

## **AIM OF THE WORK**

The aim of this study was to compare the efficacy of tramadol versus granisetron for control of shivering during spinal anesthesia.

## **PATIENTS**

- The study was carried out in Alexandria University Hospitals on 60 ASA physical status I and II patients aged between 18 – 40 years of both sexes scheduled for elective orthopedic surgeries with duration of 1 – 1.5 hours under spinal anesthesia.
- Patients were randomly-assigned (double-blind, envelope randomization) into two equal groups (30 patients each) according to the drug administrated:

**(1)      Group T :** Tramadol 1 mg/kg

**(2)      Group G :** Granisetron 40µ/kg

### **Exclusion criteria:**

Patients with any of the following conditions were excluded from the study:

- Contraindication to spinal anesthesia.
- Any contraindication to tramadol or granisetron.
- Hypo- or Hyperthyroidism.
- Pregnant females.
- Cardiopulmonary disease.
- Psychological disorders.
- A need for blood transfusion during surgery.
- An initial body temperature > 38°C or < 36°C.
- Receiving vasodilators or medications likely to alter thermoregulation.
- Known history of alcohol or substance abuse.

## METHODS

### **Pre-operative assessment:**

After approval of the medical ethical committee and an informed written consent taken from all patients included in this study, the patients were assessed thoroughly by:

- Detailed medical and surgical history taking.
- Full clinical examination.
- Routine laboratory investigations (complete blood picture, coagulation profile, blood urea, serum creatinine and fasting blood sugar).

### **Anesthesia:**

- Basic non-invasive monitors were connected and intravenous access was established.
- Intra-venous (i.v.) fluids –Normal Saline 0.9%- were preheated to 37°C in a warmed cabinet and given without in-line warming. No other warming device was used. The intra-venous fluids were infused at a rate of 10 ml/kg over 30 minutes before spinal anesthesia, then were reduced to 6 ml/kg/h.
- Sterilization of the skin was done by povidone-iodine 10% solution.
- Infiltration of the skin and subcutaneous tissue at the site of spinal needle injection with 3ml of 2% xylocaine was done after complete aseptic technique.
- Subarachnoid anesthesia was instituted at either L3/4 or L4/5 interspaces. Hyperbaric bupivacaine (5 mg/ml) 15 mg was injected using 27G Quincke spinal needle.
- The study drugs were diluted to a volume of 10 ml and presented as coded syringes by an anesthesiologist who was blinded to group allocation.
- Before starting surgery, sensory block was assessed with a pinprick test at 5 min intervals till the desired block level was achieved.
- Supplemental oxygen (5 L/min) was delivered via facemask during the operation.
- All patients were covered with one layer of surgical drapes over the chest, thighs and calves during the operation and one cotton blanket over the entire body after operation.
- All theatres in which the operations will be performed will be maintained at constant humidity (70%) and an ambient temperature of around 23°C.
- No means of active rewarming were used.
- The presence of shivering was observed by an observer blinded to the study drug(s) administered.
- After appearance of shivering, patients were given the study drug as an i.v. bolus according to the group they were randomly assigned to.
- If the treatment by tramadol or granisetron was regarded as ineffective (Grade 3 or 4 in the shivering score), i.v. pethidine 25 mg was administered.

## Measurements

The following parameters were measured for all patients:

### 1- Demographic data :

- Age (years).
- Gender (sex).
- Body weight (kilograms).
- Operation performed (type and duration).

### 2- Hemodynamic parameters:

- Heart rate (beat/min).
- Mean blood pressure (mmHg).
- Body temperature (°c).

These hemodynamic parameters were continuously monitored using Drager Infinity XL 24 multi channel monitor and recorded before intrathecal injection and thereafter every 15 minutes till 3 hours postoperatively.

### 3- Temperature monitoring:

- a- Body temperatures (tympanic) was recorded with an ear thermometer (OMRON Medizintechnik GmbH, Mannheim, Germany). It was measured before intrathecal injection and 15 minutes intervals till the end of the operation.
- b- The ambient temperature was measured by a wall thermometer and maintained at 23°C.

### 4- Onset of shivering:

The time in minutes at which shivering started after spinal anesthesia.

### 5- Shivering score:

**Table (1): Shivering score. (Wrench score)**

Score	Observation
0	No shivering.
1	Piloerection or peripheral vasoconstriction but no visible shivering.
2	Muscular activity in only one muscle group.
3	Muscular activity in more than one muscle group but not generalized.
4	Shivering involving the whole body.

**6- Disappearance of shivering:**

Time of disappearance of shivering was recorded in minutes.

**7- Sedation scale:**

**Table (2): Sedation scale. (Filos scale)**

<b>Score</b>	<b>Observation</b>
<b>1</b>	Fully awake and oriented.
<b>2</b>	Drowsy.
<b>3</b>	Eyes closed but arousable to command.
<b>4</b>	Eyes closed but arousable to mild physical stimulation.
<b>5</b>	Eyes closed but unarousable to mild physical stimulation.

**8- Side effects:**

Side effects like nausea, vomiting, bradycardia (<50/min), and hypotension (>20% of baseline) were recorded.

Bradycardia and hypotension were treated with atropine and ephedrine respectively in titrated doses if required.

Nausea and vomiting were treated with metoclopramide 10 mg IV if required.

## Statistical analysis

The clinical and laboratory results obtained were statistically analyzed using SPSS/PC\* (Statistical package for social science for personal computers).

### 1. Arithmetic mean ( $\bar{X}$ ):

Was calculated as follows:

$$\bar{x} = \frac{\sum x}{n}$$

Where:  $\bar{x}$  = arithmetic mean

$\sum x$  = Sum of observations

n = number of observations

### 2. Standard deviation (SD):

Was calculated as follows:

$$SD = \sqrt{\frac{\sum x^2 - \frac{(\sum x)^2}{n}}{n - 1}}$$

Where:  $\sum x^2$  = sum of squared observations.

$(\sum x)^2$  = square of the sum of observations.

n = number of observations.

### 3. "t" test:

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{S_p^2 \left( \frac{1}{n_1} + \frac{1}{n_2} \right)}}$$

$$S_p^2 = \frac{S_1^2 (n_1 - 1) + S_2^2 (n_2 - 1)}{n_1 + n_2 - 2}$$

Where:  $S_p^2$  = Pooled variance.

$S_1^2$  = Variance of sample (1).

$S_2^2$  = Variance of sample (2).

$n_1$  = Size of sample (1).

$n_2$  = Size of sample (2).

$\bar{X}_1$  = Mean of sample (1).

$\bar{X}_2$  = Mean of sample (2).

$S_1$  = Standard deviation of sample (1).

S<sub>2</sub> = Standard deviation of sample (2).

#### 4. Chi-square (X<sup>2</sup>):

For comparison between distribution of patients according to different items of study and use this formula for calculation:

$$X^2 = \sum \frac{(O - E)^2}{E}$$

O = Observed results

E = Expected results

(O - E)<sup>2</sup> = *differance* squared

Where E =  $\frac{\text{Total row x total column}}{\text{Grand total}}$

\* Statistical analysis was done at level of significance of P<sub>≤</sub>0.05

## **RESULTS**

The present study was carried out on 60 patients, 18-40 years old, ASA I-II. The patients were randomly-assigned into two groups: Tramadol Group (T) and Granisetron group (G), each group is formed of 30 patients. The patients were operated upon for elective orthopedic surgical procedures under spinal anesthesia in the orthopedic department of the Alexandria Main University Hospital.

From the present study the following results were obtained:

