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EVALUATION OF INTRA-OPERATIVE TRAMADOL FOR PREVENTION OF CATHETER RELATED BLADDER DISCOMFORT

Anaesthesiology

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ABSTRACT

AIM OF THE STUDY: To evaluate the efficacy of intraoperative tramadol for the prevention of catheter related bladder discomfort.

MATERIALS AND METHODS: This propective, randomized, double blind study was conducted on a total of 70 patients posted for elective orthopedic surgery.

PLACE OF STUDY -Trichy SRM Medical college hospital & Research centre After appropriate ethical committee approval and informed consent. Except for the 1.5mg/kg tramadol given to the case population. all other steps in providing anesthesia to the two groups were kept identical.

RESULTS: Analysis of the monitored date shows that the patients in the case group (receiving Tramadol) showed a decrease in both the occurrence as well as the severity of catheter related bladder discomfort which was statistically significant. Although a few patients did manifest the side effects of intravenous tramadol like sedation. PONV and respiratory depression, the number of patients who suffered these side effects were not clinically significant and moreover these side effects manifested to a level which was easily remediable.

CONCLUSION: In agreement to previous studies, considerable number of patients in the study group did manifest the symptoms of catheter related bladder discomfort in the control population concreting the fact that CRBD is indeed a common and distressing complication in patients emerging from general anaesthesia who had a urinary catheterization during surgery. Intraoperative tramadol is indeed effective in the prevention as well as in reducing the severity of catheter related bladder discomfort.

KEYWORDS

Tramadol, intraoperative tramadol, catheter related bladder discomfort, CRBD

INTRODUCTION

Catheter related bladder discomfort (CRBD) is defined as an urge to void or discomfort in the suprapubic region; observed after operation in patients who are awakening from anaesthesia and have had an urinary catheterization during operation. This symptom complex is extremely distressing to the patient in the postoperative setting and may lead to exacerbated postoperative pain and reduced quality of life.

Tramadol is a centrally acting, synthetic opioid analgesic with weak opioid agonist properties. It inhibits of inhibition of type-1 muscarinic(M1) and type-3 muscarinic (M3) receptors5,6,7. Tramadol is a potent analgesic routinely use for postoperative pain relief with minimal respiratory discomfort.

AIM OF STUDY

The study was aimed at evaluating intraoperative tramadol for the prevention of catheter related bladder discomfort.Entry of actions depolarize the smooth muscle membrane potential. If the extent of stretch is mild there is low activation and the membrane potential rests at more depolarized level, predisposing the cell to activation by lower level of muscarinic aganist. If the extent of the stretch is more significant, the activation of action channels may be sufficient to depolarize the cell sufficiently for Initiation of an action potential, although individual cells may contract spontaneously contraction of the bladder as a whole generally requires stimulation by parasympathetic nerves33. When the membrane is sufficiently depolarized, Ca2+ channels in the sacroplasmic reticulum open, flooding the cell with calcium and resulting in an action potential, thereby leading to spontaneous phase activity in bladder.

Between contractions, the sarcoplasmic reticulum accumulates calcium to levels far above those of the cytosol by means of a calcium ATPase. Calcium stores in the sarcoplasmic reticulum can be released in the absence of action potentials by exposure to caffeine which renders the Ca0+ channels sensitive to normal ambient cytoplasm calcium levels.

MATERIALS AND METHODS

All the patients included in the study will underwent a detailed pre-anaesthetic checkup. Patients and nearest relatives are given a consent form and written informed consent was taken.

Age and Weight were noted.

Pulse rate, blood pressure, respiratory rate, relevant clinical signs if any are recorded. Patients were allocated randomly by envelope method using random number table into two groups of 35 each.

Group A (Tramadol Group) – Received tramadol 1.5mg/kg 30 min before extubation.

Group B (Control Group) – Received normal saline 2ml 30 min before extubation.

PREMEDICATION

The patients were asked to keep nil orally for 8 hours prior to the procedure.

All were given Tab. Diazepam 10mg PO and Tab. Ranitidine 150mg. PO on preoperative night.

MONITORS

ECG

Pulse Ox meter

Non-invasive blood pressure monitor.

