COMPARISON OF STUDY OUTCOMES BETWEEN OFF PUMP CORONARY ARTERY BYPASS GRAFTING & ON PUMP CORONARY ARTERY BYPASS GRAFTING IN PATIENTS WITH MILD TO MODERATE RISK.

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ABSTRACT

BACKGROUND:

OPCABG precludes the use of cardiopulmonary bypass & its complications. Indian surgeonsare practicing OPCABGs (70%-80%) than western counterparts (25%). Guidelines suggest OPCABG in high-risk patients.

AIM OF THE STUDY:

To study the efficacy of OPCABG over conventional CABG exclusively even in mild to moderate risk patients.

SETTINGS AND DESIGN:

Retrospective observational study

METHODS AND MATERIALS:

Retrospective analysis of 100 patients who have undergone OPCABG & ONCABG 50 each, at our institute from May 2019 - September 2019. Preoperative variables like age, gender, history of prior MI, diabetes mellitus, hypertension, stroke, smoking, risk assessment using EUROSCORE II. coronary angiographic findings like number of diseased coronaries (DVD/TVD/LM), EF, RWMA, severity of MR, total duration of surgery, number of grafts, LIMA to LAD grafts, perioperative inotrope & blood products used, post operative ICU stay & duration of mechanical ventilation.

RESULTS:

The study results were (p value <0.0001) for following variables- duration of surgery, duration of ICU stay &mechanical ventilation, number of LIMA – LAD grafts, perioperative use of blood products in OPCABG compared to ONCABG group.

CONCLUSION:
Mild - moderate risk patients who undergoneOPCABG had better outcomes when compared to on pump, in terms of number of LIMA-LAD grafts received, duration of surgery, mechanical ventilation, length of ICU stay & perioperative blood products use.

Keywords
OPCABG, ONCABG, outcomes,patients with mild to moderate risk.

INTRODUCTION

Coronary artery disease remained as leading cause of death worldwide & contribute to major loss of health system cost & resources [1].

Coronary artery bypass grafting is the standard procedure for coronary revascularization. Although conventional CABG is considered as gold standard to perform delicate coronary anastomoses using cardio-pulmonary bypass, this concept of blood less field associated with many negative effects of CPB includes trauma to blood, inflammatory response, non-pulsatile flow and risk of embolization [2].

OPCABG precludes the use of cardiopulmonary bypass & its complications. Indian surgeons are practicing OPCABGs (70%-80%) than western counterparts (25%). EACTS / ESC Guidelines suggest the use of OPCABG (class IB) in only high-risk patients such as patients with multivessel coronary disease, severe LV dysfunction etc [3].

MATERIALS AND METHODS

After obtaining institutional ethical committee approval, this retrospective study conducted on patients undergone Coronary artery bypass grafting performed by surgeons of similar expertise in both OPCABG & conventional CABG from month of May 2019 to September 2019. The study population n=120, were divided into two groups 50 each, Group I - OPCABG and Group II- ONCABG. 20 patients were excluded from this study due to inadequate data.

$$n = \frac{2[(a+b)^2\sigma^2]}{(\mu_1 - \mu_2)^2}$$

Fig.1. sample size formula.

Using the above formula, sample size was determined while maintaining two-sided alpha error at 5% and power at 80%. Each group needed at least 23 individuals, but for greater validation, 50 patients were chosen for each group.

Surgical technique:

The standard midline sternotomy was performed to expose the heart in both surgical approaches. For OPCABG commercially available cardiac positioning techniques & stabilizers were used. For ONCABG, the cardiopulmonary bypass technique established by aortic inflow cannulation & superior & Inferior vena cava cannulation was used. Myocardial protection may be achieved by intermittent antegrade cold blood cardioplegia. CPB flow was maintained at 2.5l/min/m^2. The conventional anastomosis is the left anterior descending artery (LAD) with left internal mammary artery, great saphenous vein &/or radial artery anastomosis with other target vessels in both surgical techniques. Except for differences in surgical techniques, in hospital patient management was found to be similar.

Study outcomes observed:

Pre-operative variables were age, gender, h/o of prior MI, diabetes mellitus, hypertension, stroke, smoking, risk assessment using stroke index, EuroSCORE ii, number of diseased coronaries (DVD/TVD/LM), EF, RWMAS, severity of MR.

Intra operative variables were total duration of surgery, total number of grafts, frequency of LIMA to LAD grafting, peri operative use of blood products, perioperative inotrope use.

Post operative variables- total duration of ICU stay, duration of mechanical ventilation were compared between the two groups.

STATISTICAL ANALYSIS:

Data was entered in MS excel and analysis was done using SPSS 21.0 version. Data was presented as Mean and Standard deviation for continuous variables and as percentages for categorical variables. A Chi-square test was done to find out any association between categorical variables. Independent sample t test was compared when applied to quantitative variables (Age, weight, onset and the duration of surgery, ICU stay & duration of mechanical ventilation) between the groups (I and II). A *p* value of less than or equal to 0.05 was considered significant.

RESULTS:

