Section: Anaesthesia

Original Research Article

A RANDOMISED COMPARATIVE STUDY OF ESMOLOL AND LABETALOL IN ATTENUATING HAEMODYNAMIC RESPONSES AFTER MODIFIED ELECTROCONVULSIVE THERAPY

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Received : 19/05/2024
Received in revised form : 15/07/2024
Accepted : 31/07/2024

Keywords:
Electroconvulsive therapy (ECT), haemodynamic responses, Esmolol, Labetalol, sympathetic nervous system.

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DOI: 10.47009/jamp.2024.6.4.76

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2024; 6 (4); 376-382

Abstract

Background: Modified Electroconvulsive therapy (ECT) is used to treat acute depression and chronic depression resistant to pharmacological therapy under general anaesthesia. Many drugs are used by various routes in attenuating the physiological haemodynamic responses during ECT. This study was done to compare the effects of Esmolol and Labetalol in the attenuation of haemodynamic responses after ECT.

Materials and Methods: 90 patients aged 18-60 years were randomly divided into three groups. Baseline parameters were recorded. Group C received 5 ml of normal saline (Control/placebo), group E received 1mg/kg Esmolol, and group L received 0.25mg/kg Labetalol after induction. Heart rate (HR), systolic BP (SBP), and diastolic BP (DBP) were recorded at 1 minute after the above test drugs administration and 1,3,5 and 10 minutes after modified ECT. Hypertension and tachycardia occurred due to sympathetic nervous system activation even after modified ECT which required attenuation for the smooth conduct and post-procedural recovery of the patients included in the study.

Result: It was found that Esmolol significantly attenuated the degree of tachycardia and hypertension in the first three minutes compared to the placebo whereas the rise in heart rate was attenuated from 5 to 10 minutes and blood pressure was attenuated from 3 to 10 minutes in the Labetalol group in comparison to placebo after the initiation of modified ECT.

Conclusion: It was concluded that Esmolol was effective in blunting the hemodynamic responses in the first three minutes, whereas Labetalol was effective from three to ten minutes after the initiation of modified ECT.

INTRODUCTION

Electroconvulsive therapy (ECT) consists of programmed electrical stimulation of the central nervous system to initiate seizure activity which causes changes in the brain chemistry, that will reverse the symptoms of many psychiatric illnesses, especially depression [1,2]. Here, the patients received high doses of electric current without anaesthesia in older days, which led to vertebral or long bone fractures due to violent muscle contractures, short-term memory loss, and other serious side effects. Modified ECT is accepted due to the administration of general anaesthesia to decrease the physical and psychological trauma associated with conventional Electroconvulsive therapy[3,4]. Activation of the central nervous system during ECT leads to the release of catecholamines which leads to an increase in the blood pressure and heart rate. These physiological effects of ECT lead to infarction, ischemia or even stroke in patients with pre-existing cardiac and cerebrovascular diseases[5,6]. Many drugs are used by various routes in attenuating the physiological responses during ECT[7,8]. Esmolol is an ultrashort-acting beta 1 selective adrenergic blocker[9,10], whereas Labetalol is a combined alpha-1 and beta blocker. In this study, a comparison between Esmolol and Labetalol for attenuation of hemodynamic responses after modified ECT in the immediate post-procedure period of up to ten minutes was evaluated.

Aims and Objectives

The aim of the present study was to compare the effects of Esmolol and Labetalol in the attenuation of hemodynamic responses after modified ECT. The comparison of the effects of these drugs was done by monitoring and comparing the following parameters

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in both groups. Heart rate (HR), systolic and diastolic BP (SBP and DBP) at

- Baseline
- 1 minute after administration of the test drug
- 1,3,5 and 10 minutes after modified ECT procedure

Primary Objective: To study the effects of Esmolol and Labetalol in the attenuation of hemodynamic responses after modified ECT.

Secondary Objective: To study the change in HR, SBP and DBP from baseline at different time intervals.

MATERIALS AND METHODS

This was a prospective randomized controlled double-blinded study. After the Institutional Ethical Committee approval and informed written consent obtained from the patients and their family members, the study was conducted in 90 eligible ASA Grade I and II patients undergoing modified ECT who were randomly divided into three groups, each group having thirty patients.

