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RESEARCH ARTICLE

Hypothermic Cardiopulmonary Bypass in CABG surgery, it is the time to revise our protocols

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ABSTRACT

Background: Hypothermia during coronary artery bypass grafting (CABG) procedures using cardiopulmonary bypass (CPB) technique is a defensive maneuver. Since most surgeons worldwide are accustomed to the use of "mild" hypothermia for such procedures, this study hope to discover whether "moderate" hypothermia had a more significant impact on lowering tissue oxygen consumption during cardiac surgery, taking into account that the risks of exposing the patient to "mild" hypothermia are similar to the risks of moderate hypothermia. Furthermore, the study sought to weigh the benefits of "mild" hypothermia against those of normothermia with regards to their impact on tissue oxygen consumption.

purposes: To evaluate the total body oxygen consumption under different ranges of body temperature during surgery performed with the aid of CPB, ending with recommendations regarding the range of temperature that yield a preferential clinical outcome as a result of lower oxygen consumption.

Methods: between December 2014 and April 2015, 70 consecutive patients (55 males and 15 females), undergoing coronary artery bypass grafting surgery (CABG), allocated into three groups regarding the core temperature (Group 1 with normothermia 35-37°C, Group 2 with mild hypothermia 32-35°C, Group 3 with moderate hypothermia 28-32°C).

Results: There were no significant changes in Group 1 and Group 2 during CPB, however, for Group 3, there was a remarkable decrease in the oxygen consumption (VO_2).

Conclusions: Moderate hypothermia rather than mild hypothermia proves to be of more benefit to the tissues when compared to normothermic conditions, as it significantly reduces tissue oxygen consumption. Moreover, even normothermia was found to be superior to mild hypothermia due to the latter's adverse effects while maintaining similar results with regards to oxygen consumption.

Keywords: Mild hypothermia, Oxygen consumption, Oxygen delivery, Normothermia, CABG, Moderate hypothermia, Cardiopulmonary bypass.

Introduction

Hypothermia has been a fundamental part of any cardiac surgery that involves Extra Corporeal Circulation (ECC) since the pioneer days of cardiac surgery. It was adopted to protect organs from the effects of low-flow perfusion, a consequence related to the use of precocious ECC systems that were incapable of delivering sufficient blood flow. Since its introduction in the 1950s, further improvement in ECC techniques has been achieved.[1]

Recent progress in ECC technologies has changed these circumstances. The pumps that are currently in use are more efficient and can provide sufficient blood flow under normothermic Cardiopulmonary Bypass (CPB) conditions, currently used oxygenators have a greater oxygenating capacity, the biocompatibility of the whole ECC system has been improved, which leads to less adverse effects on the patient. Due to the high reliability of all components of the ECC system, a malfunction of the machine or oxygenator occurs very rarely. Such progress has altered both our concepts regarding this issue and our approach to it.[2]

Temperature management during CPB remains controversial, with gaps in our knowledge concerning a variety of aspects of temperature management.[3,4]

This study aims to emphasize whether the "moderate" or "mild" hypothermia have a more impact on lowering tissue oxygen consumption during cardiac surgery. Furthermore, this study is sought to weigh the benefits of "mild" hypothermia against those of normothermia concerning their impact on tissue oxygen consumption. [5]

Methods

STUDY DESIGN AND SETTINGS:

This is a prospective, experimental and comparative study, conducted at Iraqi Center for Heart Diseases and Ibn Al-Bitar Specialized Cardiac Surgery Center. The study was done on (70) patients who were admitted to these two centers to have coronary artery bypass grafting surgery (CABG) between December 2014 and April 2015. The study was done according to the cooperation with the department of physiology, College of medicine, Al-Mustansiriyah University, in Baghdad.

The study was done according to the code of ethics and approved by the ethical committee in Iraqi Center for Heart Diseases and Ibn Al-Bitar Specialized Cardiac Surgery Center. We have explained the aim, benefits and the expected risks of the study to all the participants and their signed consent forms were taken prior to the surgery.