A. DEMOGRAPHIC DATA

TABLE -1: COMPARISON OF GENDER DISTRIBUTION IN TWO GROUPS

GROUPS	MALE	FEMALE	TOTAL	*p value*
GROUP 1	34	16	50	0.828.
GROUP 2	35	15	50	
TOTAL	69	31	100	

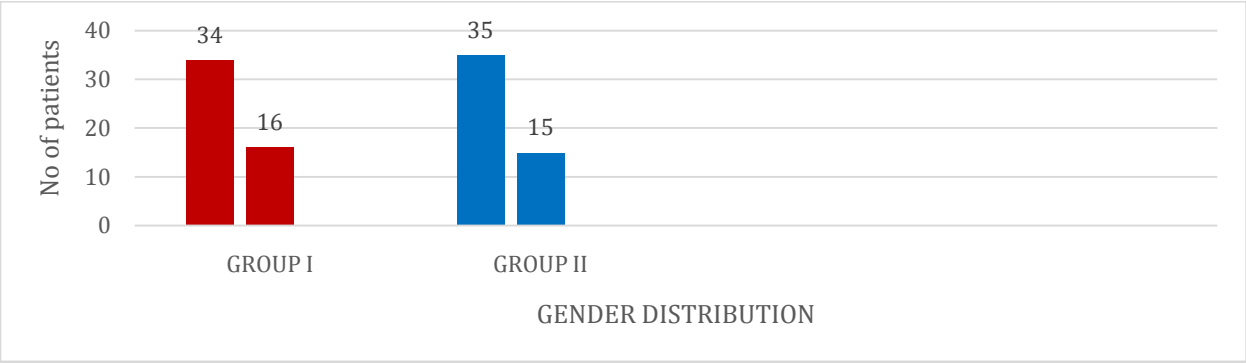


FIGURE -1: COMPARISON OF GENDER DISTRIBUTION IN TWO GROUPS

TABLE-2: COMPARISON OF MEAN AGE DISTRIBUTION IN TWO GROUPS

GROUP 1	GROUP 2	*p value*
60.64 ± 11.07	58.84 ± 9.06	0.375

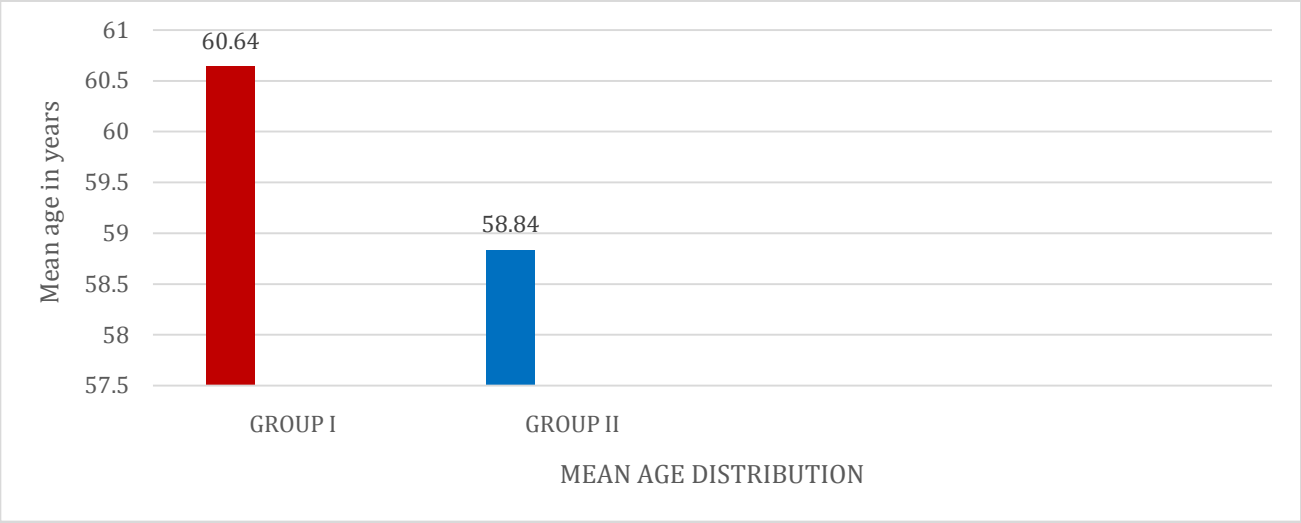


FIGURE-2: COMPARISON OF MEAN AGE DISTRIBUTION IN TWO GROUPS

TABLE-3: HISTORY OF PRE-OPERATIVE MI IN BOTH GROUPS

GROUPS	YES	NO	TOTAL	*p value*
GROUP 1	37	13	50	0.219
GROUP 2	42	8	50	
TOTAL	79	21	100	

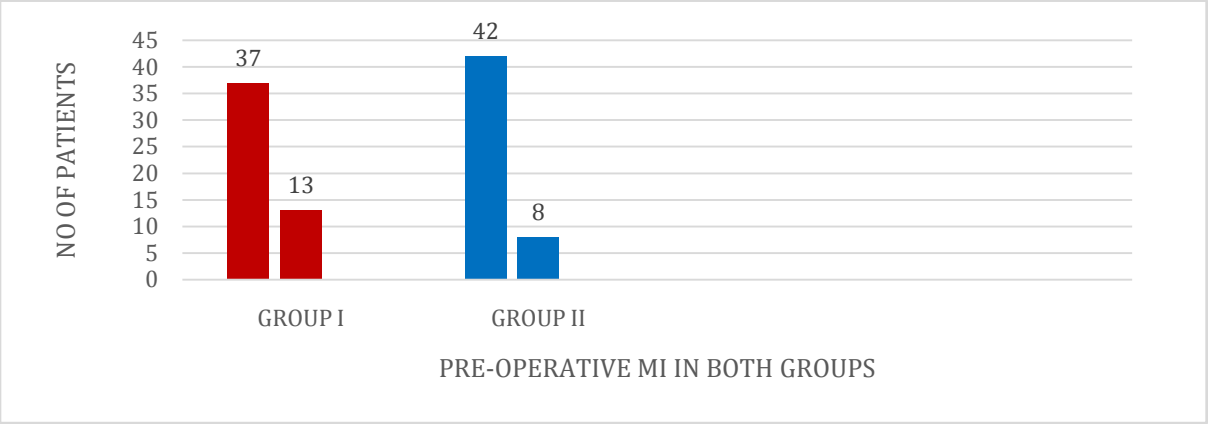


