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ORIGINAL ARTICLE

PRE-EMPTIVE ORAL CLONIDINE FOR IMMEDIATE POSTOPERATIVE PAIN IN SURGERIES UNDER SUB-ARACHNOID BLOCK

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ABSTRACT: BACKGROUND: Pre-emptive analgesia is a treatment that is initiated before the surgical procedure in order to reduce sensitization of central and peripheral pain pathways produced by pain signals evoked by tissue damage. Clonidine has demonstrated efficacy in clinical trials as pre-emptive analgesic in postoperative pain management. **OBJECTIVE:** The present study was conducted to evaluate postoperative analgesic benefit in patients administered clonidine or placebo for below umbilical surgeries to be performed under subarachnoid block (SAB) using 3ml 0.5%bupivacaine & to compare their postoperative efficacy with respect to duration of analgesia, 24hrs postoperative requirements of total analgesics and study side effects. **MATERIAL & METHODS:** Sixty patients of either sex (30 per group, 20-65yrs, ASA class I-II) received either oral placebo (group PC) or clonidine 150µg (group CL) one hr preoperatively. The postoperative Visual Analogue Scale (VAS) score was assessed for 24hrs every 2hrly. The patients were given iv Diclofenac75mg as rescue analgesic at VAS ≥4.The time at which patient demanded rescue analgesic for first time & total requirement of 24 hrs postoperative analgesics was noted. **STATISTICAL ANALYSIS:** Software used in the analysis was EPI info software (3.4.3). Data was reported as mean value ± SD, P-value of < 0.05 was considered statistically significant. Unpaired T – test was used to find out significance between two samples. The comparison of normally distributed continuous variables between the groups was performed by means of one-way analysis of variance **(**ANOVA) and, if appropriate, followed by Dunnett multiple comparison tests. Nominal categorical data among study groups were compared using the chi-square test. Results: Total duration of analgesia in Group-CL was significantly more than Group-PC. (492.66 ±78.29 min. Group-CL, 264.83 ±13.67 min. Group-PC, p=0.000), lower rescue analgesic requirement in Group-CL than in Group-PC (2.20 ±0.61 Group-CL, 4.03 ± 0.66 Group-PC, p=0.000). **CONCLUSION:** Pre-emptive oral clonidine appears to be effective in prolongation of postoperative analgesia with decreased rescue analgesic requirements. The main side effects observed were hypotension & bradycardia.

KEYWORDS: Pre-emptive analgesia, Clonidine, Acute Post-operative pain, Multimodal analgesia.

INTRODUCTION: Pre-emptive analgesia, an evolving clinical concept, involves the introduction of an analgesic regimen before the onset of noxious stimuli, with the goal of preventing sensitization of nervous system to subsequent stimuli that could amplify pain. Since, the timing of noxious stimuli is known; surgery offers the most promising setting for pre-emptive analgesia.[1]

Pre-emptive analgesia has three objectives: 1.To reduce pain resulting from the activation of the inflammatory mechanisms triggered by surgical incision. 2. To hinder the pain memory response of the CNS. 3. To ensure a good control of post-operative pain in order to avoid the development of chronic pain.[2]

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Subarachnoid block a popular anaesthetic technique commonly used for below umbilical and lower extremity surgeries plays pivotal role in control of intraoperative pain only. Hence, researchers have used battery of drugs intrathecally like vasoconstrictors, (epinephrine) opoids, (fentanyl, buprenorphine) benzodiazepines, (midazolam) ketamine and many others as adjuvant to local anaesthetics to prolong the duration of sensory block & achieve longer perioperative analgesia.[3]

Since each of these adjuvant have certain limitations of their own, search for better options for acute postoperative analgesia research is still continuing, as, poorly controlled postoperative pain results in harmful acute effects(adverse physiological response) and chronic effects(delayed long-term recovery) and chronic pain syndrome.[4]

Control of perioperative pain (Pre-emptive analgesia)and the fashion in which it is implemented (Multimodal approach) may be important in facilitating short and long term patient convalescence after surgery.[5]Central sensitization and hyper excitability develop after surgical incision and results in amplification of postoperative pain.

Preventing the establishment of altered central processing by analgesic treatment may result in short term (reduction in postoperative pain and accelerated recovery) and long term benefits during convalescence.[6,7]

Previously the drugs used for acute & chronic pain were categorically different. Opioids, NSAIDS & local anaesthetics were tools for dealing with acute pain and tricyclic antidepressants (TCAs) were used for chronic neuropathic conditions.