INCLUSION CRITERIA:

Any patient who was referred to Iraqi Center for Heart Diseases and Ibn Al-Bitar Specialized Cardiac Surgery Center to have CABG during the studied period was included in this study.

EXCLUSION CRITERIA:

The following patients were excluded from the study:

1. Patients who were in need to have other cardiac procedures (e.g. valve replacement).
2. Patients with ($T_4 > 22 + T_3 > 7$) pmol/L + (TSH < 0.2) mU/L which considered as possibly hypothyroidism.
3. Patients with ($T_4 < 8 + T_3 < 2.5$) pmol/L + (TSH > 5) mU/L which considered as possibly hyperthyroidism.
4. Patients with (S. Creatinine > 1.8 mg/dL) + (Blood Urea > 65 mg/dL).
5. Patients with (S.GPT, S.GOT) levels defined as: 20 < S.GPT, S.GOT < 5 U/L.
6. Patient who have Hb level as: 17 < Hb < 10. [6]

The reason for excluding these patients is to avoid any factor that may affect O_2 consumption/ metabolism.

RANDOMIZATION:

Patients were allocated into three groups according to the surgeon's preferences, where some surgeons prefer to do the surgery on normothermia, others prefer to cool the patients to mild or moderate hypothermia. Group 1 has (normothermia 35-37°C) included patient who were subjected to normothermia during the procedure. Group 2 (Mild Hypothermia 32-35°C) has included patients who had undergone the procedure under mild hypothermia. While Groups 3 (moderate hypothermia 28-32°C) has included patients who had the procedure under moderate hypothermia protocol as in (Table 1). [7,8]

Table 1: patients features for the three groups of temperature						
	Group 1 (37-35)°C		Group 2 (35-32)°C		Group 3 (32-28)°C	
	No.	(%)	No.	(%)	No.	(%)
patients	17	24.3	36	51.4	17	24.3
	Mean	**Std. dev.**	**Mean**	**Std. dev.**	**Mean**	**Std. dev.**
Age (years)	57.3	7.5	59.2	7.6	57.6	9.9
Height (cm)	168.9	9.3	170.1	9.2	172.3	9.4
Weight (kg)	79.9	12.8	80.6	14.4	83	15.6
Body Surface Area	1.89	0.2	1.9	0.2	1.95	0.24
Ejection Fraction	57.4	8.7	56.1	13.6	57.3	8.9
Cardiopulmonary Bypass time	126	36.6	141.2	41.4	120	31.9
Cross Clamp time	79.75	31.7	93.7	31.5	55.4	12.8

PRIMARY END POINTS:

The endpoints of our study were to calculate the oxygen delivery (DO_2) and oxygen consumption (VO_2) through measuring blood gas parameters at the start of CPB and 10 minutes after achieving the desired thermal level.

TECHNICAL INFORMATION:

All patients were operated upon under general anesthesia (opiate-based anesthesia) by using fentanyl 5 µg/Kg, (midazolam) 0.1 mg/Kg and Inhalational agents (sevoflurane) 1-3 MAC on induction. To start the CPB, heparin has been used in a dose of 300-400 U/kg to obtain a value of activated clotting time ACT of 480 seconds or more.

Cardiopulmonary bypass (CPB) was performed using a non-pulsatile, roller pump HLM (heart-lung machine S5, Stockert Instruments Inc. Germany, and Jostra HL 20. Germany), A membrane oxygenators (Medtronic. USA and Maquet. Germany). Blood flow rate during CPB maintained at a cardiac index of 2.4 $L.min^{-1}.m^{-2}$ at normothermia, and between 2.2 and 2 $L.min^{-1}.m^{-2}$ at mild and moderate hypothermia respectively.[9] Blood was collected from the arterial and venous ports of the oxygenator.