FIGURE-3: HISTORY OF PRE-OPERATIVE MI IN BOTH GROUPS

TABLE-4: HISTORY OF SMOKING IN BOTH GROUPS

GROUPS	YES	NO	TOTAL
GROUP 1	7	43	50
GROUP 2	3	47	50
TOTAL	10	90	100

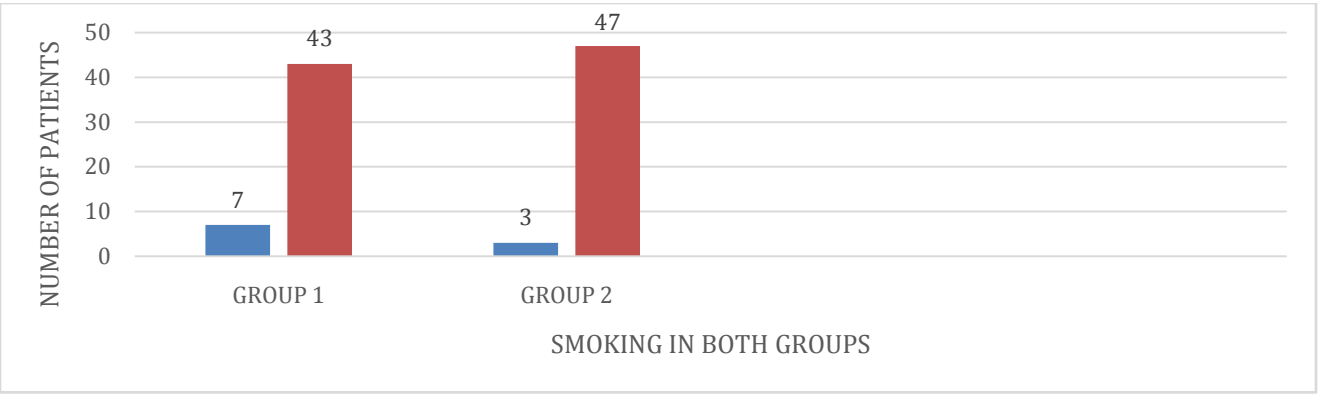


FIGURE-4: HISTORY OF SMOKING IN BOTH GROUPS

TABLE-5: HISTORY OF HYPERTENSION IN BOTH GROUPS

GROUPS	YES	NO	TOTAL
GROUP 1	35	15	50
GROUP 2	39	11	50
TOTAL	74	26	100

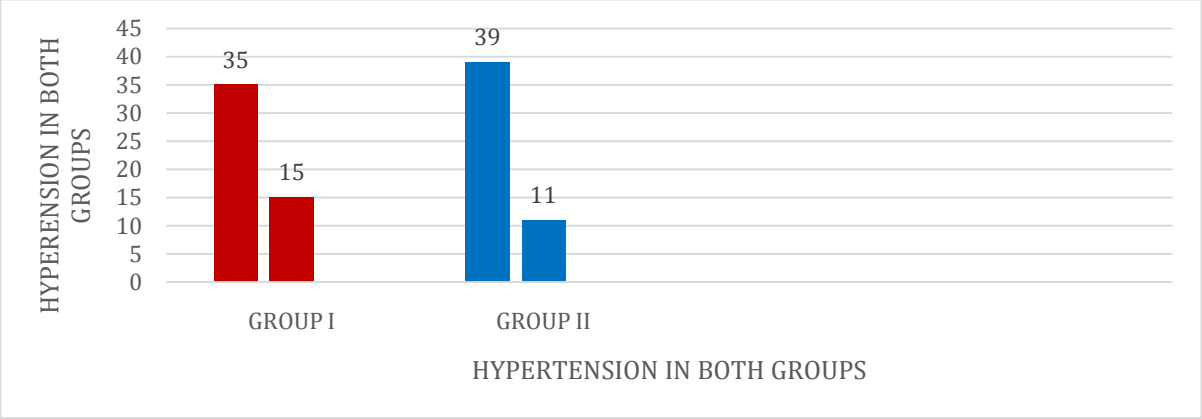


FIGURE-5: HISTORY OF HYPERTENSION IN BOTH GROUPS

TABLE-6: HISTORY OF TYPE 2 DIABETES MELLITUS IN BOTH GROUPS

GROUPS	YES	NO	TOTAL
GROUP 1	29	21	50
GROUP 2	28	22	50
TOTAL	57	43	100

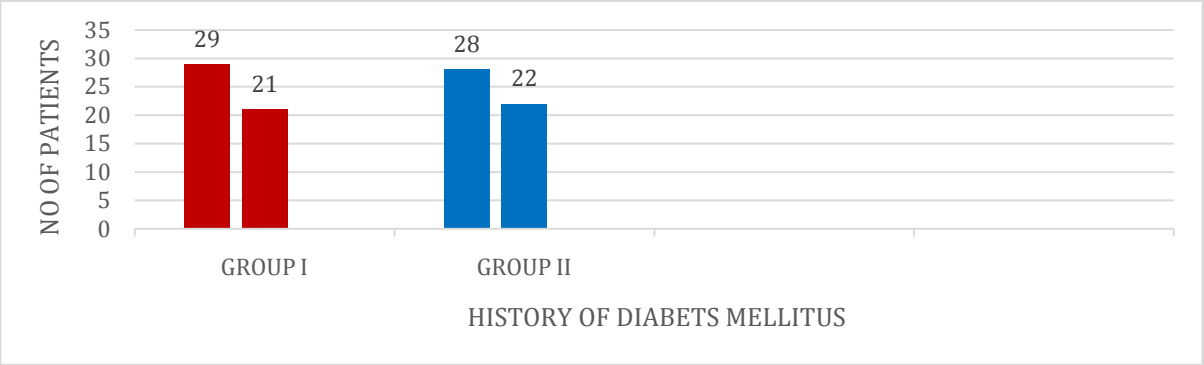
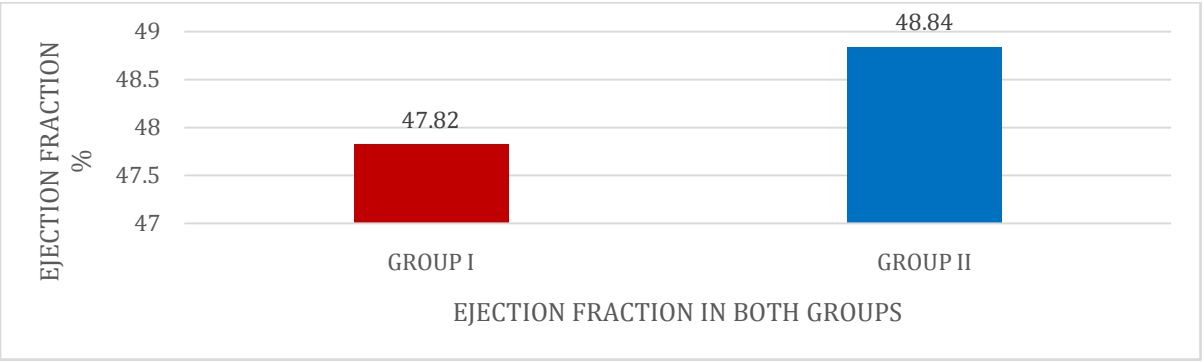