### **Demographic data (Table 3-5, Figures 5-7)**

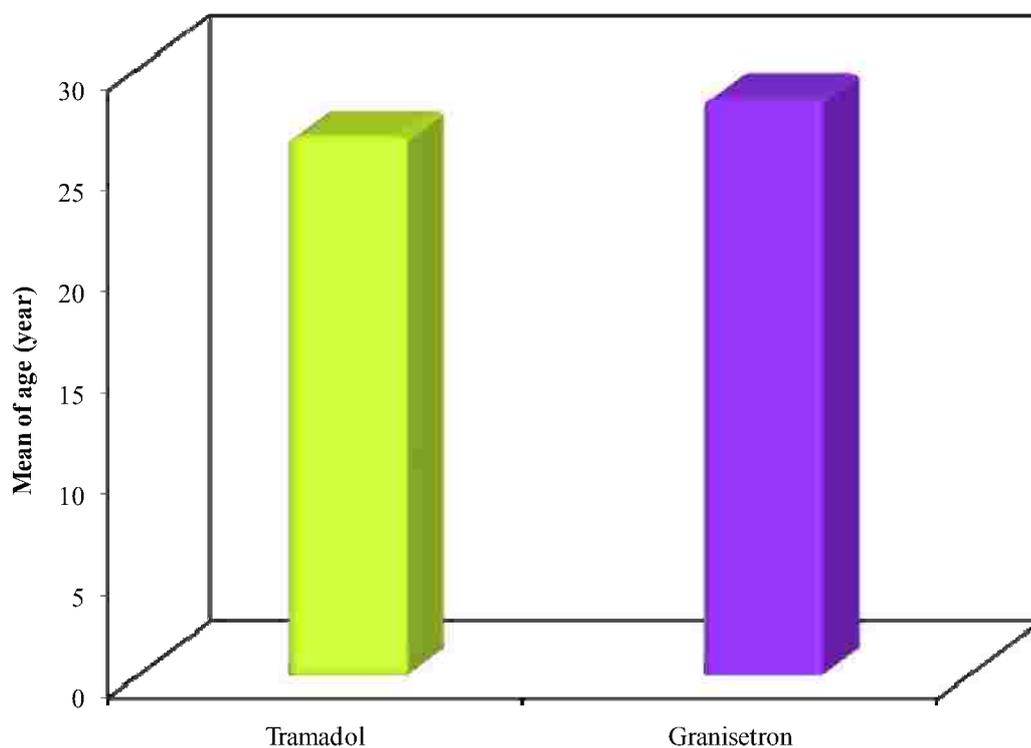
#### **Age (years)**

The age ranged between 19-39 and 19-38 year with a mean of  $26.57 \pm 5.61$  and  $28.4 \pm 4.78$  (years) for the two studied groups T and G respectively. There were no statistical significant difference between the two studied groups regarding age ( $P=0.178$ ).

**Table (3): Comparison between the two studied groups regarding age (Years)**

	Age	
	Tramadol	Granisetron
1	22	22
2	19	27
3	26	29
4	33	28
5	29	29
6	22	33
7	23	32
8	25	27
9	35	26
10	39	33
11	23	30
12	23	26
13	25	24
14	23	31
15	20	26
16	35	29
17	24	27
18	23	34
19	31	35
20	30	38
21	25	19
22	24	25
23	23	32
24	19	30
25	26	23
26	27	29
27	35	38
28	29	19
29	38	24
30	21	27
<b>Min.</b>	19.0	19.0
<b>Max.</b>	39.0	38.0
<b>Mean</b>	26.57	28.40
<b>SD.</b>	5.61	4.78
<b>Median</b>	25.0	28.50
<b>T</b>	1.363	
<b>P</b>	0.178	

t: Student t-test



**Figure (5): Comparison between the two studied groups regarding age (Years)**

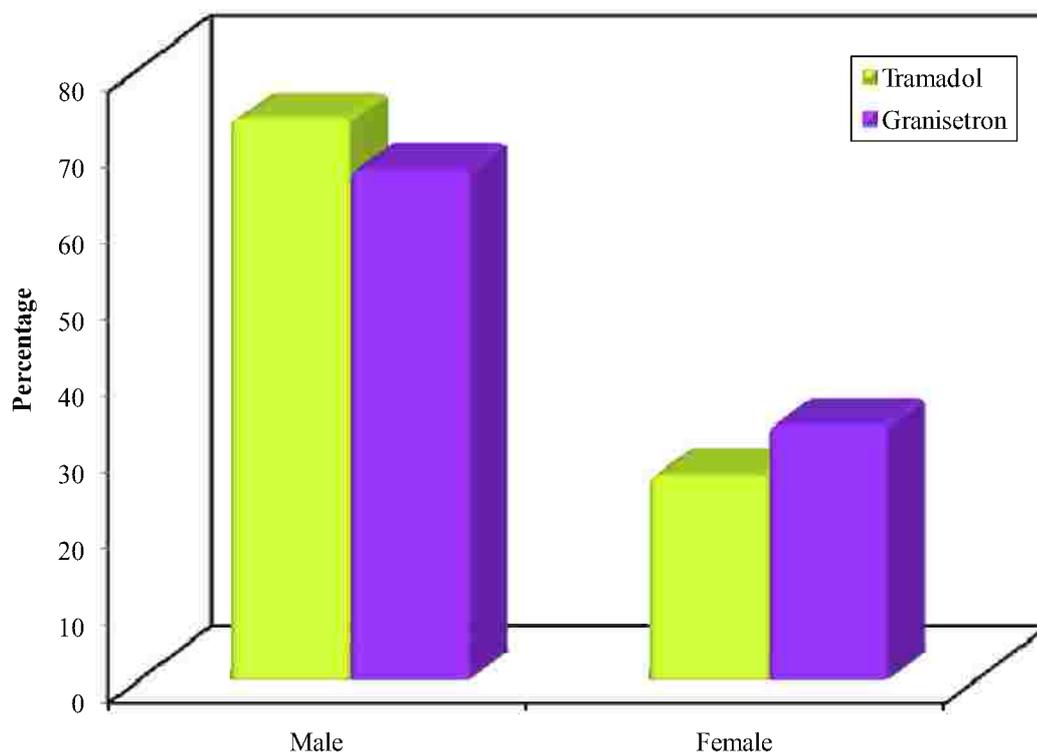
**Sex**

Group T included 22 male and 8 females compared to 20 males and 10 females in group G. There was no statistical significant difference between the two studied groups regarding sex (P=0.573).

**Table (4): Comparison between the two studied groups regarding sex**

	Sex	
	Tramadol	Granisetron
1	Female	Female
2	Male	Male
3	Male	Female
4	Male	Male
5	Male	Male
6	Female	Female
7	Male	Male
8	Male	Male
9	Male	Female
10	Male	Male
11	Female	Female
12	Male	Male
13	Male	Male
14	Male	Male
15	Female	Female
16	Male	Male
17	Male	Male
18	Male	Male
19	Female	Female
20	Female	Female
21	Male	Male
22	Male	Male
23	Female	Male
24	Female	Female
25	Male	Male
26	Male	Male
27	Male	Male
28	Male	Female
29	Male	Male
30	Male	Male
<b>Male</b>	22 (73.3%)	20 (66.7%)
<b>Female</b>	8 (26.7%)	10 (33.3%)
$\chi^2$	0.317	
P	0.573	

$\chi^2$ : Chi square test



**Figure (6): Comparison between the two studied groups regarding sex**

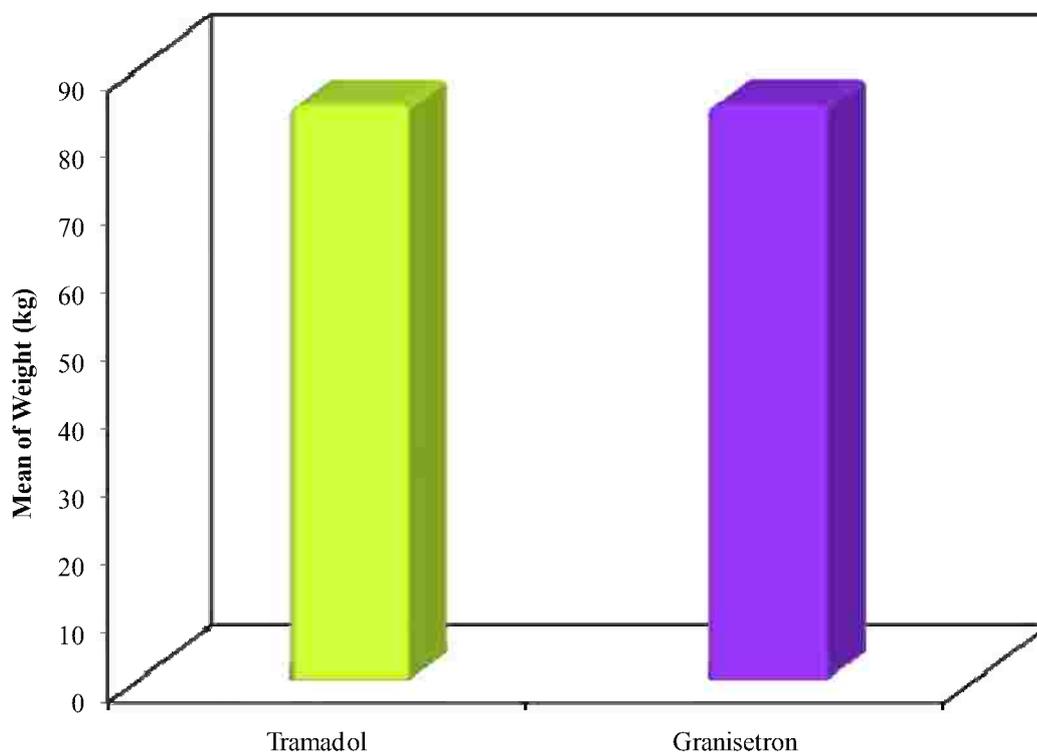
**Weight (kilograms)**

The weight ranged between 74-95 and 74-96 with a mean of  $84.37 \pm 6.27$  and  $84.43 \pm 7.54$  kilograms for group T and G respectively. There were no statistical significant difference between the studied groups ( $P=0.777$ ).

