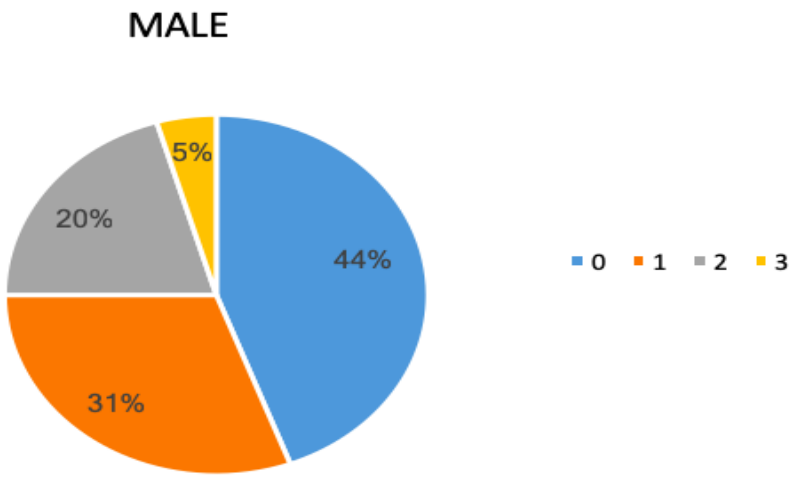
MAP3 (Mean Arterial Pressure after Propofol Injection)		
DRUG	**MEAN**	**STANDARD DEVIATION**
LCT	80.1100	9.5842
MCT/LCT	79.9000	8.3382

t=0.165, p=0.869, R=NS

Pain occurred due to Propofol (LCT or MCT/LCT) in both the sex groups:

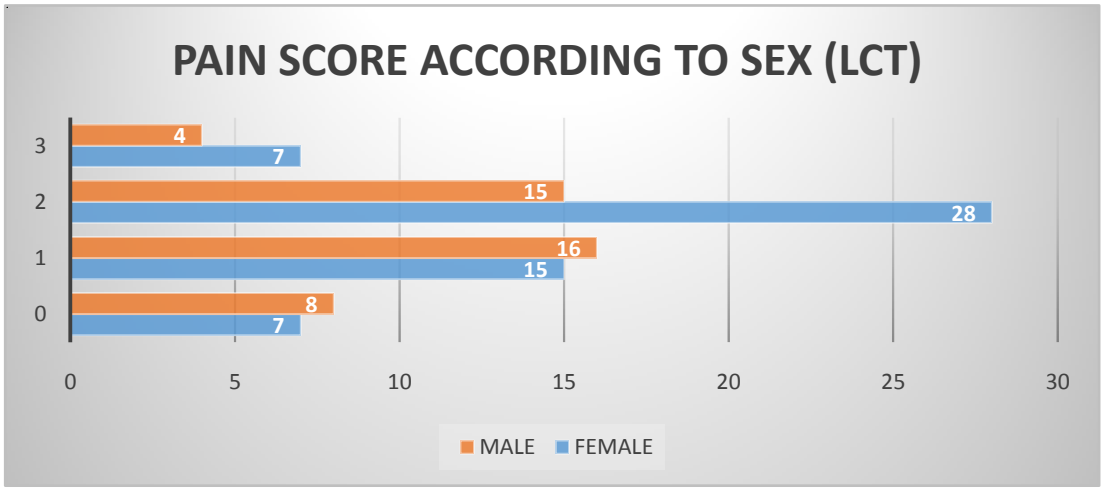


Pie chart shows the incidence and severity of pain in females in both the groups



Pie chart shows the incidence and severity of pain in males in both the groups

Graph 7 and Table 7:- Incidence & severity of pain in group A according to sex

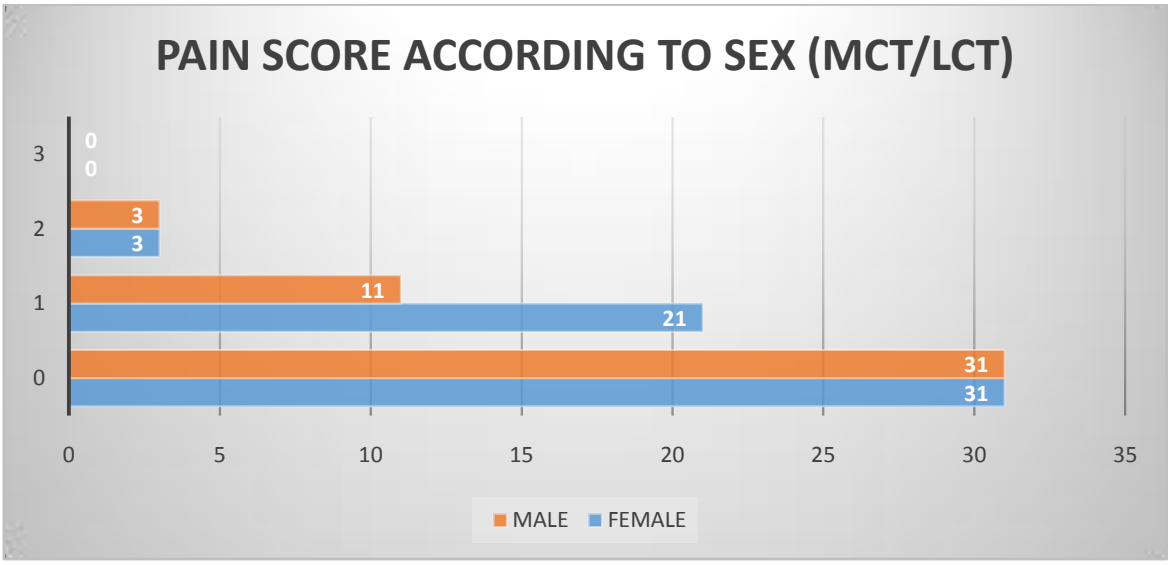


PAIN SCORE ACCORDING TO SEX (LCT) (McCrirrick and Hunter Scale)			
PAIN	**FEMALE**	**MALE**	**TOTAL**
0	7	8	15
1	15	16	31
2	28	15	43
3	7	4	11

$\chi 2=2.937$; $p=0.230$; $df=2$; R=NS

The results revealed that out of 57 female patients, 50 (87.71%) and 43 male patients, 35 (81.39%) had pain. Although pain in female patients was slightly higher.

Graph 8 and Table 8:- Incidence & severity of pain in group B according to sex



PAIN SCORE ACCORDING TO SEX (MCT/LCT) (McCrirrick and Hunter Scale)			
PAIN	**FEMALE**	**MALE**	**TOTAL**
0	31	31	62
1	21	11	32
2	3	3	6
3	0	0	0

$\chi 2=1.548$; $p=0.199$; $df=1$; R=NS

The results showed that out of 55 female patients, 24 patients (43.6%) had pain and out of 45 male patients, 14 (31.1%) had pain. Pain in female patients was slightly higher.

V. Discussion

Effective relief of pain is of paramount importance to the anaesthesiologist treating patients undergoing surgeries. Propofol belongs to a group of phenol that can irritate the skin, mucous membrane and venous intima.[13]

Various pharmacological and non-pharmacological interventions have been tried in search of elimination of propofol-induced pain. [4,14,15] Various studies have recommended using larger veins [16], decreasing speed of injection [10]; injecting the drug into a fast running IV fluid [17]; diluting it with 5 % glucose or 10% intralipid; mixing lignocaine in propofol; pretreating with lignocaine and venous occlusion; pretreating with alfentanyl, fentanyl, or pentothal; cooling propofol to 4C; injecting cold saline (4C) before propofol; or discontinuing fluid during injection.

The use of lidocaine to prevent propofol injection pain is the most common method used in clinical practice. Moreover, mixing of propofol emulsion with any other drug is not recommended by the manufactures because emulsions are thermodynamically unstable despite the use of stabilizing agent. [10]

MCT propofol has 24.5% decreased free propofol concentration in an emulsion in the aqueous phase compared with standard propofol LCT. (18) As a result, decreased incidence and severity of propofol injection pain, while maintaining the pharmacological properties of standard LCT propofol, has been reported for MCT/LCT propofol. (19)

The present study was carried out on 200 patients ranging from 18-60 years of age, ASA physical status I & II, undergoing elective surgery under general anaesthesia. Demographic profile including age, sex and weight were kept comparable in the two groups.