Clonidine an $\alpha_2$adrenoreceptor agonist whose analgesic properties have been well documented in adults by many investigators for its various routes of administration like intravenous clonidine in spine surgery,[8] intrathecally it prolongs spinal anaesthesia.[9] Oral clonidine premedication produces a significant prolongation of spinal anaesthesia with bupivacaine[10] or tetracaine[11] and provides better pain relief in the early postoperative period after minor orthopedic surgeries.[12] Recently the role as oral pre-emptive analgesic of clonidine[13-15] for postoperative pain relief has been reviewed.

With the concept of pre-emptive analgesia for control of acute postoperative pain our primary aim was to evaluate postoperative analgesic benefit in patients administered clonidine or placebo as oral premedication for below umbilical surgeries performed under SAB & to study its postoperative efficacy with respect to duration of analgesia, total postoperative requirement of analgesics and to study side effects, if any, attributable to clonidine.

MATERIALS AND METHODS: In this double-blind, randomized, controlled clinical trial, after approval from institutional ethical committee, and with written informed consent, sixty, American Society of Anesthesiologists (ASA) class I or II patients of either sex, between 20-65yrs, undergoing below umbilical surgeries, with estimated surgery duration of 90-120mins.to be performed under SAB were recruited. Patients with positive history of clonidine or antihypertensive consumption, history of seizure, psychiatric disorders, drug abuse, known liver and renal disease, chronic pain syndrome, intake of analgesic drugs during last 24hrs, known sensitivity to bupivacaine, clonidine, patient refusal, contraindication to SAB, pregnancy were excluded from the study.

A thorough clinical assessment and routine investigations like hemoglobin, TLC, DLC, Urine examination, x-ray chest, electrocardiogram and other specific investigations were done. Patients were assigned to one of the two treatment groups of 30 each in parallel, double blind, randomized

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manner with the help of a computer-generated table of random numbers. Patients in treatment group were given Tab clonidine 150µg (Group-CL) and those in control group (Group-PC) received placebo 1hr preoperative by a staff nurse who was not involved in the study.

After placement of standard noninvasive monitoring devices like NIBP, pulse oximetry and ECG, (baseline values were noted) preloading with 10ml/kg RL containing 50mg ranitidine was done. SAB was performed using 3ml 0.5% hyperbaric bupivacaine & surgery was performed after confirmation of successful blockade with proper height of analgesia. Fluid administration was continued intra operatively.

Hypotension, fall in mean arterial pressure by 20%of baseline was treated by fluid bolus & intravenous (iv) ephedrine 6mg. Bradycardia, fall in heart rate by 20%of baseline was treated with iv atropine0.6mg.No analgesic or sedative was given intra operatively.

The anesthesiologists who was blinded to the patient group, assessed pain postoperatively by VAS scale (a horizontal 0-10cm straight line with left end of the line expressing no pain and the right end-worst pain) immediate postoperatively and every 2hrs thereafter for 24hrs, which was explained to the patient preoperatively.

Any patient with VAS score≥4, during above period received iv diclofenac 75mg. Time since SAB to first dose of analgesic and total requirement of analgesic in first 24hrs in each group, along with any side effects like dizziness, somnolescence, diplopia, vomiting, confusion, nausea, urinary retention were recorded.

Ramsay sedation was observed during immediate postoperative period till 24 hours using Ramsay sedation score from 1 to 6. Patients with sedation scale ≥4 were considered as sedated.

RESULTS:

Statistical Analysis: Sample size was calculated by using EPI info software (3.4.3) in consultation with statistician, minimum sample size was calculated 30 in each group, considering confidence interval of 95 %, power 90 % with 1:1 Unpaired T – test was used to find out significance between two samples. Data was reported as mean value ±SD =. P-value of < 0.05 was considered statistically significant for total duration of analgesia, time to first rescue analgesia, comparison of VAS.

Results are expressed as the number, percentages, mean ± SD as appropriate.

The comparison of normally distributed continuous variables between the groups was performed by means of one-way analysis of variance (ANOVA) and, if appropriate, followed by Dunnett multiple comparison tests.

Nominal categorical data among study groups were compared using the chi-square test.

Demographic Comparison: Sixty patients, thirty in each group, were included in this study and analyzed. The groups were comparable with respect to demographic characteristics like age, weight, physical status, and duration of surgery (Table 1) The types of surgery conducted were also similar. (Table 2).

Post-Operative Analgesia: The total postoperative analgesia duration (time from spinal analgesia to first dose of analgesic) was 264.83 ±13.67 min. in Group-PC and in CL group it was 492.66 ±78.29 min. (Table 3)Statistically highly significant variation was found in mean total duration of analgesia in both the groups (p-value=0.000) The total requirement of analgesic in first 24h was 4.03 ± 0.66 in

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Group-PC, and 2.20 ±0.61 in Group-CL(Table 4).The difference was statistically significant.(p-value=0.000).