Inclusion Criteria

- Psychiatric patients undergoing modified ECT
- ASA Grade I and II patient
- Either sex
- Age between 18-60 years

Exclusion Criteria

- Patients with 2ND degree AV conduction block or greater
- Bradycardia (HR less than 50/min)
- SBP less than 90mm of Hg.
- Asthmatic patients
- Patients with history of drug allergy
- Patients with a history of recent Myocardial infarction (within 3 months)

The patients were pre-medicated with Injection Glycopyrrolate 0.2 mg 30 minutes before ECT. They were shifted to the ECT room and the IV line was secured. Group C (Control group) received normal saline 5ml, Group E (Esmolol group) received 1mg/kg of Esmolol, and Group L (Labetalol group) received 0.25mg/kg of labetalol.

Preoperative Evaluation

A routine pre-anaesthetic assessment of the patient included history regarding the severity and duration of symptoms, history of any other systemic illness, and history of any other previous surgeries. A detailed examination was done by assessing the general condition, airway, nutritional status, weight, and height of the patient. A thorough systemic examination of the cardiovascular and respiratory systems was carried out. The following basic investigations like haemoglobin, urine examination for sugar, albumin and microscopy, blood sugar, blood urea, serum creatinine, standard 12 lead ECG, echocardiography, serum electrolytes, and X-ray chest were done for all patients. A pulse oximeter, non-invasive blood pressure, and 3 lead ECG were attached to all the patients for haemodynamic monitoring. Baseline PR, SBP, and DBP were recorded and marked as "o".

Procedure

Patients were preoxygenated with 100% Oxygen and induced with Injection Propofol 2 mg/kg. Immediately after induction, patients in the control group received normal saline 5ml bolus and groups E and L received Injection Esmolol 1 mg/kg and Injection Labetalol 0.25 mg/kg respectively as bolus diluted to 5 ml. After that, the BP cuff was inflated above the SBP to isolate the other limb and then, Injection of Succinylcholine 1mg/kg was given. ECT current was given after two minutes of administration of the test drug after applying an oral soft bite block. The electric shock current applied to all the patients included in the study was the same.

The ECT electrodes were placed temporally. A Monitored Electroconvulsive Therapy Apparatus (MECTA) was used to deliver the electrical stimulus. Assessment of the effectiveness of the electric current applied in ECT was made by seeing the tonic-clonic seizures in the isolated arm. Patients were ventilated with 100% oxygen by controlled and assisted method until spontaneous respiration returned. After 1 minute of administration of the test drug, PR, SBP, and DBP were monitored and recorded as "X". After 1 minute, 3 minutes, 5 minutes, and 10 minutes of ECT, the same parameters were recorded and marked as A,B,C,D accordingly. A fall in blood pressure more than 25% from baseline was considered hypotension and was treated with IV fluid bolus and a fall in pulse rate less than 50/min was considered as bradycardia and treated with Injection Atropine 0.3 mg intravenous stat dose.

Statistical Evaluation

Statistical analysis was done using the Statistical Package for Social Science (SPSS16.0 Evaluation version) software. Descriptive statistics were expressed as frequency and percentages for nominal data and mean and standard deviation (SD) for continuous data. Comparison of categorical data between the groups was performed using the chi-square test and Fisher's exact correction was used when the cell values were less than 5. Normally distributed continuous data was analyzed using the ANOVA test. Post-hoc analysis was done using the Bonferroni test. ANOVA of repeated measures was used to compare the variables at various time points with baseline values. A two-tailed 'p' value of less than 0.05 was considered statistically significant for all these tests. According to Kelsey Fleiss's technique,

Two-sided significance level: 95
Power (1 – beta): 80
The ratio of sample size, unexposed/exposed: 0.5
Control (unexposed): 33%
Esmolol and Labetalol group: Exposed: 66.6%
Odd's ratio: 4
Therefore, the sample size was calculated as 90.

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RESULTS

The demographic profile was similar between the three groups there was no statistically significant difference between these three groups.