FIGURE 6: HISTORY OF TYPE 2 DIABETES MELLITUS IN BOTH GROUPS

TABLE-7: COMPARISON OF EJECTION FRACTION IN BOTH GROUPS

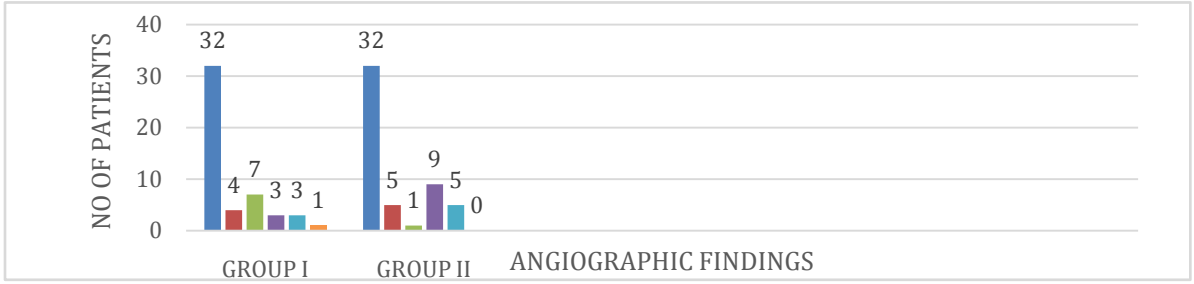
GROUP 1	GROUP 2	*p* VALUE
47.82 ± 10.25	48.84 ± 9.51	0.607



GRAPH-7: COMPARISON OF EJECTION FRACTION IN BOTH GROUPS

TABLE-8: COMPARISON OF ANGIOGRAPHIC FINDINGS IN BOTH GROUPS

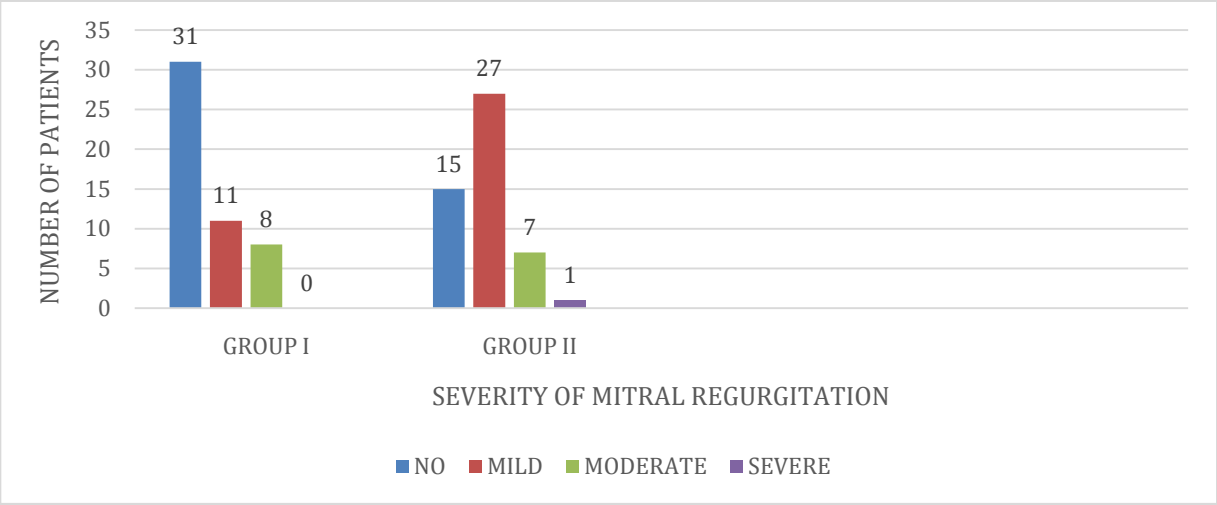
TYPE	GROUP 1	GROUP 2
TVD	32	32
DVD	4	4
LM	7	0
LM + TVD	3	9
LM + DVD	3	5
LM + SVD	1	0