Mean Ramsay sedation score (Table 4) was significant up to 8 hrs in CL group, after that till 24 hours it was not significant. Sedation was observed up to 8 hrs postoperatively in CL group which was statistically significant when compared to control group. Bradycardia and hypotension (Table 6) was observed in 2 patients each in CL group which was statistically significant. p=0.004No episodes of bradycardia and hypotension were observed in control group.

DISCUSSION: Multimodal treatment of postoperative pain using adjuncts like α_2- adrenergic agonists is becoming more common. Clonidine, $\alpha_2$adrenergic agonists, produces analgesia at spinal and supra spinal sites of action. Its oral administration results in dose dependent analgesia, sedation and hemodynamic depression.

We have used clonidine in dose of 150 µg which is similar to previous studies[14-16].Pilot cases were carried out using 300µg clonidine prior to conducting the present study, it revealed significant incidence of bradycardia hence in present study smaller dose of clonidine i.e. 150µg was used.

Administration of clonidine 1 hr prior to surgery appeared in order to attain maximal plasma concentration at the time of surgical stimuli, as oral clonidine gets rapidly absorbed with peak within 1-2 hr.[17]The mean duration of postoperative analgesia in control and clonidine group was 264.83 ± 13.67 minutes, 492.66 ±78.29 minutes respectively, showing statistically significant increase in postoperative analgesia duration.

The comparison of total post-operative analgesia duration amongst clonidine & control was also significant (p-value 0.000) (Table 3) and shows that clonidine has prolonged postoperative analgesia duration.

Dziubdziela W et[22] al studied effect of oral and im clonidine 150µg as premedication, on 0.5%hyperbaric bupivacaine, in lower limb orthopedic surgeries and observed prolongation of sensory analgesia and reduction in early postoperative analgesic requirements.

Aftab Beigh[14] et al observed that 150µg clonidine 90min before spinal anaesthesia with Lignocaine produced adequate postoperative analgesia and significant prolongation of sensory and motor block without any significant haemodynamic disturbances. Many studies have revealed that oral clonidine administered 1-3 hrs before spinal anaesthesia significantly prolongs sensory and motor block produced by different local anaesthetics.[15-18]

Additionally, there is studies[19-23] of pre-emptive oral clonidine used in various surgeries under spinal and general anaesthesia, observing prolongation of postoperative analgesia duration.

The mean requirement of rescue analgesia doses in both the groups are (table 4): Control group 4.03 ± 0.66, Clonidine group 2.20 ± 0.61, the difference in the dose requirement is highly significant (p= 0.000). Aftab Beigh A et al[14] observed that the number of request for analgesia in postoperative period was significantly less in clonidine gr 5 (16.67) and 14 (46.67) in control group (p<0.001).

CL group had more sedation throughout the postoperative period than in control group. Mean Ramsay sedation score was 1 in control gr (Table 5) throughout the postoperative period. In CL gr (2.76, 2.2, 2.0) mean sedation scores were statistically significant (p=0.000) till 8 hours postoperatively compared to control group. No study in the past has compared postoperative sedation of pre-emptive oral clonidine.

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These side effects are usually not disabling and antianxiety effect appears to be beneficial. This did not seem to affect the outcome of the patients. As per our standard monitoring care with regular monitoring of respiration and pulse oximetry for first 24 hours, no patients in this study had respiratory depression or desaturation.

We did not know whether somnolence and dizziness affected the patients' ability to ambulate, but it may have caused patients to report lower pain scores, since these patients may have reduced ability or reduced motivation to report pain. However, we specifically assessed movement pain by asking them to move from lying to sitting, which should limit the amount of bias secondary to this side effect. We observed bradycardia in two patients after SAB in the CL group (Table 6) which required treatment with single dose of Inj atropine 0.6mg I.V.

There was incidence of hypotension in two patients of CL gr (Table 6) after SAB which responded to single dose of Inj ephedrine 6mg I.V. The hypotension and bradycardia may be due to either central effect or to a direct action on peripheral $\alpha_2$adrenoreceptors. Postoperative Nausea and vomiting in control group could be because of more number of NSAIDs (I.V. Diclofenac) required in this group.

This study design, has certain limitations, in that, single dose of clonidine has been used. The half-life of clonidine is 9-12hrs respectively which may have resulted with decreased effect over time and conclusion about the optimal dose and duration of the treatment cannot be made for these particular types of surgeries.