End-tidal CO_2monitor

PROCEDURE

Patients meeting the inclusion criteria during the pre anaesthetic checkup were randomly assigned into two groups of 35 each with the help of computer – generated table of random numbers. Depending on the results of the randomization process, patients received medication [diluted in 2ml of normal saline (NS)].i.v.30 min before extubation. Patients in the control (C) group received tramadol 1.5mg/kg (Cipls Health Biotech Private Limited, Solan, India). These medications were administered by a blinded anesthesia registrar who was not involved in the study.

Premedication consisted of 05.mg/kg oral midazolam 2hr before surgery. Induction of anaesthesia was done with propofol 2mg/kg. Tracheal intubation was facilitated by vecuronium bromide 0.1mg/kg. Urinary catheterization was done using 16 Fr Foley's catheter and its

balloon was inflated with 10ml distilled water after induction of anaesthesia, Urinary catheter was inserted after its lubrication with K-Y jelly (a water based lubrication gel) and was fixed in the supraubic area with an adhesive tape without any traction and was always left to free drainage into an urobag. Anaesthesia was maintained using 70% nitrous oxide in oxygen, propofol infusion at 50-150 microgram/kg/min and intermittent dosage of veeuronium as and when required.

At the end of surgery, all patients received a combination of neostigmine 0.05mg/kg and glycopyrrolate 0.01mg/kg for reversal of vecuronium and were transferred to the post-anaesthesia care unit (PACU) after extubation. Another independent anaesthesia registrar (G.D.Y) blinded to the group allocation observed the incidence and severity of CRBD.

Severity of CRBD was received as none when patients did not complain of any CRBD even on asking, as mild when reported by patients only on questioning, as moderate when reported by the patients on their own along with behavioural responses. Behavioural responses observed were flailing limb, strong vocal response and attempt to pull out catheter.

The severity of PONV was graded on a four point ordinal scale from 0 to 3 (0=no nausea, 1=mild nausea, 2=moderate nausea, 3=severe nausea with vomiting) ondansetron 4mg iv was given to all patients with PONV of grade 3 as rescue antiemetic. level of sedation was assessed by the Ramsey sedation scale (1:Anxious, agitated or restless; 2: Cooperative, oriented and tranquil; 3: Asleep, responds to command; 4:Brisk response to light glabellas tap or loud noise; 5:Sluggish response to light glabellas tap or loud noise; 6:No response) Patients with sedation scale of >4 were considered sedated, Respiratory depression was defined as ventilator frequency <8 breaths / ioin and oxygen annulations without oxygen supplementation.

ANALYSIS AND RESULTS

Statistical Analysis

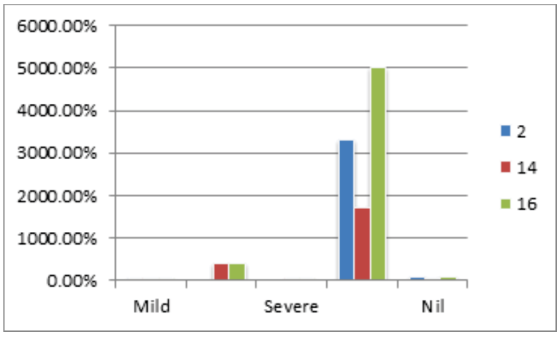
Data were analyzed using computer software, statistical package for social sciences (SPSS) version 10. Data are expressed in its frequency and percentage as well as mean and standard deviation. To elucidate the associations and comparisons between different parameters. Chi square (x2) test was used as antiperameteric test . Student's test was used to compare mean values between two groups . Analysis of variance (ONE WAY ANOVA) were performed as parametric test to compare different variables Duncan's Multiple Range test was also performed to elucidate multiple comparisons . For all statistical evaluations , a two-tailed probability of value .< 0.05 was considered significant.