GRAPH-8: COMPARISON OF ANGIOGRAPHIC FINDINGS IN BOTH GROUPS

TABLE-9:COMPARISON OF SEVERITY OF MITRAL REGURGITATION IN BOTH GROUPS

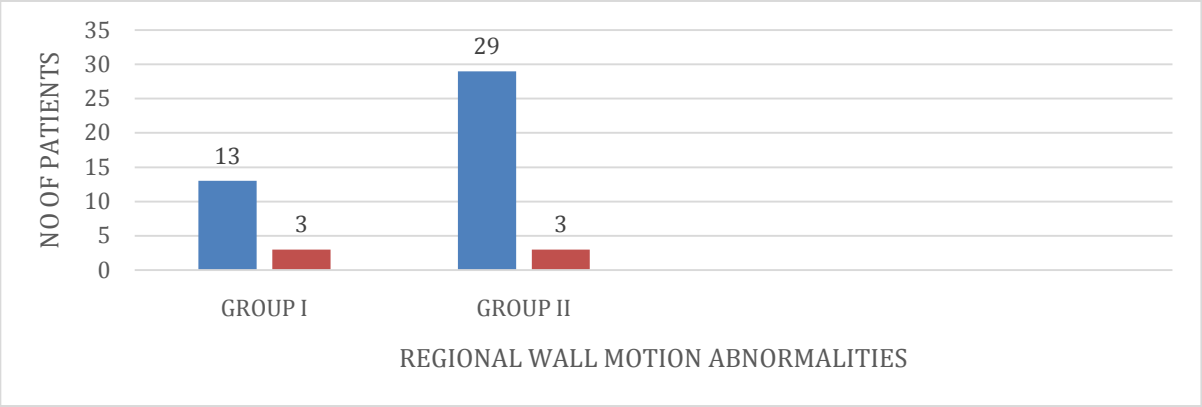
SEVERITY	**GROUP 1**	**GROUP 2**
NO MR	31	15
MILD MR	11	27
MODERATE MR	8	7
SEVERE MR	0	1



GRAPH-9:COMPARISON OF SEVERITY OF MITRAL REGURGITATION IN BOTH GROUPS

TABLE- 10: REGIONAL WALL MOTION ABNORMALITIES IN BOTH GROUPS

	GROUP 1	**GROUP 2**
RWMA	13	29
GLOBAL HYPOKINESIA	3	3
NO RWMA	34	28
TOTAL	50	50

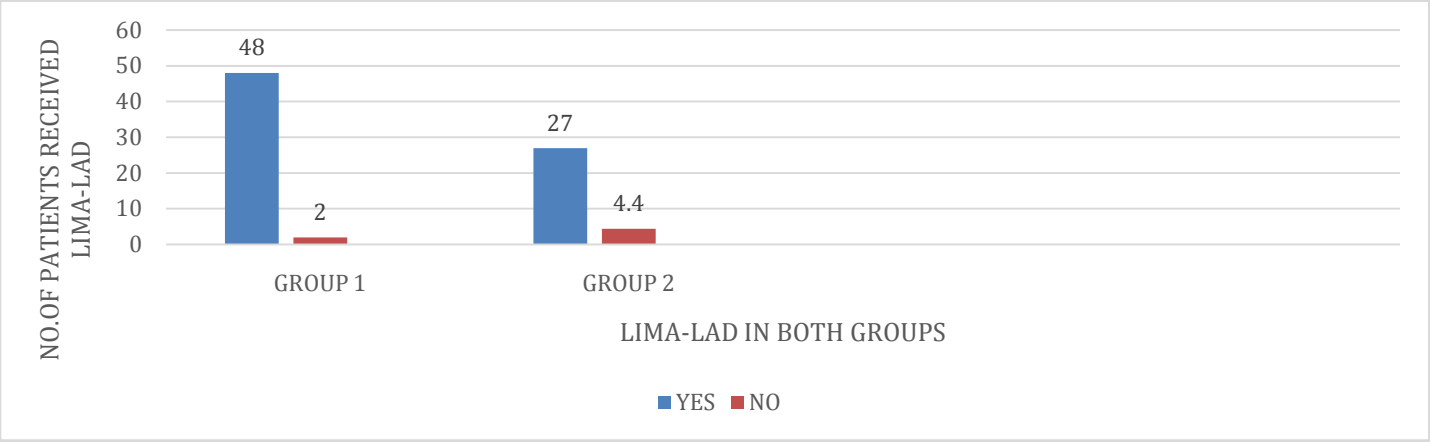


GRAPH-10:REGIONAL WALL MOTION ABNORMALITIES INBOTH GROUPS

B.INTRAOPERATIVE VARIABLES:

TABLE-11: COMPARISON OF NUMBER OF LIMA – LAD GRAFTING IN BOTH GROUPS

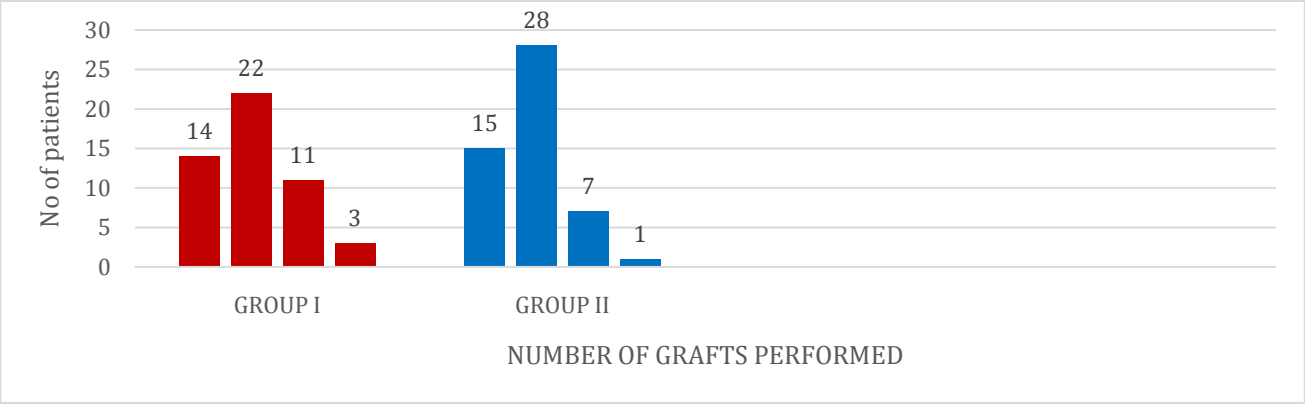
GROUPS	YES	NO	TOTAL
GROUP 1	48	02	50
GROUP 2	27	23	50
TOTAL	75	25	100