**Table (5): Comparison between the two studied groups regarding weight (Kilograms)**

	Weight	
	Tramadol	Granisetron
1	80	96
2	90	74
3	85	82
4	86	85
5	75	89
6	89	78
7	95	92
8	76	90
9	88	77
10	74	84
11	75	94
12	88	90
13	91	78
14	90	77
15	78	93
16	77	79
17	80	81
18	86	89
19	82	82
20	81	83
21	83	92
22	91	87
23	78	83
24	86	84
25	89	79
26	93	78
27	95	76
28	77	95
29	86	90
30	87	76
<b>Min.</b>	74.0	74.0
<b>Max.</b>	95.0	96.0
<b>Mean</b>	84.37	84.43
<b>SD.</b>	6.27	6.54
<b>Median</b>	86.0	83.50
<b>T</b>	0.040	
<b>P</b>	0.968	

t: Student t-test



**Figure (7): Comparison between the two studied groups regarding weight (Kilograms)**

**Duration of Surgery (Minutes) (Table 6, Figure 8)**

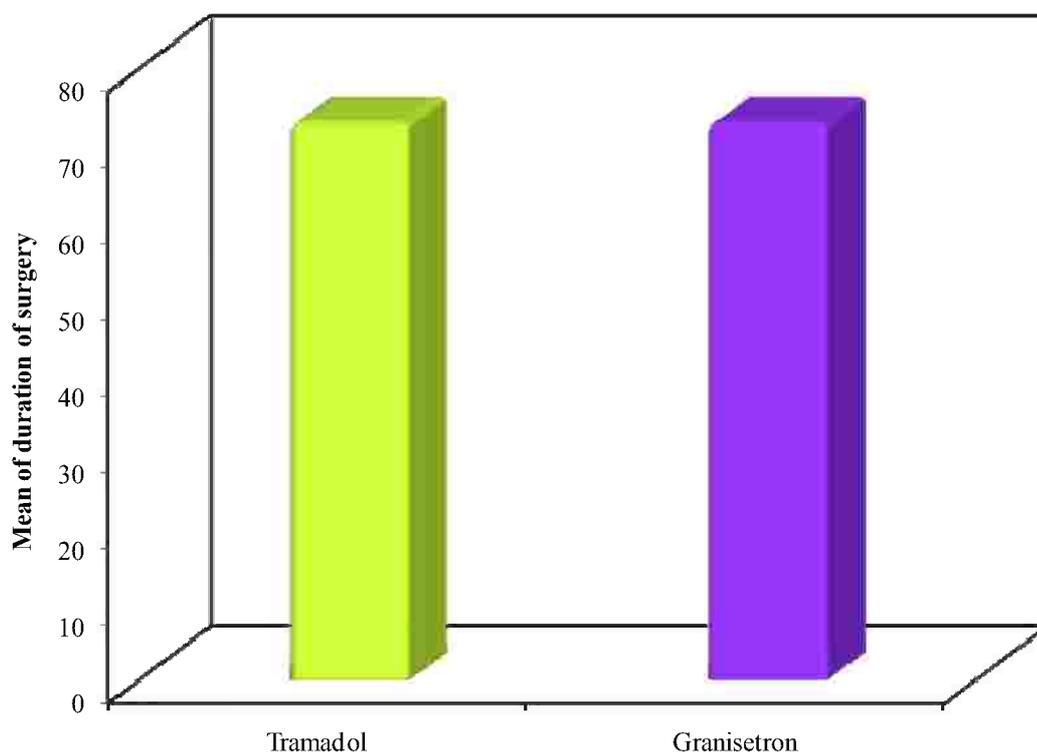
The duration of surgery ranged between 60-90 and 60-90 (minutes) with a mean of  $72.83 \pm 8.38$  and  $72.83 \pm 8.38$  for group T and G respectively. There were no statistical significant difference between the studied groups ( $P=1.000$ ).

**Table (6): Comparison between the two studied groups regarding duration of surgery (Minutes)**

	Duration of surgery	
	Tramadol	Granisetron
1	65	60
2	60	90
3	80	65
4	65	80
5	90	80
6	75	75
7	75	70
8	70	70
9	70	65
10	65	65
11	60	60
12	85	90
13	80	80
14	70	70
15	70	70
16	65	70
17	90	65
18	80	80
19	70	85
20	60	70
21	70	75
22	65	80
23	75	80
24	70	70
25	80	65
26	85	70
27	80	75
28	70	65
29	75	60
30	70	85
Min.	60.0	60.0
Max.	90.0	90.0
Mean	72.83	72.83
SD.	8.38	8.58
Median	70.0	70.0
T	0.00	
P	1.000	

t: Student t-test

\*: Statistically significant at  $p \leq 0.05$



**Figure (8): Comparison between the two studied groups regarding duration of surgery (Minutes)**

### **Changes in Heart Rate (beats/minute) (Tables 7-9, Figure 9)**

In group T, it was found that the heart rate immediately before spinal anesthesia ranged between 80-91, with a mean of  $85.2 \pm 3.23$  (beat/min). After the spinal anesthesia, the fifteen alternative time of follow up showed a significant decrease in heart rate.

In group G, the heart rate immediately before spinal anesthesia ranged between 82-90 with a mean of  $85.47 \pm 2.84$  (beats/min). After the spinal anesthesia, the fifteen alternative time of follow up showed a significant increase in heart rate.

On comparing the two studied groups, it was found that immediately before spinal anesthesia, heart rate ranged between 80-91 and 82-90 with a mean of  $85.2 \pm 3.23$  and  $85.47 \pm 2.84$  (beat/minute) for group T and G respectively. Statistically, it was found that there was no significant difference between the two studied groups immediately before spinal anesthesia. However, all over the period of follow up, it was found that group T had lower value than group G which had higher value of heart rate.

## Results

**Table (7): Distribution of the studied cases regarding heart rate in Tramadol group (Beat/Minute)**

	Before	After							
		15 min.	30 min.	45 min.	60 min.	75 min.	90 min.	120 min.	180 min.
1	86	85	83	82	82	81	84	85	82
2	90	82	84	85	82	84	84	83	84
3	85	85	83	84	80	82	84	82	84
4	88	80	84	80	82	81	82	80	82
5	88	80	81	84	83	81	85	84	81
6	86	82	81	88	82	82	86	88	81
7	82	81	82	84	83	80	83	85	85
8	82	80	83	84	76	84	75	81	85
9	90	82	81	82	81	81	80	81	85
10	87	83	84	81	83	80	85	81	77
11	82	82	87	79	80	80	82	80	83
12	82	83	82	81	83	80	82	84	84
13	83	75	80	82	81	81	75	81	85
14	86	80	82	81	82	80	84	81	84
15	86	82	87	88	85	81	88	83	84
16	83	80	84	81	80	80	81	85	85
17	90	82	82	87	85	84	81	83	85
18	82	85	81	83	86	81	82	84	83
19	91	85	85	83	81	84	82	87	83
20	83	83	81	81	83	85	81	80	83
21	88	85	85	81	84	81	82	83	85
22	83	83	82	81	86	80	88	81	86
23	83	85	83	88	81	90	84	81	81
24	82	81	84	84	83	83	83	85	85
25	90	81	81	80	80	80	81	80	81
26	82	85	85	84	85	82	80	85	81
27	82	81	81	80	80	80	83	85	85
28	89	80	81	84	83	84	81	83	81
29	80	80	78	80	81	81	82	82	82
30	85	82	82	80	82	82	84	85	85
<b>Min.</b>	80.0	75.0	78.0	79.0	76.0	80.0	75.0	80.0	77.0
<b>Max.</b>	91.0	85.0	87.0	88.0	86.0	90.0	88.0	88.0	86.0
<b>Mean</b>	85.20	82.0	82.63	82.73	82.17	81.83	82.47	82.93	83.23
<b>SD.</b>	3.23	2.26	2.01	2.57	2.12	2.18	2.86	2.18	1.99
<b>Median</b>	85.0	82.0	82.0	82.0	82.0	81.0	82.0	83.0	84.0
<b>P</b>		0.003*	0.017*	0.045*	0.004*	0.001*	0.033*	0.128	0.501

p<sub>1</sub>: Stands for adjusted Bonferroni p-value for ANOVA with repeated measures for comparison between pre with each other period