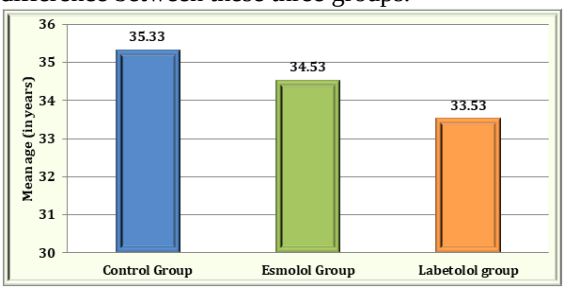

Figure 1: Age wise distribution of cases

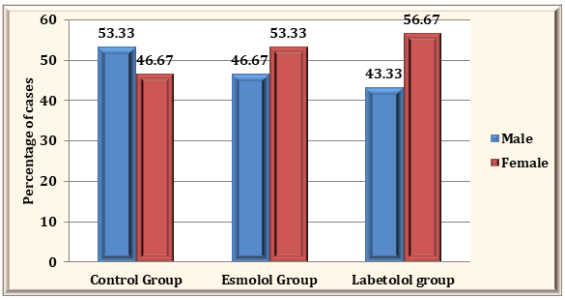

Figure 2: Gender wise distribution in all groups

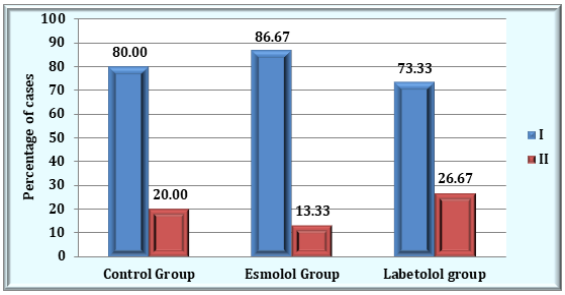

Figure 3: ASA Grading wise distribution in all groups

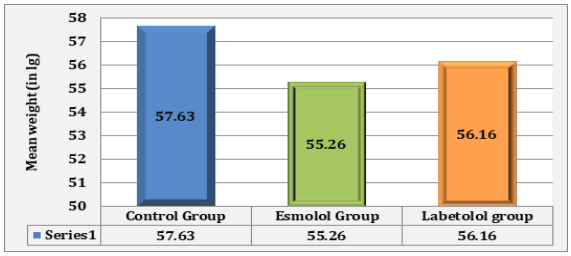

Figure 4: Weight wise comparison in all groups

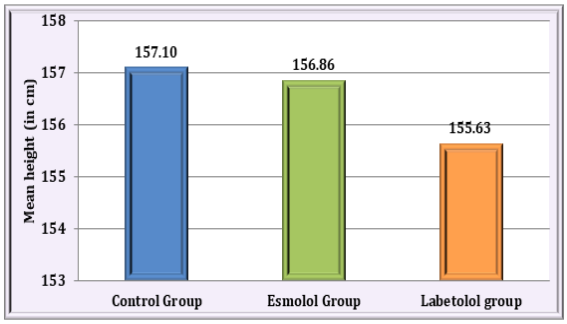

Figure 5: Height wise comparison in all groups

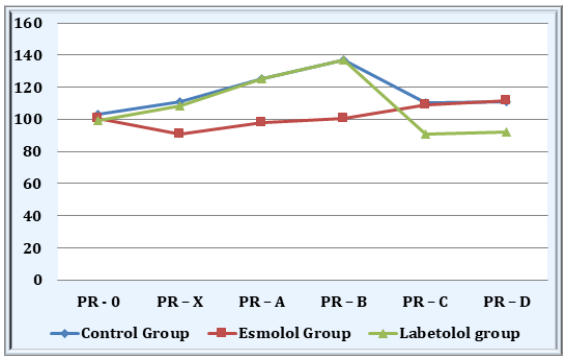

Figure 6: Mean changes in pulse rate

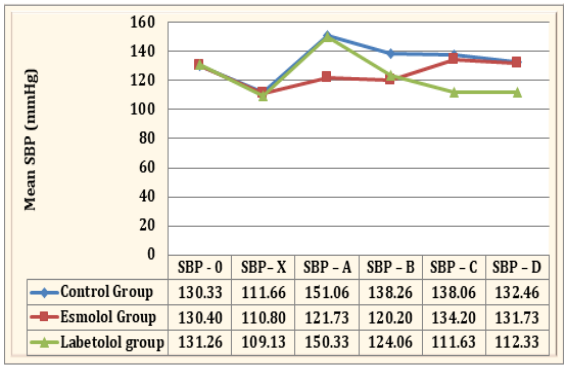

Figure 7: Mean systolic blood pressure changes

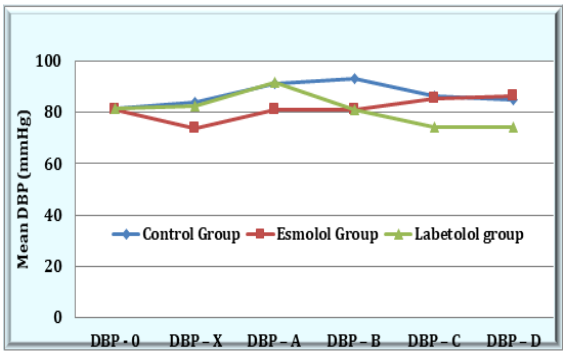

Figure 8: Mean Diastolic blood pressure changes

Table 1: Age-wise distribution of cases

Age (in years)	Control Group	Esmolol Group	Labetalol group	Total
18 – 28	08 (26.67%)	13 (43.33%)	07 (23.33%)	28 (31.11%)
29 – 39	14 (46.67%)	11 (36.67%)	17 (56.67%)	42 (46.67%)
40 – 50	07 (23.33%)	05 (16.67%)	05 (16.67%)	17 (18.89%)
>50	01 (3.33%)	01 (3.33%)	01 (3.33%)	03 (3.33%)
Total	30 (100%)	30 (100%)	30 (100%)	90 (100%)
Mean age	35.33±7.94	34.53±9.22	33.53±8.02	ANOVA p =0.222

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Statistical analysis – p value between groups

Control vs Esmolol group p= 0.092
Control vs Labetalol group p= 0.386
Esmolol vs Labetalol group p= 0.374

Table 2: Gender wise distribution in all groups

Gender	Control Group	Esmolol Group	Labetalol group	Total
Male	16 (53.33%)	14 (46.67%)	13 (43.33%)	43 (47.78%)
Female	14 (46.67%)	16 (53.33%)	17 (56.67%)	47 (52.22%)