	Group A	**Group B**	**p-value**
Mean Age (years) ± SD	37.14 ± 13.5729	39.8500 ± 13.3714	0.156
Sex (F:M)	57 : 43	55 : 45	0.776
Mean weight (kg) ± SD	55.8500 ± 10.8128	56.6000 ± 9.1574	0.456
ASA Grade I:II	79 : 21	70 : 30	0.144

All the patients were comparable with respect to age, sex, weight and ASA status.

	LCT	MCT/ LCT
No Pain (0)	15	62
Pain (≥1)	85	38

Pain	Group A	Group B
0	15	62
1	31	32
2	43	6
3	11	0

$\chi 2=67.104$; $p=0.000$; $df=2$; R=SSS

Pain score and drugs were dependent on each other since $\chi 2$ was highly significant.

Group A: Propofol LCT was injected in the vein of the forearm. 85% of the patients felt pain, 31% patients had mild pain (score 1), 43% patients had moderate pain (score 2) and 11% patients felt severe pain (score 3).

Group B: Propofol MCT/ LCT was injected in the vein of the forearm. 62 % patients did not feel any pain (score 0). 38% of patients felt pain. 32% patients complained of mild pain (score 1), 6% patients had moderate pain (score 2) and none of the patients had severe pain.

We found reduction in incidence and severity of pain with Propofol MCT/ LCT versus Propofol LCT (38% Vs 85%); (p=0.0001).

Larsen et al [20] in 2001 reported that propofol MCT/LCT decreased the incidence of pain on injection ranging from 64% to 37% relative to propofol LCT.

Kam et al [21] in 2004 reported an incidence of pain on injection in 38% patients receiving propofol MCT/ LCT compared to 36% patients receiving propofol LCT.

Yew et al [22] in 2005 reported that the pain on injection associated with propofol MCT/LCT was similar to the pain associated with propofol LCT-lignocaine admixture (24%). In the study they sought to determine if adding lidocaine to propofol-MCT/LCT was more effective in decreasing pain compared with propofol-MCT/LCT alone or conventional propofol-lidocaine mixtures.

Woon et al (2005) [23] reported incidence of pain on injection in 24% patients receiving propofol LCT premixed with lignocaine and propofol MCT/ LCT emulsion.

Kunitz O et al (2004) [24] reported pain on injection caused by propofol-LCT with pre-treatment of lignocaine and propofol MCT/LCT alone was shown to be equivalent.

Krobbuaban B et al [25] in 2008 compared the pain on injection felt following the administration of propofol MCT/LCT to propofol MCT/LCT plus 20mg lignocaine for the induction of anaesthesia. The overall incidence of pain on injection was 33% in the propofol MCT/ LCT alone and 23% in the propofol MCT/ LCT plus lignocaine.

Burimsittichai R et al [26] reported that injection of new propofol MCT/ LCT solution was an alternative in reducing pain sensation to propofol LCT with pre-treatment of lignocaine.

In our study it was seen that heart rate and mean arterial pressure decreased after propofol injection in both the groups.

	Propofol LCT	Propofol MCT/ LCT	p-value
HR1	84.5300 ± 9.8201	82.8900 ± 8.6712	0.212
HR2	81.9300 ± 8.3560	80.0600 ± 7.7431	0.102
HR3	72.7200 ± 9.4185	70.0200 ± 7.6778	0.101

	Propofol LCT	Propofol MCT/ LCT	p-value
MAP1	92.4600 ± 10.1756	94.1800 ± 9.9650	0.229
MAP2	90.5600 ± 9.982	91.9800 ± 9.2321	0.298
MAP3	80.1100 ± 9.842	79.9000 ± 8.3382	0.869

VI. Conclusion

The study showed that propofol MCT/ LCT causes less incidence and severity of pain in comparison to propofol LCT. The difference of pain score between group A & Group B was highly significant. ($p<0.0001$)

Since pain on injection is a common problem in clinical use, propofol MCT/ LCT is superior to propofol LCT especially when addition of other drugs is undesirable.

Hence our opinion is propofol MCT/ LCT effectively causes less pain compared to propofol LCT on propofol injection, in non- premedicated patients. Thus propofol MCT/LCT should be preferred over traditional LCT emulsion.

Baseline mean arterial pressure (MAP1), mean arterial pressure before propofol injection (MAP2) and mean arterial pressure after propofol injection (MAP3) in both the groups was comparable.

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