\*: Statistically significant at  $p \leq 0.05$

**Results**

**Table (8): Distribution of the studied cases regarding heart rate in Granisetron group (Beat/Minute)**

	Before	After							
		15 min.	30 min.	45 min.	60 min.	75 min.	90 min.	120 min.	180 min.
<b>1</b>	85	91	94	92	90	91	93	92	92
<b>2</b>	88	93	93	92	92	95	92	91	93
<b>3</b>	83	80	92	91	92	90	95	95	93
<b>4</b>	88	91	92	90	92	91	90	95	92
<b>5</b>	82	90	90	90	92	95	89	92	96
<b>6</b>	82	93	90	93	90	90	92	94	95
<b>7</b>	86	80	93	90	95	90	95	99	92
<b>8</b>	84	98	85	94	91	92	92	91	95
<b>9</b>	88	91	95	92	88	91	96	94	94
<b>10</b>	90	81	91	98	95	90	93	87	86
<b>11</b>	89	95	92	90	95	86	90	94	99
<b>12</b>	82	92	90	86	92	99	96	94	95
<b>13</b>	88	93	94	91	90	93	95	94	91
<b>14</b>	87	80	99	92	92	95	94	92	90
<b>15</b>	88	99	93	95	94	94	98	95	97
<b>16</b>	83	80	93	92	90	93	98	95	85
<b>17</b>	85	91	93	89	97	99	95	90	92
<b>18</b>	82	81	95	100	93	96	93	95	96
<b>19</b>	89	91	93	94	99	86	93	92	92
<b>20</b>	84	92	94	92	85	88	96	100	85
<b>21</b>	88	94	94	92	91	98	96	95	91
<b>22</b>	82	80	93	92	97	99	97	94	94
<b>23</b>	82	93	99	94	95	90	94	89	96
<b>24</b>	82	95	94	100	100	93	92	91	94
<b>25</b>	89	90	93	90	94	90	91	94	94
<b>26</b>	82	81	92	93	94	92	96	91	90
<b>27</b>	88	90	93	93	91	94	91	93	92
<b>28</b>	89	80	90	95	94	95	94	92	95
<b>29</b>	85	82	82	84	84	86	85	84	85
<b>30</b>	84	82	80	82	84	85	85	85	85
<b>Min.</b>	82.0	80.0	80.0	82.0	84.0	85.0	85.0	84.0	85.0
<b>Max.</b>	90.0	99.0	99.0	100.0	100.0	99.0	98.0	100.0	99.0
<b>Mean</b>	85.47	88.30	92.03	91.93	92.27	92.20	93.20	92.63	92.20
<b>SD.</b>	2.84	6.28	3.96	3.84	3.83	3.92	3.23	3.42	3.79
<b>Median</b>	85.0	91.0	93.0	92.0	92.0	92.0	93.50	93.50	92.50
<b>P</b>		0.844	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*

p<sub>1</sub>: Stands for adjusted Bonferroni p-value for ANOVA with repeated measures for comparison between pre with each other period

\*: Statistically significant at p ≤ 0.05

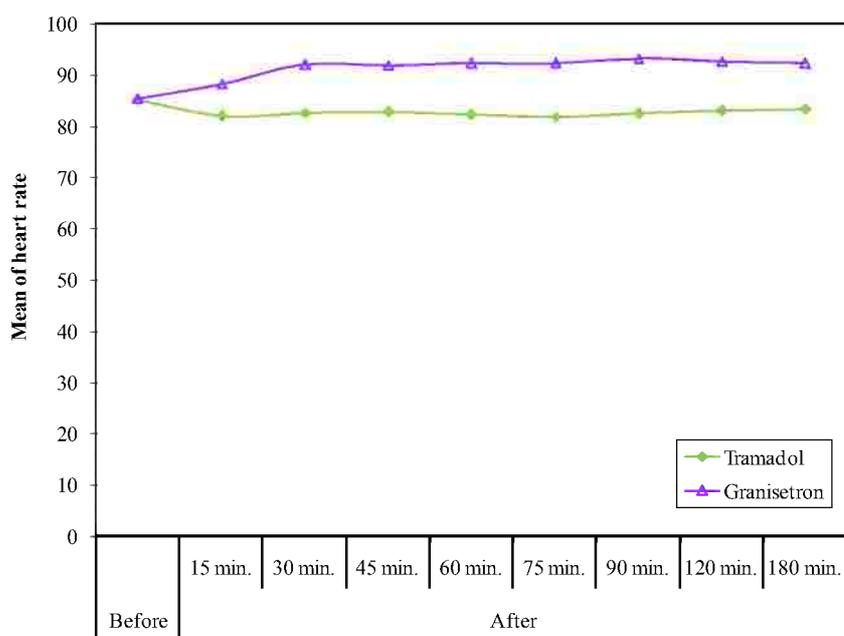
**Results**

**Table (9): Comparison between the two studied groups regarding heart rate (Beat/Minute)**

	Before	After							
		15 min.	30 min.	45 min.	60 min.	75 min.	90 min.	120 min.	180 min.
<b>Tramadol</b>									
Min.	80.0	75.0	78.0	79.0	76.0	80.0	75.0	80.0	77.0
Max.	91.0	85.0	87.0	88.0	86.0	90.0	88.0	88.0	86.0
Mean	85.20	82.0	82.63	82.73	82.17	81.83	82.47	82.93	83.23
SD.	3.23	2.26	2.01	2.57	2.12	2.18	2.86	2.18	1.99
Median	85.0	82.0	82.0	82.0	82.0	81.0	82.0	83.0	84.0
<b>Granisetron</b>									
Min.	82.0	80.0	80.0	82.0	84.0	85.0	85.0	84.0	85.0
Max.	90.0	99.0	99.0	100.0	100.0	99.0	98.0	100.0	99.0
Mean	85.47	88.30	92.03	91.93	92.27	92.20	93.20	92.63	92.20
SD.	2.84	6.28	3.96	3.84	3.83	3.92	3.23	3.42	3.79
Median	85.0	91.0	93.0	92.0	92.0	92.0	93.50	93.50	92.50
<b>T</b>	0.340	5.169*	11.594	10.900	12.634	12.664*	13.620	13.102	11.465
<b>P</b>	0.735	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*

t: Student t-test

\*: Statistically significant at  $p \leq 0.05$



**Figure (9): Comparison between the two studied groups regarding heart rate (Beat/Minute)**

**Changes in Mean arterial blood pressure (mmHg) (Tables 10-12, Figure 10)**

In group T, it was found the mean arterial blood pressure, immediately before spinal anesthesia, ranged between 82-97 (mmHg), with a mean of  $93.70 \pm 3.42$ . Fifteen minutes later on, there was a significant decrease in mean arterial blood pressure reaching  $84.87 \pm 1.78$ . At 30, 45, 60, 75 and 90 minutes after spinal anesthesia, there was a significant decrease in mean arterial blood pressure from the base line, while at 120 and 180 minutes, there was no significant difference from base line. In group G, it was found the mean arterial blood pressure, immediately before spinal anesthesia, ranged from 86-97 (mmHg), with a mean of  $93.7 \pm 2.42$ . Fifteen minutes later on, significant decrease in mean arterial blood pressure reaching  $85.03 \pm 1.33$ . At 30, 45, 60, 75 and 90 minutes after spinal anaesthesia, there was a significant decrease in mean arterial blood pressure from the base line, While at 120 and 180 minutes, there was no significant statistical difference from the baseline.

On comparing the two studied groups, it was found that the mean arterial blood pressure, immediately before spinal anesthesia, ranged from 82.0-97.0 (mmHg) in the two groups with a mean of  $93.70 \pm 3.42$  and  $93.70 \pm 2.42$  for group T and G respectively. Statistically, there were no significant difference between the two studied groups regarding MABP at all time periods of the operations.

## Results

**Table (10): Distribution of the studied cases regarding mean arterial blood pressure in tramadol group (mmHg)**

	Before	After							
		15 min.	30 min.	45 min.	60 min.	75 min.	90 min.	120 min.	180 min.
1	96	86	91	92	93	93	94	95	96
2	94	85	89	90	91	92	92	93	94
3	92	83	87	88	89	90	92	93	94
4	92	83	87	88	89	90	90	91	92
5	93	84	88	89	90	91	91	92	93
6	97	87	92	93	94	94	95	96	97
7	97	87	92	93	94	94	95	96	97
8	92	83	87	88	89	90	90	91	92
9	95	86	90	91	92	92	93	94	95
10	95	86	90	91	92	92	93	94	95
11	92	83	87	88	89	90	90	91	92
12	95	86	90	91	92	92	93	94	95
13	97	87	92	93	94	94	95	96	97
14	96	86	91	92	93	93	94	95	96
15	93	84	88	89	90	91	91	92	93
16	93	84	88	89	90	91	91	92	93
17	96	86	91	92	93	93	94	95	96
18	97	87	92	93	94	94	95	96	97
19	93	84	88	89	90	91	91	92	93
20	94	85	89	90	91	92	92	93	95
21	97	87	92	93	94	94	95	96	97
22	97	87	92	93	94	94	95	96	97
23	93	84	88	89	90	91	91	92	93
24	95	86	90	91	92	92	93	94	95
25	95	86	90	91	92	92	93	94	95
26	92	83	87	88	89	90	90	91	92
27	93	84	88	89	90	91	91	92	93
28	94	85	89	90	91	92	92	93	94
29	82	80	80	85	82	84	85	86	88
30	84	82	84	84	84	85	85	86	85
<b>Min.</b>	82.0	80.0	80.0	84.0	82.0	84.0	85.0	86.0	85.0
<b>Max.</b>	97.0	87.0	92.0	93.0	94.0	94.0	95.0	96.0	97.0
<b>Mean</b>	93.70	84.87	88.97	90.07	90.90	91.47	92.03	93.03	94.03
<b>SD.</b>	3.42	1.78	2.65	2.33	2.80	2.33	2.57	2.57	2.70
<b>Median</b>	94.0	85.0	89.0	90.0	91.0	92.0	92.0	93.0	94.50
<b>P</b>		<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	0.083	1.000

p<sub>1</sub>: Stands for adjusted Bonferroni p-value for ANOVA with repeated measures for comparison between pre with each other period