Total	30	30	30	90 (100%)

Statistical analysis – p value between groups

Control vs Esmolol group p= 0.796
Control vs Labetalol group p= 0.605
Esmolol vs Labetalol group p=0.795

Table 3: ASA Grading wise distribution in all groups

ASA	Control Group	Esmolol Group	Labetalol group	Total
I	24 (80.0%)	26 (86.67%)	22 (73.33%)	72 (80.0%)
II	06 (20.0%)	04 (13.33%)	08 (26.67%)	18 (20.0%)
Total	30	30	30	90 (100%)

Statistical analysis – p value between groups

Control vs Esmolol group p= 0.730
Control vs Labetalol group p= 0.761
Esmolol vs Labetalol group p=0.333

Table 4: Weight and height-wise comparison in all groups

Weight (in kgs)	Control Group	Esmolol Group	Labetalol group	ANOVA
Mean±SD	57.63±6.69	55.26±7.77	56.16±7.24	0.446
Height (in cm)				
Mean±SD	157.10±4.11	156.86±2.25	155.63±2.97	0.169

Statistical analysis – p value between groups

Weight (in kg)
Control vs Esmolol group p= 0.211
Control vs Labetalol group p= 0.418
Esmolol vs Labetalol group p=0.644

Height (in cm)
Control vs Esmolol group p= 0.786
Control vs Labetalol group p= 0.065
Esmolol vs Labetalol group p=0.075

Table 5: Mean changes in pulse rate

Pulse Rate (b/min)	Control Group		Esmolol Group		Labetalol group		ANOVA
	Mean	SD	Mean	SD	Mean	SD	
PR - 0	103.00	10.85	100.73	3.12	99.06	3.81	0.090
PR – X	110.80	3.38	90.66	3.29	108.53	4.29	<0.0001
PR – A	125.26	6.40	98.26	2.50	125.00	4.16	<0.0001
PR – B	136.66	4.66	100.46	3.00	136.73	2.49	<0.0001
PR – C	110.16	8.13	109.00	5.50	91.06	3.14	<0.0001
PR – D	111.26	5.29	111.60	7.41	92.13	3.31	<0.0001