OBSERVATIONS AND RESULTS

Table 1. CRBD score at 0Hr (Immediately after surgery)

CRBD 0 Hr	Cases	Control	Total
Mild	4	13	17
	11.40%	37.10%	24.30%
Moderate	-	3	3
		8.60 %	4.30 %
Severe	-	3	3
		8.60 %	4.30 %
Nil	31	16	47
	88.60 %	45.70%	67.10%

Chi square: 15.552: P < 0.01



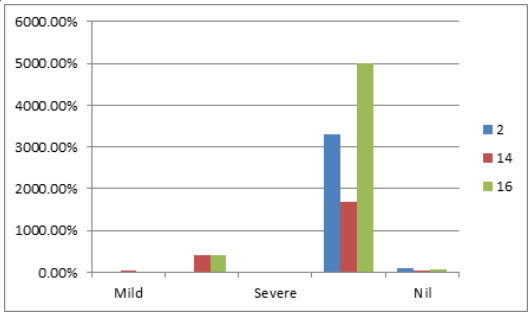
The above graph shows that CRBD is lesser in the case population than in the control population at 0 hrs; that is immediately after the surgery is over and the patient gets conscious. The corresponding table above depicts that there is a 42% decrease of CRBD in the case population corresponding to the control population at 0hrs.

Table 2. CRBD score at 1 Hr (1 Hr after surgery)

CRBD 0 Hr	Cases	Control	Total
Mild	2	14	16
	5.70%	40.00%	22.90%
Severe	-	4	4
		11.40 %	5.70 %
Nil	33	17	50
	94.30 %	48.60%	71.40%

Chi square : 18.120;p<0.001

Fig 2. Distribution of CRBD at 1 hr



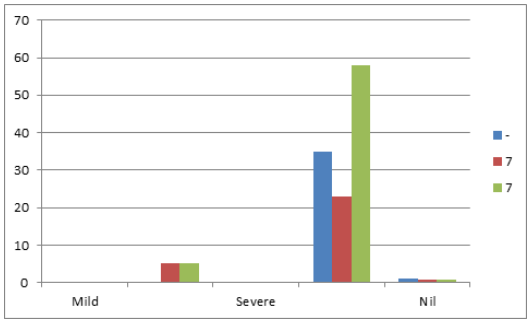
The above graph shown that CRBD is lesser in the case population than in the control population at 1hrs; that is, an hour after the surgery is over. The coresponding table above depicts that there is a 44% decrease of CRBD in the use population corresponding to the control population at 1 hrs.

Table 3. CRBD score at 2 Hr (2 Hr after surgery)

CRBD 2 Hr	Cases	Control	Total
Mild	-	7	7
		20.00%	10.00%
Severe	-	5	5
		14.30 %	7.10 %
Nil	35	23	58
	100 %	65.70%	82.90%

Chi square: 14.483; p<0.01

Fig3. Distribution of CRBD at 5hr



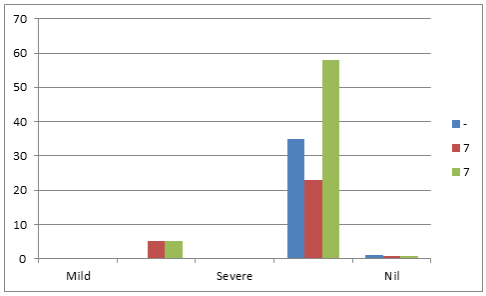
The above graph shows that CRBD is lesser in the case population than in be control population at 2 hrs; that is, two hours after the surgery is over. The corresponding table above depicts that there is a 34% decrease of CRBD in the uase population corresponding to the control population at 2hrs.

Table 4. CRBD score at 2 Hr (2 Hr after surgery)

CRBD 2 Hr	Cases	Control	Total
Mild	-	7	7
		20.00%	10.00%
Moderate	-	5	5
		14.30 %	7.10 %
Nil	35	23	58
	100 %	65.70%	82.90%

Chi square: 14.483; p<0.01

Fig5. Distribution of CRBD at 6hr



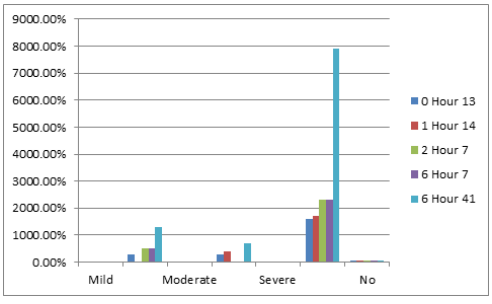
The above graph shows that CRBD is lesser in the case population than in be control population at 6 hrs; that is, two hours after the surgery is over. The corresponding table above depicts that there is a 34% decrease of CRBD in the uase population corresponding to the control population at 6hrs.