\*: Statistically significant at  $p \leq 0.05$

**Results**

**Table (11): Distribution of the studied cases regarding mean arterial blood pressure in Granisetron group (mmHg)**

	Before	After							
		15 min.	30 min.	45 min.	60 min.	75 min.	90 min.	120 min.	180 min.
<b>1</b>	95	86	90	91	92	92	93	94	95
<b>2</b>	97	87	92	93	94	94	95	96	97
<b>3</b>	92	83	87	88	89	90	92	93	94
<b>4</b>	94	85	89	90	91	92	92	93	94
<b>5</b>	96	86	91	92	93	93	94	95	96
<b>6</b>	95	86	90	91	92	92	93	94	95
<b>7</b>	95	86	90	91	92	92	93	94	95
<b>8</b>	97	87	92	93	94	94	95	96	97
<b>9</b>	95	86	90	91	92	92	93	94	95
<b>10</b>	96	86	91	92	93	93	94	95	96
<b>11</b>	92	83	87	88	89	90	90	91	92
<b>12</b>	96	86	91	92	93	93	94	95	96
<b>13</b>	95	86	90	91	92	92	93	94	95
<b>14</b>	92	83	87	88	89	90	90	91	92
<b>15</b>	92	83	87	88	89	90	90	91	92
<b>16</b>	94	85	89	90	91	92	92	93	94
<b>17</b>	93	84	88	89	90	91	91	92	93
<b>18</b>	94	85	89	90	91	92	92	93	94
<b>19</b>	92	83	87	88	89	90	90	91	92
<b>20</b>	93	84	88	89	90	91	91	92	93
<b>21</b>	93	84	88	89	90	91	91	92	93
<b>22</b>	95	86	90	91	92	92	93	94	95
<b>23</b>	92	83	87	88	89	90	90	91	92
<b>24</b>	94	85	89	90	91	92	92	93	94
<b>25</b>	93	84	88	89	90	91	91	92	93
<b>26</b>	97	87	92	93	94	94	95	96	97
<b>27</b>	94	85	89	90	91	92	92	93	94
<b>28</b>	94	85	89	90	91	92	92	93	94
<b>29</b>	88	86	88	88	90	90	90	92	92
<b>30</b>	86	86	86	88	88	90	92	94	92
<b>Min.</b>	86.0	83.0	86.0	88.0	88.0	90.0	90.0	91.0	92.0
<b>Max.</b>	97.0	87.0	92.0	93.0	94.0	94.0	95.0	96.0	97.0
<b>Mean</b>	93.70	85.03	89.03	90.03	91.03	91.63	92.17	93.23	94.10
<b>SD.</b>	2.42	1.33	1.69	1.67	1.69	1.27	1.58	1.55	1.63
<b>Median</b>	94.0	85.0	89.0	90.0	91.0	92.0	92.0	93.0	94.0
<b>P</b>		<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	0.001*	1.000	1.000

p<sub>1</sub>: Stands for adjusted Bonferroni p-value for ANOVA with repeated measures for comparison between pre with each other period

\*: Statistically significant at p ≤ 0.05

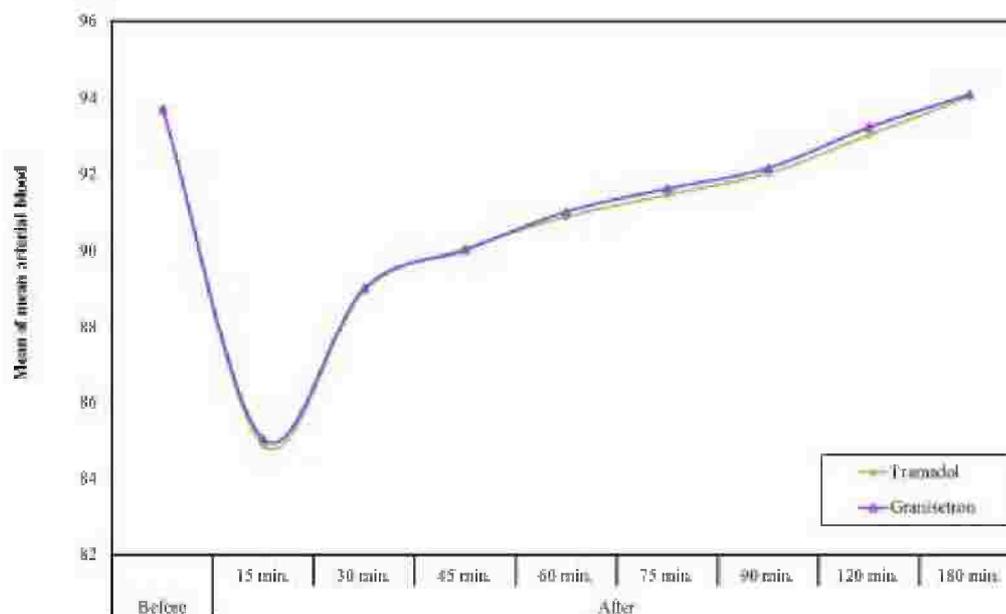
## Results

**Table (12): Comparison between the two studied groups regarding mean arterial blood pressure (mmHg)**

	Before	After							
		15 min.	30 min.	45 min.	60 min.	75 min.	90 min.	120 min.	180 min.
<b>Tramadol</b>									
Min.	82.0	80.0	80.0	84.0	82.0	84.0	85.0	86.0	85.0
Max.	97.0	87.0	92.0	93.0	94.0	94.0	95.0	96.0	97.0
Mean	93.70	84.87	88.97	90.07	90.90	91.47	92.03	93.03	94.03
SD.	3.42	1.78	2.65	2.33	2.80	2.33	2.57	2.57	2.70
Median	94.0	85.0	89.0	90.0	91.0	92.0	92.0	93.0	94.50
<b>Granisetron</b>									
Min.	86.0	83.0	86.0	88.0	88.0	90.0	90.0	91.0	92.0
Max.	97.0	87.0	92.0	93.0	94.0	94.0	95.0	96.0	97.0
Mean	93.70	85.03	89.03	90.03	91.03	91.63	92.17	93.23	94.10
SD.	2.42	1.33	1.69	1.67	1.69	1.27	1.58	1.55	1.63
Median	94.0	85.0	89.0	90.0	91.0	92.0	92.0	93.0	94.0
<b>T</b>	0.00	0.412	0.116	0.064	0.223	0.344	0.242	0.366	0.116
<b>P</b>	1.000	0.682	0.908	0.949	0.824	0.732	0.809	0.716	0.908

t: Student t-test

\*: Statistically significant at  $p \leq 0.05$



**Figure (10): Comparison between the two studied groups regarding mean arterial blood pressure (mmHg)**

### **Changes in Core (tympanic) Temperature (°C) (Tables 13-15, Figure 11)**

In group T, it was found that the core temperature, immediately before spinal anesthesia, ranged between 36.4-37.2 (°C) with a mean of  $36.82 \pm 0.27$ . Fifteen minutes after spinal anesthesia, there was significant decrease in the core temperature with a mean of  $36.8 \pm 0.54$ . Later on, all over the time periods of spinal anesthesia, there was significant decrease in core temperature.

In group G, it was found that core temperature, immediately before spinal anesthesia, ranged between 36.3-37 (°C) with a mean of  $36.79 \pm 0.20$ . Fifteen minutes after spinal anesthesia, there was no significant difference in the core temperature. Later, all over the time periods of the study, there was no significant difference in core temperature as well.

On comparing the two studied groups, it was found that immediately before spinal anesthesia, the core temperature ranged between 36.3-37.2 (°C) with a mean of  $36.85 \pm 0.23$ . There was no statistical significant difference between the two studied groups regarding core temperature immediately before intrathecal injection. However, all over the period of follow up, it was found that group T had lower values than group G which had higher values of core temperature.