Statistical analysis – p value between group

	C vs E	C vs L	E vs L
PR – 0	0.276	0.066	0.069
PR – X	<0.0001	0.027	<0.0001
PR – A	<0.0001	0.848	<0.0001
PR – B	<0.0001	0.945	<0.0001
PR – C	0.517	<0.0001	<0.0001
PR – D	8.41	<0.0001	<0.0001

Table 6: Mean systolic blood pressure changes

SBP	Control Group		Esmolol Group		Labetalol group		ANOVA
	Mean	SD	Mean	SD	Mean	SD	
SBP - 0	130.33	9.74	130.40	9.81	131.26	8.42	0.911
SBP– X	111.66	9.05	110.80	7.65	109.13	5.21	0.414
SBP – A	151.06	8.63	121.73	4.44	150.33	5.04	<0.0001
SBP – B	138.26	8.80	120.20	7.22	124.06	8.78	<0.0001
SBP – C	138.06	8.63	134.20	7.90	111.63	5.48	<0.0001
SBP – D	132.46	6.44	131.73	7.21	112.33	7.24	<0.0001

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Statistical analysis – p value between group

	C vs E	C vs L	E vs L
SBP – 0	0.979	0.692	0.715
SBP – X	0.690	0.189	0.328
SBP – A	<0.0001	0.717	<0.0001
SBP – B	<0.0001	<0.0001	0.067
SBP – C	0.994	<0.0001	<0.0001
SBP – D	0.679	<0.0001	<0.0001

Table 7: Mean Diastolic blood pressure changes

DBP	Control Group		Esmolol Group		Labetalol group		ANOVA
	Mean	SD	Mean	SD	Mean	SD	
DBP - 0	81.40	5.09	81.13	6.05	81.53	5.47	0.960
DBP – X	84.06	5.26	73.70	5.46	82.53	3.27	<0.0001
DBP – A	91.06	5.81	81.26	5.18	91.80	5.95	<0.0001
DBP – B	92.93	5.77	80.80	5.67	80.93	5.93	<0.0001
DBP – C	86.36	4.23	85.26	3.17	74.46	5.88	<0.0001
DBP – D	85.13	5.08	86.20	3.72	74.13	6.70	<0.0001

Statistical analysis – p value between group

	C vs E	C vs L	E vs L
DBP – 0	0.854	0.922	0.789
DBP – X	<0.0001	0.180	<0.0001
DBP – A	<0.0001	0.631	<0.0001
DBP – B	<0.0001	<0.0001	0.924
DBP – C	0.259	<0.0001	<0.0001
DBP – D	0.357	<0.0001	<0.0001

DISCUSSION

Haemodynamic changes occurring after ECT last for 10 minutes. Esmolol and Labetalol play a role in reducing these hemodynamic changes. It was found that Esmolol at a dose of 1mg/kg was effective in attenuating the increase in HR, SBP, and DBP for up to 3 minutes but not effective in the later period of ECT (3-10 minutes). This time coincided with the onset and peak time of the Esmolol. This result was similar to that found in a study conducted by Kovac et al[9]. This study found that 0.25mg/kg Labetalol was not effective in attenuating the increase in mean HR in the first 5 minutes and SBP and DBP in the first 3 minutes. But Labetalol was effective in attenuating the HR after 5-10 minutes of ECT and SBP and DBP after 3-10 minutes of ECT. This time coincided with the onset and peak time of Labetalol. These results were similar to that found in a study conducted by Castelli & Steiner in 1995[11].