GRAPH-11: COMPARISON OF NUMBER OF LIMA – LAD GRAFTING IN BOTH GROUPS

TABLE 12: COMPARISON OF NUMBER OF GRAFTS PERFORMED IN BOTH GROUPS

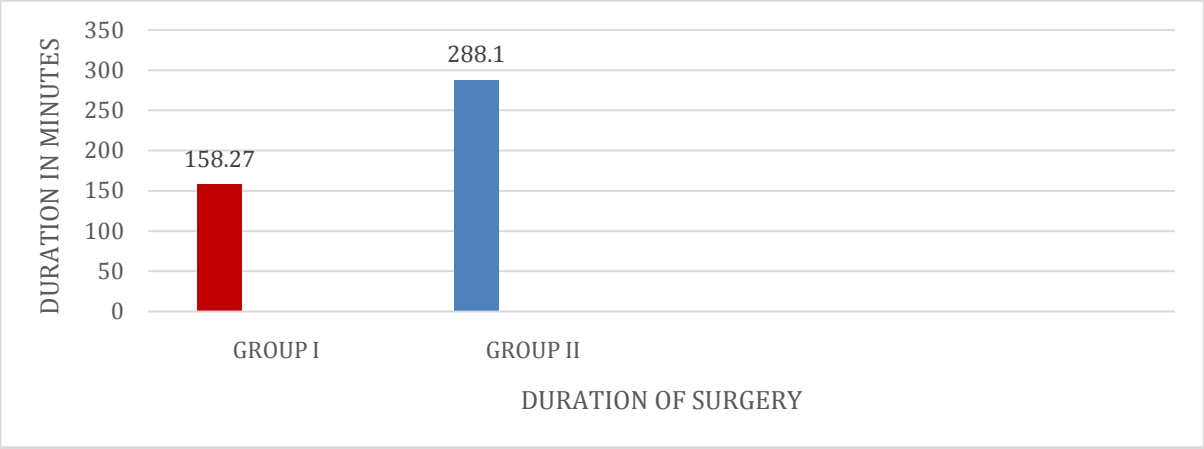
NUMBER	GROUP 1	GROUP 2
FOUR	14	15
THREE	22	28
TWO	11	7
ONE	3	0



GRAPH-12: COMPARISON OF NUMBER OF GRAFTS PERFORMED IN BOTH GROUPS

TABLE-13: COMPARISON OF DURATION OF SURGERY IN BOTH GROUPS

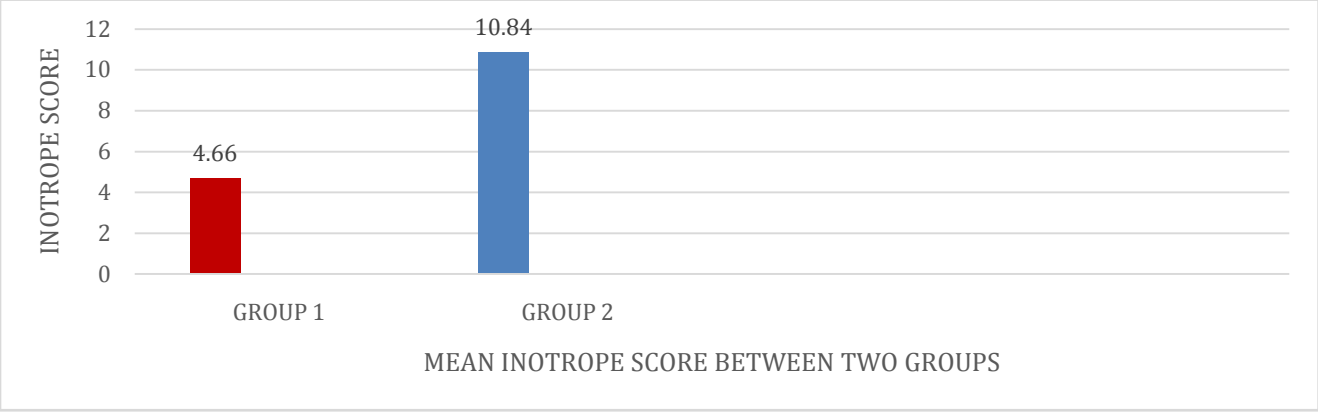
GROUP 1	GROUP 2	*p* value
158.27 ± 25.21	288.10 ± 59.19	<0.0001



GRAPH-13: COMPARISON OF DURATION OF SURGERY IN BOTH GROUPS

TABLE 14: COMPARISON OF INOTROPE SCORE IN BOTH GROUPS

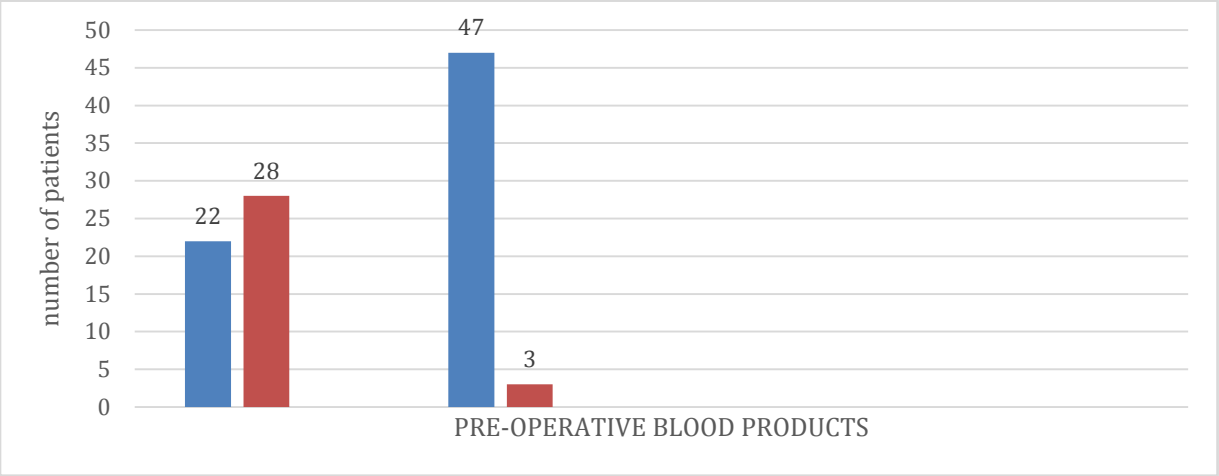
GROUP I	GROUP II	*p* value
4.66 ± 5.39	10.84 ± 4.69	0.0001