## Results

**Table (13): Distribution of the studied cases regarding Temperature in Tramadol group (°C)**

	Before	After							
		15 min.	30 min.	45 min.	60 min.	75 min.	90 min.	120 min.	180 min.
1	37.2	37.1	36.2	36.8	35.8	36.3	35.4	35.7	35.3
2	36.9	36.2	36.6	36.3	36.5	35.8	35.8	35.6	36
3	36.7	36.1	37.1	37.4	35.7	36.6	35.4	35.2	35.6
4	36.8	37.4	35.7	35.8	36	35.2	35.6	36.1	36.5
5	37.1	36.2	36.7	35.8	35.7	35.7	36	35.8	35.6
6	36.4	36.9	36.3	35.7	36.3	35.8	36.1	36	36.5
7	36.5	36.6	36.4	36	36.1	36.3	36.2	35.9	36.3
8	36.9	36.6	35.5	35.6	36	36.4	35.2	35.7	36.3
9	36.5	35.7	37	35.5	35.2	35.2	35.5	35.6	36
10	36.4	36.5	35.6	35.8	36.4	35.7	35.7	35.3	35.9
11	37.2	36.2	36.4	36.5	36.2	36.6	35.9	35.9	35.5
12	36.7	36.5	35.5	36.4	36	36.7	36	35.7	35.4
13	37.2	35.9	37.1	37.2	35.6	35.2	35.8	36	36.1
14	36.6	35.7	35.8	36.7	35.8	35.8	35.5	35.5	36
15	37	36.9	35.4	35.9	37.2	36.4	36	35.8	36
16	36.6	36.5	36.1	36.7	36.2	36.6	35.8	36.2	36.5
17	37.1	36.7	36.6	35.2	35.4	35.2	36	35.8	35.2
18	36.6	37	36.7	35.2	35.6	35.5	36	35.2	35.6
19	36.9	36	36.7	36.4	35.2	36	36.2	35.2	35.3
20	36.9	36.7	37.2	35.2	35.2	35.7	35.2	36.1	36.2
21	36.6	35.7	36.2	36.8	35.7	35.2	36.2	36.3	36.1
22	36.6	35.7	36.1	37.1	35.4	35.4	35.4	35.9	35.6
23	37.1	37	37.2	35.2	36.6	36.5	35.3	35.6	36.1
24	36.9	37.3	35.8	35.2	37.2	36.3	35.3	35.3	35.8
25	36.4	35.7	37	37.2	35.8	35.7	35.4	35.2	35.2
26	36.6	36.6	35.7	35.8	37.2	35.4	35.8	35.8	36.3
27	37.2	35.7	36.7	35.2	36	35.8	35.2	35.3	35.2
28	37.2	35.7	35.4	37.3	35.2	35.5	36.2	36.2	35.6
29	37	35.8	35.9	36	36	35.8	36	36.2	36.5
30	36.9	36	36.1	36.3	36.3	36.5	36.5	37	37.3
<b>Min.</b>	36.40	35.70	35.40	35.20	35.20	35.20	35.20	35.20	35.20
<b>Max.</b>	37.20	37.40	37.20	37.40	37.20	36.70	36.50	37.0	37.30
<b>Mean</b>	36.82	36.35	36.29	36.14	35.98	35.89	35.75	35.77	35.92
<b>SD.</b>	0.27	0.54	0.58	0.71	0.57	0.50	0.36	0.41	0.50
<b>Median</b>	36.90	36.35	36.25	36.0	36.0	35.80	35.80	35.80	36.0
<b>P</b>		0.006*	0.002*	0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*

p<sub>1</sub>: Stands for adjusted Bonferroni p-value for ANOVA with repeated measures for comparison between pre with each other period

\*: Statistically significant at  $p \leq 0.05$

**Results**

**Table (14): Distribution of the studied cases regarding Temperature in Granisetron group (°C)**

	Before	After							
		15 min.	30 min.	45 min.	60 min.	75 min.	90 min.	120 min.	180 min.
1	36.6	36.6	37	37	37	36.6	36.7	36.6	36.9
2	37	36.8	36.6	36.5	35.5	37	35.5	36.8	37
3	36.6	36.8	36.9	36.8	36.8	35.5	36.8	36.7	37
4	36.8	36.6	36.7	36.8	36.8	36.9	36.8	36.7	36.7
5	36.4	36.8	36	35.8	35.8	36.7	36.8	36.6	36.9
6	36.6	36.7	36.6	36.4	35.4	35.5	35.5	37	37
7	37	36.7	36.9	36.8	36.8	36.8	36.9	36.8	36.8
8	36.8	36.8	36	36.9	35.9	36.8	37	35.5	36.8
9	36.8	37	36.9	36.7	36.7	36.9	36.7	36.7	37
10	36.9	36	36.6	35.8	35.8	36.8	36.7	36.7	36.8
11	37	36.7	36	36.9	36.9	35.5	36.6	36.6	36.8
12	37	36	37	36.6	36.6	36.7	36.8	35.5	36.8
13	36.6	36.9	36.8	36.8	36.8	36.9	36.7	36.7	37
14	36.7	36.8	36.6	36.6	36.6	35.5	36.8	37	36.8
15	37	36.8	36	36.7	35.7	37	37	36.6	36.6
16	37	36.7	36.8	35.5	35.5	36.6	36.7	36.7	37
17	36.6	36	36.6	36.8	36.8	35.4	36.8	36.8	36.6
18	36.6	36.8	36	37	37	36.7	36.8	36.6	36.6
19	37	37	36.6	36.4	35.4	36.7	35.5	37	36.7
20	36.3	36.8	36.6	36.6	36.6	36.6	36.6	36.8	36.8
21	36.8	36	36.9	36.6	36.7	36.8	36.8	36.7	36.9
22	36.6	36.6	36	36.6	36.9	36.6	35.5	36.8	36.9
23	36.8	36.8	36.9	36.8	36.7	36.6	36.7	36.8	36.6
24	37	36.7	35.8	36.9	36.9	36.7	37	36.8	36.8
25	36.8	36.7	37	36.6	36.9	36.7	36.8	36.9	37
26	36.9	37	37	37	36.9	36.9	36.8	36.8	36.8
27	36.8	36.9	36.9	36.9	36.6	36.9	37	37	36.8
28	37	36.9	36.8	36.6	36.6	36.8	37	36.7	36.8
29	36.8	36.5	36.3	36.8	36.5	36.6	36.8	36.8	36.8
30	37	36.3	36.5	36.5	36.7	36.8	36.8	37	37.2
<b>Min.</b>	36.30	36.0	35.80	35.50	35.40	35.40	35.50	35.50	36.60
<b>Max.</b>	37.0	37.0	37.0	37.0	37.0	37.0	37.0	37.0	37.20
<b>Mean</b>	36.79	36.66	36.58	36.62	36.46	36.55	36.63	36.69	36.84
<b>SD.</b>	0.20	0.30	0.38	0.36	0.54	0.50	0.46	0.35	0.15
<b>Median</b>	36.80	36.75	36.60	36.70	36.70	36.70	36.80	36.75	36.80
<b>p</b>		1.000	0.289	1.000	0.182	0.352	1.000	1.000	1.000

p<sub>1</sub>: Stands for adjusted Bonferroni p-value for ANOVA with repeated measures for comparison between pre with each other period