Demographic Profile: The mean age, sex distribution, BMI (weight and height), and ASA classification were comparable in all three groups and there was no statistically significant difference between these groups. **(Figures 1 to 5 and Tables 1 to 4)**

Changes In Heart Rate (Figure 6 and Table 5)

Comparison of Esmolol with the Control group

In both the Control and Esmolol groups, the baseline mean HR was the same. The difference between mean HR was not statistically significant (p value = 0.28). After 1 minute of ECT, the mean HR in the Control group was 125.2 whereas in the Esmolol group, it was 98.3. The difference between the mean HR was statistically significant (p value < 0.05). After 3 minutes of ECT, the mean HR in the Control group was 137.5 and in the Esmolol group was 100.5. The difference in the mean HR between the Control group and the Esmolol group was statistically significant (p value = 0.0001). The mean HR in the Control group after 5 minutes and 10 minutes of ECT was 108.1 and 111.4 and in the Esmolol group was 109.0 and 109.9. The difference between the mean HR between the Control group and in Esmolol group after 5 and 10 minutes of ECT was statistically insignificant (p value = 0.44 and 0.22 respectively). This clearly showed that Esmolol was effective in attenuating the increase in HR in the immediate period which is 1 to 3 minutes after ECT but not effective in attenuating the rise in HR in the later period (3 to 10 minutes after ECT). This result was similar to the result of the study conducted by D O'Flaherty et al who found that Esmolol is preferred to Nitroglycerine to control the heart rate[10].

Comparison of Labetalol with the Control group

In both the Control and Labetalol groups, baseline mean HR was the same. The difference between mean HR was not statistically significant (p value = 0.105). After 1 min of ECT, the mean HR in the Control group was 125.2 whereas in the Labetalol group, it was 125.0. The difference between the mean HR was statistically insignificant (p value = 0.88). After 3 min of ECT, the mean HR in the Control group was 137.5 and in the Labetalol group was 136.0. The difference in the mean HR between the Control group and the Labetalol group was statistically insignificant (p value = 0.32). The mean HR in the Control group after 5 minutes and 10 minutes of ECT was 108.1 and 114.4 and in the Labetalol group was 91.1 and 92.1. The difference between the mean HR between the Control group and

ISSN (O): 2687-5365; ISSN (P): 2753-6556

the Labetalol group after 5 and 10 minutes of ECT was statistically significant (p value < 0.0001). This clearly showed that Labetalol was not effective in attenuating the increase in HR in the immediate period which is 1 to 5 minutes after ECT but effective in attenuating the rise in HR in the later period (5 to 10 minutes after ECT). This result was similar to the study conducted by Jung Hee Ryu et al who compared the effects of Labetalol and Nicardipine in attenuating the stress response in ECT[12].

Changes in Systolic BP (Figure 7 and Table 6)

Comparison of Esmolol with the Control group

In both the Control and Esmolol groups, the baseline SBP was the same. The difference between mean SBP was not statistically significant (p value = 0.95). After 1 minute of ECT, the mean SBP in the Control group was 152.5 whereas in the Esmolol group, it was 121.5. The difference between the mean SBP was statistically significant (p value < 0.0001). After 3 min of ECT, the mean SBP in the Control group was 137.6 and in the Esmolol group was 119.5. The difference in the mean SBP between the Control group and the Esmolol group was statistically significant (p value < 0.0001). The mean SBP in the Control group after 5 minutes and 10 minutes of ECT was 138.3 and 131.9 respectively and in the Esmolol group was 135.4 and 132. The difference in mean SBP between the Control group and the Esmolol group after 5 and 10 minutes of ECT was statistically insignificant (p value = 0.18 and 0.88 respectively). This clearly showed that Esmolol was effective in attenuating the increase in SBP in the immediate period which is 1 to 3 minutes after ECT but not effective in attenuating the rise in SBP in the later period (3 to 10 minutes after ECT). This result was similar to the result of the study conducted by Castelli & Steiner in 1995 who compared the effects of Esmolol and Labetalol in ECT for stress attenuation [11].

Comparison of Labetalol with the Control group

In both the Control and Labetalol groups, baseline SBP was the same. The difference between mean SBP was not statistically significant (p value = 0.88). After 1 minute of ECT, the mean SBP in the Control group was 152.3 whereas in the Labetalol group was 150.3. The difference between the mean SBP was statistically insignificant (p value = 0.19). After 3 minutes of ECT, the mean SBP in the Control group was 137.6 and in the Labetalol group was 124.1. The difference in the mean SBP between the Control group and the Labetalol group was statistically significant (p value < 0.0001). The mean SBP in the Control group after 5 minutes and 10 minutes of ECT was 138.3 and 131.9 and in the Labetalol group was 111.6 and 112.3. The difference between SBP in the Control group and the Labetalol group after 5 and 10 minutes of ECT was statistically significant (p value < 0.0001). This clearly showed that Labetalol was not effective in attenuating the increase in SBP in the immediate period that is 1 to 3 minutes and after ECT but effective in attenuating the rise in SBP in the later period (3 to 10 minutes after ECT). This result was similar to the result of a study conducted by MB Weinger et al who found that Labetalol is preferred over Fentanyl in stress attenuation in ECT[13].