The samples were immediately analyzed by (OPTI cassette E-Ca for (OPTI CCA-TS Blood Gas and Electrolyte Analyzers by OPTI Medical Systems, Inc. USA, and Siemens RAPID Lab 248 Blood Gas Analyzer, Germany) according to the patient's temperature for blood gases, pH, hematocrit, hemoglobin concentration, and oxygen saturation.

Arterial and venous blood samples were collected (1) at the baseline (sample 1) 5-10 minutes after conducting the CPB. (2) The controlled temperature (sample 2) after at least 10 minutes from reaching the desired temperature. Oxygen delivery (DO_2) and oxygen consumption (VO_2) were calculated at each experimental time using Fick principle. [10]

STATISTICAL ANALYSIS:

Data were translated into a computerized database structure. Statistical analyses were computer assisted using SPSS version 21. A multiple linear regression model was used to study the net and independent effect of a set of an explanatory variable on a quantitative outcome (dependent) variable. All the (70) patients were tested by unpaired t-test, and because of missing data, only fifty-nine (59) patients tested by paired t-test and ANOVA test for the blood gas analysis. Both unpaired and paired t-test had comparable values of significance. Cohen's d is a standardized measure of effect size for the difference between two means, which can be compared across different variables and studies since it has no unit of measurement. Cohen's d < 0.3 (small effect), 0.3-0.7 (medium effect), while 0.8 and higher is a (large effect). A P<0.05 level of significance was considered statistically significant.

Results

Accidental higher levels of (Hb) in (Group 3) were the cause of higher levels of oxygen delivery (DO_2) at (sample 1). While the results of the effect of temperature on (DO_2) for the three groups was tested at (sample 2), at which the temperature was settled on plateau phase during CPB (i.e. normothermia, mild or moderate hypothermia), it was found that there are no significant differences among them (0.11) (Table 2).

The data of (Group 1) and (Group 2) showed that there were no noticeable changes in the oxygen consumption (VO_2) during CPB for each group (Table 3), and by comparing between the determined groups (Table 4). While for (Group 3), there was a remarkable decrease in the (VO_2) (<0.001) (Table 3).

Table 2: Oxygen delivery during CPB			
	Oxygen delivery (ml/min)		
Thermal stat	Baseline	Temperature control	changes during bypass
Effect of Mild hypothermia compared to Normothermia			
Difference in mean	-49.1	-47.5	1.6
Cohen's d	-0.33	-0.36	0.02
P (Bonferronni t-test) for difference in mean	1	0.87	1
Effect of Moderate hypothermia compared to Normothermia			
Difference in mean	162	34.6	-127.3
Cohen's d	0.83	0.25	-1.53
P (Bonferronni t-test) for difference in mean	0.038	1	0.001
Effect of Moderate hypothermia compared to mild hypothermia			
Difference in mean	211.1	82.1	-128.9
Cohen's d	1.43	0.71	-1.43
P (Bonferronni t-test) for difference in mean	<0.001	0.12[NS]	<0.001

Table 3: Oxygen consumption during CPB							
		Oxygen consumption (ml/min)					
Thermal state of each operation		Baseline	Temperature control	changes during bypass	P (Paired t-test)	Cohen's d
Normothermia (37-35) °C	Range	(95.82 to 260.63)	(109.76 to 238.48)	(-69.2 to 62.1)	0.47	
	Mean	168.2	176.5	8.3		0.2
	SD	48.3	35	36.7		
	SE	14.57	10.57	11.07		
	N	11	11	11		
Mild hypothermia (35-32) °C	Range	(88.44 to 285.23)	(103.22 to 273.38)	(-55.4 to 91.4)	0.09	
	Mean	154	164.3	10.3		0.28
	SD	37.5	36.1	32.9		
	SE	6.62	6.38	5.82		
	N	32	32	32		
Moderate hypothermia (32-28) °C	Range	(51.59 to 261.74)	(84.22 to 175.92)	(-93.5 to 85.4)	<0.001	
	Mean	182	139.5	-42.5		-1.03
	SD	53.4	24.1	41.4		
	SE	13.34	6.03	10.34		
	N	16	16	16		
	P (ANOVA)=	0.12	0.013	<0.001		
SD: standard deviation, SE: standard error.						