\*: Statistically significant at p ≤ 0.05

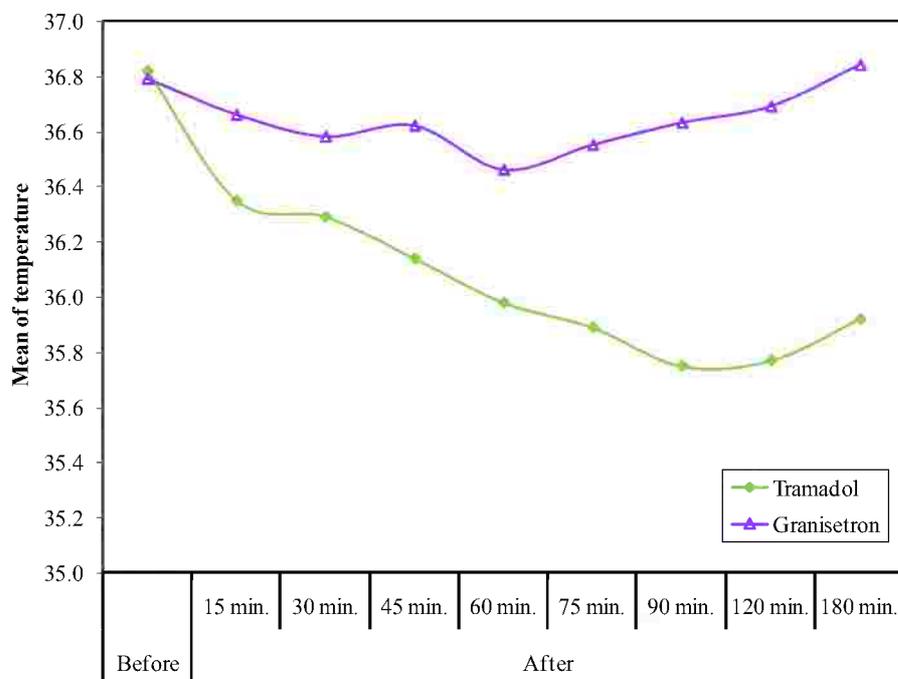
## Results

**Table (15): Comparison between the two studied groups regarding Temperature (°C)**

	Before	After							
		15 min.	30 min.	45 min.	60 min.	75 min.	90 min.	120 min.	180 min.
<b>Tramadol</b>									
Min.	36.40	35.70	35.40	35.20	35.20	35.20	35.20	35.20	35.20
Max.	37.20	37.40	37.20	37.40	37.20	36.70	36.50	37.0	37.30
Mean	36.82	36.35	36.29	36.14	35.98	35.89	35.75	35.77	35.92
SD.	0.27	0.54	0.58	0.71	0.57	0.50	0.36	0.41	0.50
Median	36.90	36.35	36.25	36.0	36.0	35.80	35.80	35.80	36.0
<b>Granisetron</b>									
Min.	36.30	36.0	35.80	35.50	35.40	35.40	35.50	35.50	36.60
Max.	37.0	37.0	37.0	37.0	37.0	37.0	37.0	37.0	37.20
Mean	36.79	36.66	36.58	36.62	36.46	36.55	36.63	36.69	36.84
SD.	0.20	0.30	0.38	0.36	0.54	0.50	0.46	0.35	0.15
Median	36.80	36.75	36.60	36.70	36.70	36.70	36.80	36.75	36.80
<b>t</b>	0.492	2.702*	2.274*	3.325*	3.346*	5.074*	8.137*	9.380*	9.755*
<b>p</b>	0.625	0.010*	0.027*	0.002*	0.001*	<0.001*	<0.001*	<0.001*	<0.001*

t: Student t-test

\*: Statistically significant at  $p \leq 0.05$



**Figure (11): Comparison between the two studied groups regarding Temperature (°C)**

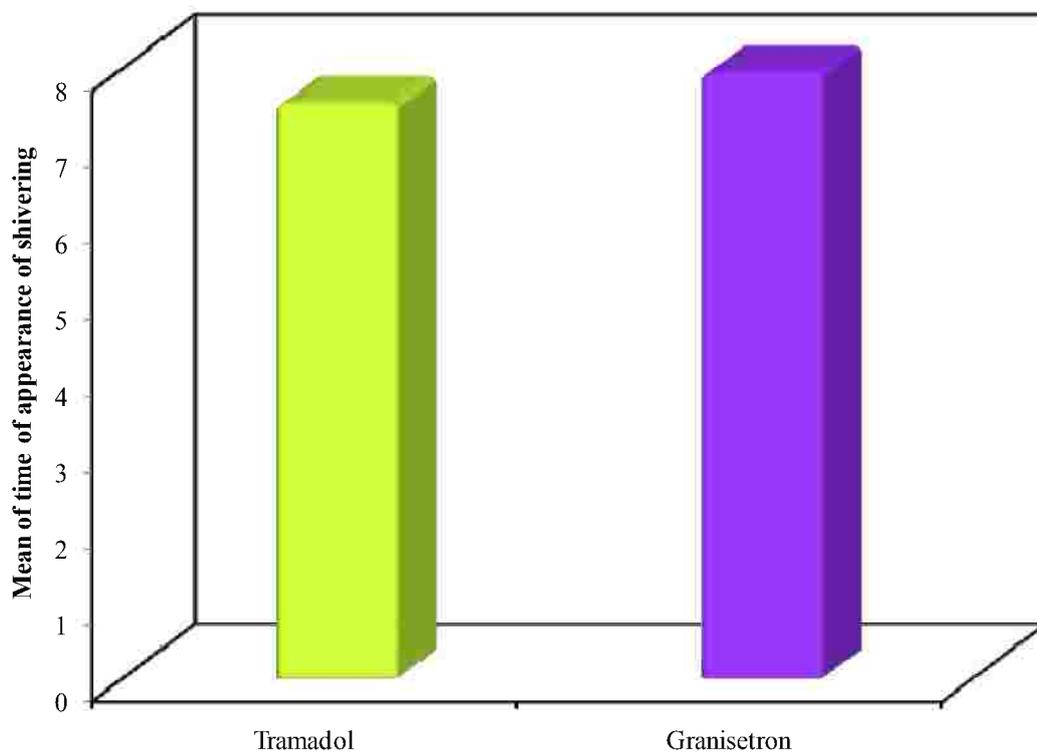
**Onset of Shivering (Table 16 , Figure 12)**

Comparison between the two studied groups regarding onset of shivering was presented in table (16), it showed that the onset of shivering in group T ranged between 3-15(minutes) with a mean of  $7.53 \pm 3.01$ , while in Group G it ranged between 3-14(minutes) with a mean of  $7.93 \pm 3.30$ . There was no statistical significant difference between the two groups ( $P=0.490$ ).

**Table (16): Comparison between the two studied groups regarding the onset of shivering (Minutes)**

	Onset of shivering	
	Tramadol	Granisetron
1	5	14
2	4	9
3	6	8
4	5	6
5	9	5
6	12	12
7	8	3
8	14	6
9	9	5
10	5	4
11	4	9
12	6	10
13	11	11
14	10	8
15	6	4
16	3	6
17	15	14
18	11	6
19	9	7
20	8	8
21	7	6
22	8	9
23	6	14
24	5	3
25	4	5
26	10	7
27	8	6
28	5	8
29	6	12
30	7	13
<b>Min.</b>	3.0	3.0
<b>Max.</b>	15.0	14.0
<b>Mean</b>	7.53	7.93
<b>SD.</b>	3.01	3.30
<b>Median</b>	7.0	7.50
<b>T</b>	0.490	
<b>P</b>	0.626	

t: Student t-test



**Figure (12): Comparison between the two studied groups regarding onset of appearance of shivering (Minutes)**

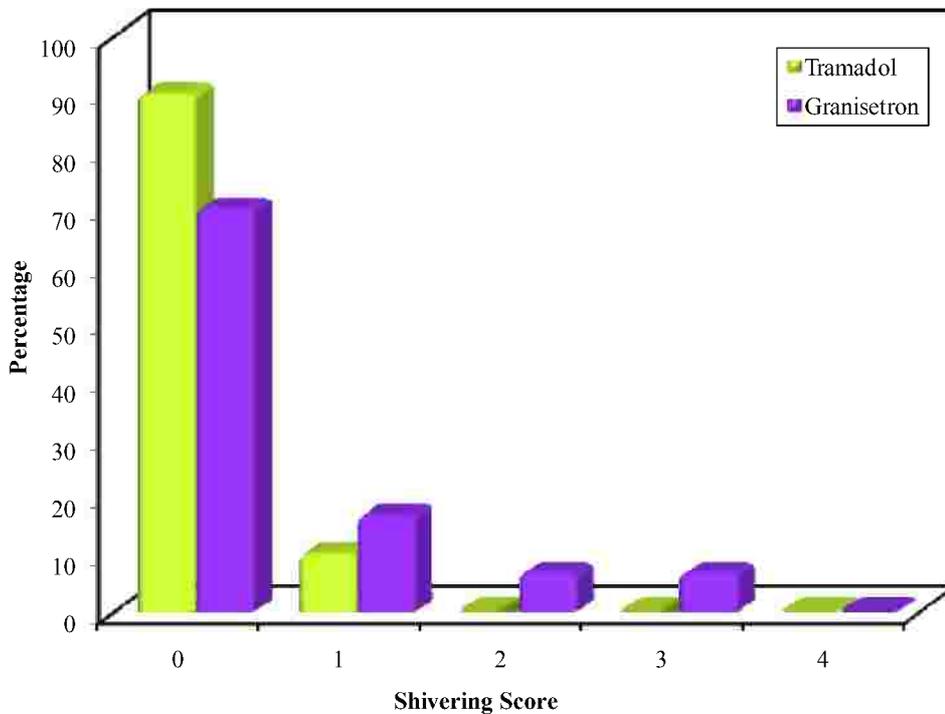
**Shivering Score (Table 17, Figure 13)**

Comparison between the two studied groups regarding shivering score was presented in table (17), it showed that, there was no statistical significant difference between the two groups (P=0.161).