Table 5. CRBD score at different hours of observation after surgery in Control

Respiratory depression	Period				Total
	0 Hour	1 Hour	2 Hour	6 Hour	
Mild	13	14	7	7	41
	37.10 %	40.00 %	20.00 %	20.00 %	29.30%
Moderate	3	-	5	5	13
	8.60%	-	14.30 %	14.30 %	9.30 %
Severe	3	4	-	-	7
	8.60%	11.40%	-	-	5.00%
No	16	17	23	23	79
	45.70%	48.60 %	65.70 %	65.70 %	56.40 %

Chi square: 18.755; p<0.05

Fig6. Distribution based on CRBD score at different hours of observation in control



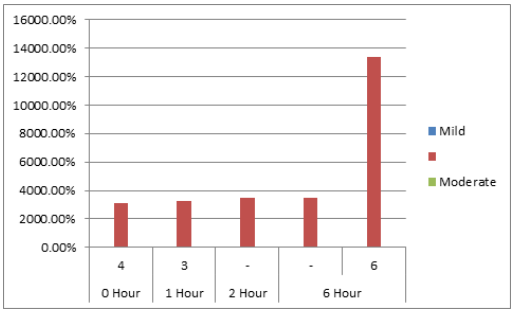
CRBD in control population highest in the immediate post operative period (0 hrs) and at 1hr after surgery.

Table 6. CRBD score at different hours of observation after surgery in Cases group

CRBD	Period				Total
	0 Hour	1 Hour	2 Hour	6 Hour	
Mild	4	3	-	-	6
	11.40 %	5.70 %	-	-	4.30%
Moderate	31	33	35	35	134
	88.60%	94.30%	100%	100 %	95.70 %

Chi square: 7.662; p<0.05

Fig7. Distribution based on CRBD score at different hours of observation in control



CRBD in the case population also shows highest incidence in the immediate post operative period (0 hrs) and at 1 hr after surgery, though lesser then in the control population.

Table7. Comparison of Different parameters between control and cases

Parameters	Group	Mean	+ SD	T value	P value
Age (overs)	Control	41.26	9.95	-0.395	>0.05
	Cases	42.26	11.18		
Height (cm)	Control	157.86	7.21	-1.894	>0.05
	Cases	161.26	7.79		
Weight (Kg)	Control	60.40	8.31	-1.809	>0.05
	Cases	65.06	12.77		
Duration (hr)	Control	3.00	0.24	1.406	>0.05
	Cases	2.86	0.55		

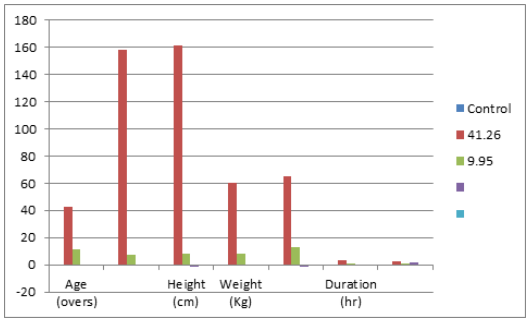
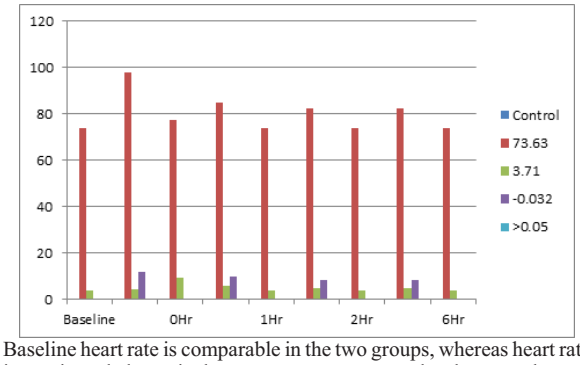


Table shows that there is no difference between the study population and be control population with respect to the above parameters.