GRAPH 14: COMPARISON OF INOTROPE SCORE IN BOTH GROUPS

TABLE-15: COMPARISON OF PERI OPERATIVE BLOOD PRODUCTS USE IN BOTH GROUPS

GROUPS	YES	NO	TOTAL
GROUP 1	22	28	50
GROUP 2	47	3	50
TOTAL	69	31	100



GRAPH-15: COMPARISON OF PERI OPERATIVE BLOOD PRODUCTS USE IN BOTH GROUPS

C.POSTOPERATIVE VARIABLES:

TABLE-16: COMPARISON OF DURATION OF ICU STAY IN BOTH GROUPS

GROUP 1	GROUP 2	*p* value
2.88 ± 0.70	3.64 ± 1.74	0.005

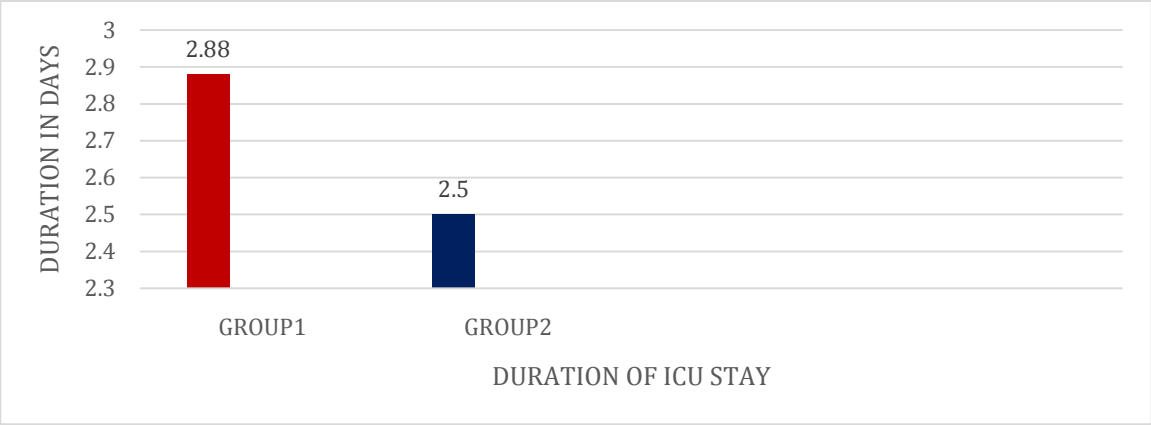


FIGURE-16: COMPARISON OF DURATION OF ICU STAY IN BOTH GROUPS

TABLE-17: COMPARISON OF HOURS OF MECHANICAL VENTILATION IN BOTH GROUPS

GROUP 1	**GROUP 2**	***p* VALUE**
9.44 ± 9.23	24.37 ± 33.04	0.005

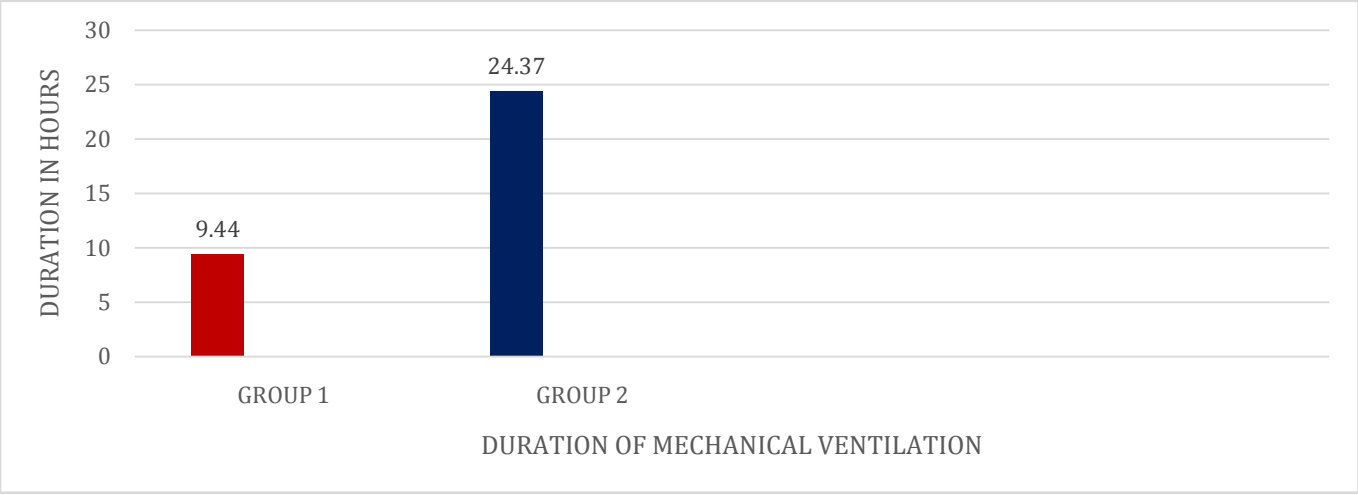


FIGURE-17: COMPARISON OF HOURS OF MECHANICAL VENTILATION IN BOTH GROUPS

DISCUSSION:

Off pump coronary artery bypass surgery is an evolution in the field of cardiac surgery. In India OPCAB has become the preferred mode of revascularization in private health care system [4]. Even though conventional CABG / ONCAB has remained the gold standard, it is associated with profound systemic inflammatory response which can cause myocardial ischemic injury, neurocognitive deficits, strokes, as well as pulmonary, renal, haematological complications. To counteract the effects of CPB, off pump CABG is the better alternative[5].