**Table (17): Comparison between the two studied groups regarding the shivering score**

	Tramadol (n = 30)		Granisetron (n = 30)	
	No.	%	No.	%
<b>Shivering Score</b>				
0	27	90	21	70
1	3	10	5	16.67
2	0	0.0	2	6.67
3	0	0.0	2	6.67
4	0	0.0	0	0.0
$\chi^2$ ( <sup>MC</sup> p)	4.503 (0.161)			

$\chi^2$ : Value for Chi square  
MC: Monte Carlo test



**Figure (13): Comparison between the two studied groups regarding the shivering score**

**Comparison between the two groups as regards the need to give pethidine (Table 18)**

Comparison between the two studied groups regarding the need to give pethidine was presented in table (18), it showed that, there was no statistical significant difference between group T and G (P=0.112).

**Table (18): Comparison between the four groups as regards the need to give pethidine**

	<b>Tramadol (n = 30)</b>		<b>Granisetron (n = 30)</b>	
	<b>No.</b>	<b>%</b>	<b>No.</b>	<b>%</b>
<b>Patients given pethidine (shivering scores 2, 3 and 4)</b>	0	0.0	4	13.33
<b><math>\chi^2</math>(<sup>FE</sup>p)</b>	4.286 (0.112)			

$\chi^2$ : Value for Chi square  
FE: Fisher Exact test

**Time of Disappearance of Shivering (Table 19, Figure 14)**

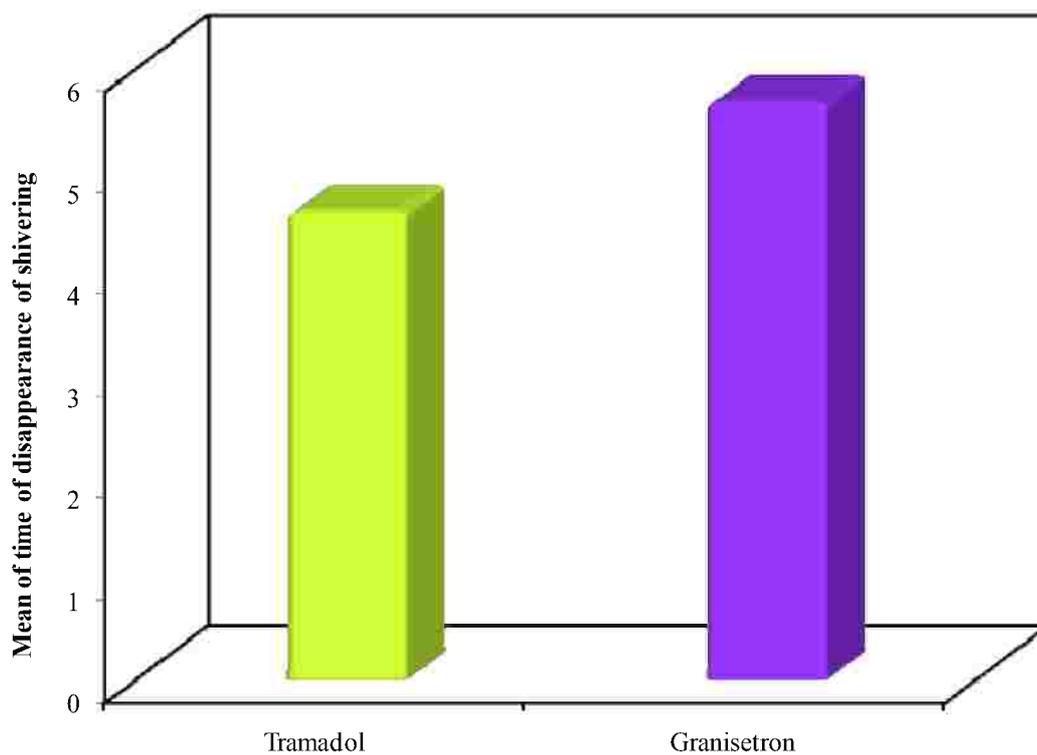
Comparison between the two studied groups regarding time of disappearance of shivering showed that, it ranged between 3-7 (minutes) in group T with a mean of  $4.59 \pm 1.28$ , while in group G it ranged between 4-8 minutes with a mean of  $5.67 \pm 1.24$ . Time of shivering to disappear was statistically lower in group T than group G ( $P=0.005$ ).

**Table (19): Comparison between the two studied groups regarding time of disappearance of shivering (Minutes)**

	Time of disappearance of shivering	
	Tramadol	Granisetron
1	5	6
2	3	-
3	5	4
4	4	5
5	5	4
6	3	-
7	6	8
8	3	5
9	4	-
10	5	5
11	-	5
12	6	6
13	4	-
14	3	-
15	7	6
16	5	5
17	5	-
18	-	4
19	3	5
20	5	8
21	6	-
22	4	6
23	3	5
24	-	-
25	6	7
26	7	6
27	3	-
28	4	8
29	4	6
30	6	5
<b>Min.</b>	3.0	4.0
<b>Max.</b>	7.0	8.0
<b>Mean</b>	4.59	5.67
<b>SD.</b>	1.28	1.24
<b>Median</b>	5.0	5.0
<b>T</b>	2.927*	
<b>P</b>	0.005*	

t: Student t-test

\*: Statistically significant at  $p \leq 0.05$



**Figure (14): Comparison between the two studied groups regarding time of disappearance of shivering (Minutes)**

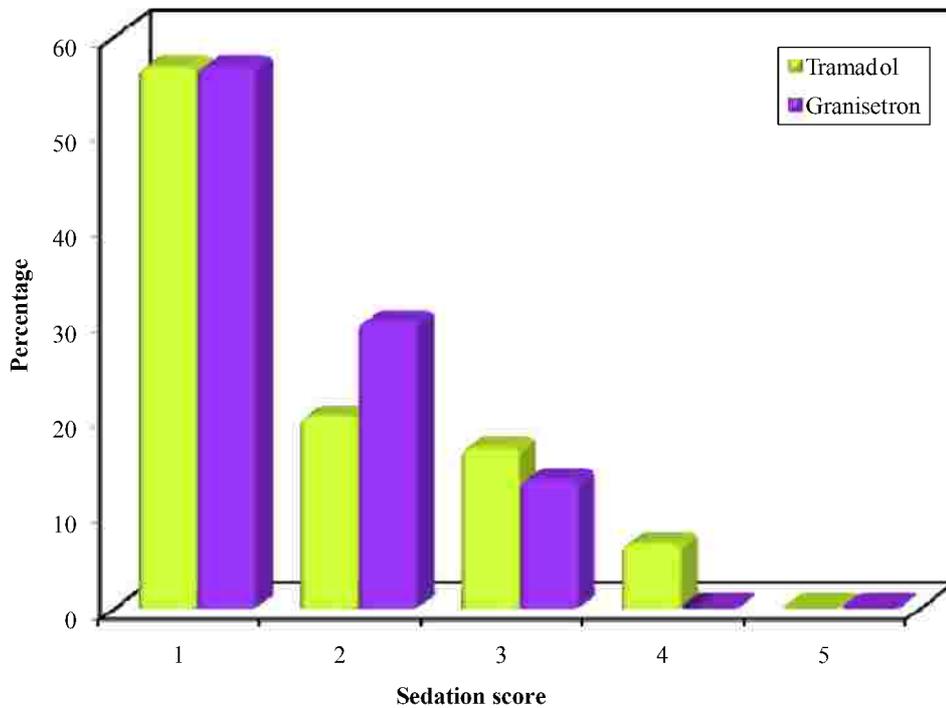
**Sedation Score (Table 20, Figure 15)**

Comparison between the two studied groups regarding sedation score was presented in table (20), it showed that, there was no statistical significant difference between group T and G (P=0.568).

**Table (20): Comparison between the two studied groups regarding the sedation score**

	Tramadol (n = 30)		Granisetron (n = 30)	
	No.	%	No.	%
<b>Sedation scale</b>				
1	17	56.67	17	56.67
2	6	20.0	9	30.0
3	5	16.67	4	13.33
4	2	6.67	0	0.0
5	0	0.0	0	0.0
$\chi^2$ ( <sup>MC</sup> p)	2.388 (0.568)			

$\chi^2$ : Value for Chi square  
MC: Monte Carlo test



**Figure (15): Comparison between the two studied groups regarding the sedation score**

**Side Effects (Table 21)**

Comparison between the two studied groups regarding the incidence of side effects was presented in table (21), it showed that, there was no occurrence of bradycardia or hypotension in group T, however there was 18 patients out of 30 had experienced nausea and vomiting in the same group. In group G, no side effects including either: bradycardia, hypotension or nausea and vomiting were witnessed.

**Table (21): Comparison between the two studied groups regarding the incidence of side effects**

	<b>Tramadol (n = 30)</b>		<b>Granisetron (n = 30)</b>	
	<b>No.</b>	<b>%</b>	<b>No.</b>	<b>%</b>
<b>Side effects</b>				
Bradycardia	0	0.0	0	0.0
Hypotension	0	0.0	0	0.0
Nausea and Vomiting	18	60.0	0	0.0