Table8. Comparison of heart rate (No/min) between control and cases

Parameters	Group	Mean	+ SD	T value	P value
Baseline	Control	73.63	3.71	-0.032	>0.05
	Cases	73.66	3.65		
0Hr	Control	97.71	4.52	11.683	<0.001
	Cases	77.60	9.14		
1Hr	Control	85.03	5.95	9.643	<0.001
	Cases	73.66	3.65		
2Hr	Control	82.23	4.85	8.356	<0.001
	Cases	73.66	3.65		
6Hr	Control	82.23	4.85	8.356	<0.001
	Cases	73.66	3.65		

Fig 8. Comparison of heart rate (No/min) between control and cases

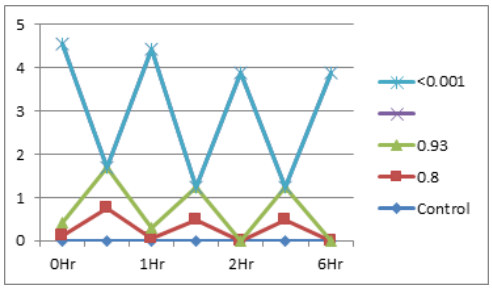


Baseline heart rate is comparable in the two groups, whereas heart rate is consistently lower in the case group as compared to the control group at all times.

Table9. Comparison CRBD score between control and cases

Parameters	Group	Mean	+ SD	T value	P value
0Hr	Control	0.80	0.93	4.109	<0.001
	Cases	0.11	0.32		
1Hr	Control	0.74	0.95	4.145	<0.001
	Cases	0.06	0.24		
2Hr	Control	0.49	0.74	3.871	<0.005
	Cases	0.00	0.00		

6Hr	Control	0.49	0.74	3.871	<0.005
	Cases	0.00	0.00		



CRBD is consistently lower in the case population than in the control population at all time periods.

Table10. Analysis of variance (One Way ANOVA) of different parameters comparing different Hours of observation after surgery for control group

Parameter	Hours	Mean	+	F Value	P Value
Heart Rate (No/Min)	0	97.71a	4.50	74.532	<0.001
	1	85.03b	5.95		
	2	82.23	4.85		
	6	82.23	4.85		
Systolic BP (mm of Hg)	0	143.60b	10.22	229.816	<0.001
	1	118.00a	12.70		
	2	118.00a	8.59		
	6	120.00b	8.59		
Diastolic BP (mm of Hg)	0	93.00b	4.56	102.868	<0.001
	1	79.89a	3.42		
	2	79.89	5.32		
	6	79.89a	5.32		
CRBD	0	0.80a	0.93	1.351	<0.001
	1	0.74a	0.95		
	2	0.49a	0.74		
	6	0.49a	0.74		

a,b,c Mean values with same superscript do not differ each other (Duncan's Multiple Range Test).

Table 11. Analysis of variance (One Way ANOVA) of different parameters comparing different Hours of observation after surgery for cases group

Parameter	Hours	Mean	+ SD	F Value	P Value
Heart Rate	0	77.60b	9.14	4.411	<0.01
	1	73.66a	3.65		
	2	73.66a	3.65		
	6	73.66a	3.65		
Systolic BP (mm of Hg)	0	120.69b	12.96	0.515	<0.05
	1	113.60a	10.37		
	2	110.57a	10.37		
	6	108.00b	10.37		
Diastolic BP (mm of Hg)	0	81.54a	5.47	0.950	<0.05
	1	76.63a	4.87		
	2	76.91a	4.87		
	6	76.91a	4.87		
CRBD	0	0.11b	0.32	2.625	<0.05
	1	0.06ab	0.24		
	2	0.00	0.00		
	6	0.00	0.00		

a. b.c Mean values with same superscript do not differ each other (Duran's Multiple Range Test).

Administration of tramadol intra-operatively prevents CRBD and we therefore conclude that i.v. tramadol 1.5 mg/kg 2.1 administered 30 min before extubation results in reduction in the incidence and severity of CRBD.

CONCLUSION

Analysis of the monitored data shows that the patients in the case group (receiving Tramadol) showed a decrease in both the occurrence as well as the severity of catheter related bladder discomfort which was statistically significant. Although a few patients did manifest the side effects of intravenous tramadol like sedation, PONV and respiratory depression, the number of patients who suffered these side effect were not clinically significant and moreover these side effects manifested to a level which was easily remediable.

In conclusion. Intraoperative tramadol is effective in reducing both the incidence as well as the severity of catheter related bladder discomfort.

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