Since an additional pre-emptive regional analgesia technique was not included in our study, which would have been beneficial to the patients and due to significant variations in the degree of postoperative pain among patients undergoing similar surgical procedures, it would be helpful to identify the patients with most likely severe postoperative pain. This should allow more aggressive analgesic therapy in such type of patients

Oral clonidine used in this study prolonged the duration of postoperative analgesia after bupivacaine spinal anaesthesia in a fashion similar to intrathecal clonidine.[24]Clonidine is highly lipid soluble and crosses tissue barriers rapidly.[25]However, the dose of oral clonidine used in our study seems too small to increase the concentration of clonidine in cerebrospinal fluid (CSF).

Castro et al[26] reported that concentration of clonidine in (CSF) after redistribution is similar after epidural and intrathecal injection and it is more than 1000 times those observed after IV administration but in sheep it was found that plasma concentration after epidural, intrathecal and IV clonidine administration was similar after first 20 mins. We believe that the mechanism by which oral clonidine prolonged the duration of postoperative analgesia after spinal anaesthesia in our study might, in part be a supra spinal action.

CONCLUSION: In conclusion, oral clonidine prolongs the duration of postoperative analgesia after bupivacaine spinal anaesthesia. Oral clonidine is good alternative in multimodal analgesia treatment approach and can be used safely for pre-emptive analgesia for acute post-operative pain control in below umbilical surgeries performed under SAB. It proved to have a better analgesic effect, reducing the total consumption of postoperative analgesic and prolonging first rescue analgesic dose but a careful haemodynamic monitoring is must.

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	PC		CL		P- value
	Mean	SD	Mean	SD	
Age (yrs)	39.83	12.33	39.50	13.18	0.45 NS, p>0.05
Gender M/ F	21:9		26:4		0.29 NS, p>0.05
Weight (kg)	54.70	6.56	60.36	6.98	0.28 NS, p>0.05
Height (cms)	157.36	5.47	163.23	6.79	0.32 NS, p>0.05

TABLE 1: Comparison of demographic characteristics of patients

Type of surgeries	PC	CL	א2-value
Inguinal Hernia	9(30%)	10(33.33%)	3.71 p=0.99 NS, p>0.05
Fracture Tibia	3(10%)	2(6.67%)	
Debridement	2(6.67%)	3(10%)	
Amputation	5(16.67%)	4(13.33%)	
Varicocele	4(13.33%)	4(13.33%)	
Appendectomy	2(6.67%)	1(3.33%)	
Skin Grafting	3(10%)	4(13.33%)	
Para umbilical hernia	2(6.67%)	2(6.67%)	
Total	**30(100%)**	**30(100%)**	

TABLE 2: Distribution of patients according to type of surgeries in three groups

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	PC		CL		P-Value
	Mean	SD	Mean	SD	
Total duration of analgesia in minutes	264.83 Min	13.67	492.66 min	78.29	0.000 S, p <0.05

TABLE 3: Comparison of total duration of analgesia in three groups.
Descriptive Statistics

	PC		CL		P-Value
	Mean	SD	Mean	SD	
Total no. of dose of analgesia	4.03	0.66	2.20	0.61	0.000 S, p<0.05

TABLE 4: Comparison of total dose of analgesia in three groups in 24 hrs post-operative.
Descriptive Statistics

Ramsay Score	Group	N	Mean	Std. Deviation	Std. Error	Minimum	Maximum
2 hrs	PC	30	1.00	0.00	0.00	1.00	1.00
	CL	30	2.76	0.77	0.14	1.00	4.00
6 hrs	PC	30	1.00	0.00	0.00	1.00	1.00
	CL	30	2.22	0.77	0.14	1.00	4.00
8 hrs	PC	30	1.00	0.00	0.00	1.00	1.00
	CL	30	2.00	0.85	0.15	1.00	4.00
12 hrs	PC	30	1.00	0.00	0.00	1.00	1.00
	CL	30	1.6	0.49	0.00	2.00	3.00
16 hrs	PC	30	1.00	0.00	0.00	1.00	1.00
	CL	30	1.51	0.77	0.14	1.00	3.00
24 hrs	PC	30	1.00	0.00	0.00	1.00	1.00
	CL	30	1.61	0.31	0.05	1.00	3.00

TABLE 5: Comparison of Ramsay Sedation Score in three groups postoperatively.
Descriptive Statistics

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Side effects	PC	CL	⨯2-value
Bradycardia	0 (0.00%)	2 (6.67%)	22.57 p=0.004 S, p<0.05
Hypotension	0 (0.00%)	2 (6.67%)	
No side effects	25(83.33%)	26 (86.67%)	
Dizziness	0 (0.00%)	0 (0.00%)	
Somnolence	0 (0.00%)	0 (0.00%)	
Others/Nausea, Vomiting/urine retention	5 (16.67%)	0 (0%)	
Total	**30 (100%)**	**30 (100%)**	

TABLE 6: Comparison of distribution of side effects in three groups

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