Changes in Diastolic BP (Figure 8 and Table 7)

Comparison of Esmolol with the Control group

In both the Control and Esmolol groups, baseline DBP was the same. The difference between mean DBP was not statistically significant (p value = 0.84). After 1 minute of ECT, the mean DBP in the Control group was 91.5 whereas in the Esmolol group, it was 81.1. The difference between the mean DBP was statistically significant (p value < 0.0001). After 3 minutes of ECT, the mean DBP in the Control group was 93.1 and in the Esmolol group was 81.1. The difference in the mean DBP between the Control group and the Esmolol group was statistically significant (p value < 0.0001). The mean DBP in the Control group after 5 minutes and 10 minutes of ECT was 86.0 and 85.1 respectively and in the Esmolol group was 83.1 and 86.5. The difference in mean DBP between the Control group and the Esmolol group after 5 and 10 minutes of ECT was statistically insignificant (p value = 0.19 and 0.23 respectively). This clearly showed that Esmolol was effective in attenuating the increase in DBP in the immediate period which is 1 to 3 minutes after ECT but not effective in attenuating the rise in DBP in the later period (3 to 10 minutes after ECT). This result was similar to the result of the study conducted by Howie et al who defined the dose of Esmolol in stress attenuation during ECT[14].

Comparison of Labetalol with the Control group

In both the Control and Labetalol groups, baseline DBP was the same. The difference between mean DBP was not statistically significant (p value = 0.81). After 1 minute of ECT, the mean DBP in the Control group was 91.5 whereas in the Labetalol group, it was 91.8. The difference between the mean DBP was statistically insignificant (p value = 0.86). After 3 minutes of ECT, the DBP in the Control group was 93.1 and in the Labetalol group was 80.5. The difference in the mean DBP between the Control group and the Labetalol group was statistically significant (p value < 0.0001). The mean DBP in the Control group after 5 minutes and 10 minutes of ECT was 86.0 and 85.1 and in the Labetalol group was 74.1 and 73.7. The difference between DBP between the Control group and the Labetalol group after 5 and 10 minutes of ECT was statistically significant (p value < 0.0001). This clearly showed that Labetalol was not effective in attenuating the increase in DBP in the immediate period which is 1 to 3 minutes after ECT but effective in attenuating the rise in DBP in the later period (3 to 10 minutes after ECT). This result was similar to the result of the study conducted by Sarvesh P Singh et al who compared the effects of Esmolol and Labetalol in the attenuation of hemodynamic responses in laryngoscopy and intubation[15].

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Side Effects

One patient from the C group, 2 patients from the E group, and 3 patients from the group developed bradycardia who were managed by IV Atropine 0.3 mg bolus dose. 3 patients from the C group, developed hypotension, 1 from E and 2 from the L group developed hypotension who were managed by IV fluid bolus. However, the incidence of complications among all three groups was statistically insignificant.

Observations

The observations noted in this study were:

1. Demographic profile was similar in all three groups and there was no statistical significant difference between these three groups.
2. Esmolol significantly reduced the HR,SBP, and DBP from 1 to 3 minutes after ECT whereas Labetalol did not produce any significant changes during that period.
3. Labetalol significantly reduced the HR from 5 to 10 minutes, SBP and DBP from 3 to 10 minutes after ECT whereas Esmolol did not produce any significant changes during that period.

CONCLUSION

It is concluded that a dose of 1mg/kg of Esmolol was effective in attenuating the hemodynamic responses to modified ECT in the first 3 minutes whereas a dose of 0.25mg/kg of Labetalol was effective in attenuating the responses in the period from 3 to 10 minutes.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556