Off pump CABG, by maintaining pulsatile flow & coronary perfusion offers better myocardial protection than with using CPB [6]

Several randomized controlled trials were conducted to compare the outcomes of off pump with on pump, most of them demonstrated that there was no difference in immediate

outcomes between the two techniques. In contrary, CORONARY trial and SMART trial demonstrated no differences in mortality, stroke, MI, Repeat revascularization and follow up mortality 1 year following surgery & demonstrated complete revascularization in patients who have undergone OPCABG[7].

Ahmed Mohammed Abdo Ismaiel; Elhusseiny Elhusseiny Gamil [8]et al conducted a prospective randomized trial on 120 patients with stable coronary artery disease who received elective CABG without any concomitant surgical interventions at El Hussein and MKH Hospitals between August 2017 & September 2019 and their study results demonstrated that ,total duration of surgery 186.5 min in OPCAB, 242 min in CPB group (*p* value = < 0.001), inotrope requirement is 10% in OPCAB group, 58.3% in CPB group (*p*= < 0.001), total number grafts performed were 177 in OPCAB group,185 in CPB group (*p*=0.15), need for blood products 13.3% to 23.3% in OPCAB and 83.3% - 91.7% in CPB group (*p*=<0.01), total duration of ICU stay was 36 hours in OPCAB and 60 hours in CPB group. Duration of mechanical ventilation was 5 hours in OPCAB group, whereas 8.5 hours in CPB group (*p*=<0.001).

The study results comparable to our study, total duration of surgery was 2.38 ± 0.25 hours In group I, 4.48 ± 0.59 hours in group II (*p*=0.0001), perioperative blood product use is more in group II (47) whereas in group I only 22 patients received blood products (*p*=0.0001). days of stay in ICU= 2.88 ± 0.70 in group I & 3.64 ± 1.74 in group II (*p*=0.005), duration of mechanical ventilation was 9.44 ± 9.23 in Group I & 24.37 ± 33.04.

In group II (p=0.005). vasoactive inotrope score was 4.66 ± 5.39 in group I and 10.84 ± 4.69

In group II *p*=0.0001). total number of grafts received were almost equal in both the groups, 12.50 ± 7.85 in group I & 12.50 ± 12.01 in group II (*p*=1.000).

Anirban kundu, Om Prakash yadava et al[9]conducted a study on Off-pump versus on-pump coronary artery bypass grafting—a surreal controversy, they have compared morbidity and mortality in women in OPCAB Vs CPB group in female patients in terms of blood requirement 2.5 ± 1.2 in OPCAB, 4.3 ± 1.4 in CPB group, *p*=0.0001, duration of ICU stay 29.3 ± 16.4, 38.3 ± 17.3, *p*= 0.0001. Days of hospital stay 6.81 ±1.6 in OPCAB group,

8.05 ± 2.1, *p*=0.001. Results are comparable to our study, In group I, 4.48 ± 0.59 hours in group II (*p*=0.0001), perioperative blood product use is more in group II (47) whereas in group I only 22 patients received blood products (*p*=0.0001). Days of stay in ICU= 2.88 ± 0.70 in group I & 3.64 ± 1.74 in group II (*p*=0.005).

Lokeswara Rao Sajja, Kunal Sarkar et al[10] conducted a randomized trial on Graft patency at 3 months after off and on-pump coronary bypass surgery(Indian Journal of Thoracic and Cardiovascular Surgery) conducted on 320 patients with multivessel coronary artery disease, on-pump CABG (n = 162) or off-pump CABG (n = 158) between March 2016 to March 2017. They have beencompared total number of grafts between off pump (420) and on pump (429), they demonstrated that there is non-inferiority attained in off pump group. The above results were compared to the results of our study where group I (12.50 ± 7.85) & group II (12.50 ± 12.01)received equal number of grafts with *p* value (1.000) non-significant. From this we conclude that number of grafts depends on technique of revascularization and skill of surgeon rather than use of cardiopulmonary bypass.

Improved intra operative doppler techniques and transit time flow meter devices can confirm adequate anastomosis, potentially limiting the effects of variations in inherent surgeon technique. OPCABG provides excellent clinical outcomes in experienced & skilled surgeon compared to conventional CABG.

David taggart et al. opined that if the surgeon is sufficiently experienced, incompleteness of revascularization is not an issue with off pump CABG. Recommended to be facile in doing off pump CABG in all cases rather than only high-risk group. CORONARY & COPCABE trial were shown equivalent degree of revascularization with both the techniques[5].

Ignacio J. Ferreira-Gonzalez et al conducted a study on outcomes of both ONCAB vs OPCAB and concluded that benefit of OPCAB is much more in patients with low pre operative risk.[11]

Note:

The critical choice to choose on versus off pump surgery, apart from the patient risk factors,it was to choose the most skilled surgeon and then to defer to that surgeon's choice of technique,

as surgical expertise plays a key role exclusively in OPCAB.

Study limitations:

Retrospective observational study, relatively small sample size&completeness of revascularization was not analyzed.

CONCLUSION:

Results of our study revealed that OPCABG is non-inferior in terms of total number of grafts received. Better outcomes observed in terms of duration of mechanical ventilation, total length of ICU stay, number of peri operative blood products use. Duration of surgery was less in OPCABG compared to ONCABG. Number of patients in group 1 (OPCABG) received more LIMA to LAD grafts compared to its conventional counterpart group 2 (ONCABG). Guidelines & recommendations for clinical practice are based on strength of evidence, Hence, to validate these results regarding the benefit of off pump CABG, there is an absolute need for conduction of varied number of large number of randomized controlled trials by performing off pump CABG even in mild to moderate risk patients.

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