Table 4: The comparison between the thermal groups regarding the oxygen consumption during CPB			
	Oxygen consumption (ml/min)		
Thermal state	Baseline	Temperature control	changes during bypass
Effect of Mild hypothermia compared to Normothermia			
Difference in mean	-14.2	-12.2	2
Cohen's d	-0.35	-0.34	0.06
P (Bonferroni t-test) for difference in mean	1	0.89	1
Effect of Moderate hypothermia compared to Normothermia			
Difference in mean	13.8	-37	-50.8
Cohen's d	0.27	-1.28	-1.28
P (Bonferroni t-test) for difference in mean	1	0.018	0.002

Effect of Moderate hypothermia compared to mild hypothermia			
Difference in mean	28.0	-24.8	-52.8
Cohen's d	0.65	-0.76	-1.47
P (Bonferroni t-test) for difference in mean	0.13	0.05	<0.001

Discussion

The importance of this study lies in the fact that the effect of temperature on the oxygen consumption, especially at mild hypothermia level, remains controversial issue due to insufficient published evidence.

The non-significant changes of (DO_2) for (group 1 and 2) during CPB indicates that there was no significant decrease in the flow rate along the CPB for (Group 1).

While for (Group 2), this result pointed out that even the reduction of the temperature to the mild hypothermia and the flow rate to (2.2 $L.min^{-1}.m^{-2}$) did not affect the supply of the oxygen during CPB. This result may explain the determination of some references for the cardiac index at normothermia is (2.2-2.5 $L.min^{-1}.m^{-2}$) such as in the study of (Murphy, II and Groom 2009). [4]

The significant decrease in (DO_2) for (Group 3) by comparing (sample 1) and (sample 2) can be explained by the reduction in blood flow rate that was in proportion to the decrease in temperature to the moderate hypothermia. However, (DO_2) for (Group 3) at (sample 2) were still have the same values of (Group 1). This result is in agreement with that was found by (Staffan Svenmarker 2009), (Pittman 2011) and (Jeremiah R. Brown 2015). [11,12,13]
The data of (VO_2) for (Group 1 and 2) showed that there were no noticeable changes during CPB for the determined groups. This result articulates that even the reduction of the temperature to the mild hypothermia and the flow rate to (2.2 $L.min^{-1}.m^{-2}$) did not affect the needs of the tissues for the oxygen during CPB. This result is agreed with that carried out by (Kiran 2010), (Ioannis Sgouralis 2015). [14]

The remarkable decline in (VO_2) for (Group 3) during CPB highlights the reduction in this parameter with the decrease in temperature, in particular for this group of patients, due to the reduction in the metabolism rate to a significant degree. This result is consistent with that was found by (Davies 2008), (Ashmore J. 2012), (Eugene A. Hessel II 2013) and (Ioannis Sgouralis 2015). [15,16,17,18]

One of the limitations of this study is the relatively small size of cases involved, because of the time factor limitation for the study to be accomplished.

The other limitation parameter that there was no detailed information about the pre and postoperative state of their organ function (e.g. renal function) to evaluate the effect of hypothermic CPB on the organ function.

Conclusions

Moderate rather than mild hypothermia is probably the level of hypothermia that significantly reduces the tissue oxygen consumption compared to patients operated upon under normothermic conditions.

Normothermia seems to be similar to mild hypothermia according to the reactions on oxygen consumption.

So, carrying out the operation under mild hypothermia has no benefit regarding the per and postoperative patients outcomes, furthermore, its adverse effects on the patient.

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