"COMPARISON OF CLINICAL EFFICACY OF ROPIVACAINE AND LIGNOCAINE WITH ADRENALINE FOR IMPLANT SURGERY ANAESTHESIA- A SPLIT MOUTH RCT " Data openly available

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Abstract

INTRODUCTION: The primary indications for utilization of long acting local anesthetics in dentistry: lengthy dental procedures for which pulpal anesthesia in excess of 90 minutes is necessary and management of postoperative pain. Ropivacaine is a local anesthetic of the amide type that chemically is homologous to bupivacaine and mepivacaine. It is available in various concentrations and is said to have inherent vasoconstrictive properties at low concentrations. The aim of the study was to evaluate and compare the clinical efficacy of ropivacaine to lignocaine for implant surgery anaesthesia. To assess the onset and duration of anaesthesia the intraoperative and post-operative pain with both local anaesthetics and the post-operative analgesics requirement. MATERIALS AND METHODS:- 15 healthy subject with bilateral missing teeth indicated for implant placement with age range of 20 -60 years, reporting to the Department of Implantology, Rajarajeswari Dental College and Hospital, Bangalore were selected for the study. The test group involves implant surgeries in which ropivacaine was used. The control group involves implant surgeries in which lignocaine with adrenaline were used. RESULTS -The results were statistically analysed. There was a statistically significant higher duration of anesthesia for the test group as compared to the control group. Ropivacaine was found to be superior to lignocaine as far as quality of anesthesia was concerned. The comparison of mean VAS scores showed that ropivacaine has better anesthetic and analgesic effect when compared to the control group. CONCLUSION: Ropivacaine 0.75% provides significantly longer duration of anesthesia than lignocaine 2% with adrenaline.

"COMPARISON OF CLINICAL EFFICACY OF ROPIVACAINE AND LIGNOCAINE WITH ADRENALINE FOR IMPLANT SURGERY ANAESTHESIA- A SPLIT MOUTH RANDOMIZED CONTROLLED CLINICAL TRIAL."

ABSTRACT :-

INTRODUCTION: The primary indications for utilization of long acting local anesthetics in dentistry: lengthy dental procedures for which pulpal anesthesia in excess of 90 minutes is necessary and management of postoperative pain. Ropivacaine is a local anesthetic of the amide type that chemically is homologous to bupivacaine and mepivacaine. It is available in various concentrations (0.75%, 0.5%, 0.375%, or 0.25%) and is said to have inherent vasoconstrictive properties at low concentrations. Ropivacaine has 75% greater margin of safety than bupivacaine. Due to its long duration of both pulpal and soft tissue anesthesia after mandibular nerve block and a lower CNS and cardiovascular toxicity, ropivacaine can be a good alternative to bupivacaine as a local anaesthetic in dental implant surgery. The aim of the study was to evaluate and compare the clinical efficacy of ropivacaine to lignocaine for implant surgery anaesthesia. To assess the onset and duration of anaesthesia the intraoperative and post-operative pain with both local anaesthetics and the post-operative analgesics requirement.

MATERIALS AND METHODS:- The present study was carried out in a total of 15 subjects with age range of 20 -60 years, reporting to the Department of Implantology, Rajarajeswari Dental College and Hospital, Bangalore 15 Healthy patients with bilateral missing teeth indicated for implant placement were randomly selected of both sexes (male and female) between age group of 20-60 years. The test group involves implant surgeries in which ropivacaine was used. The control group involves implant surgeries in which lignocaine with adrenaline were used.

RESULTS -The results were statistically analysed. There was a statistically significant higher duration of anesthesia for the test group as compared to the control group. Ropivacaine was found to be superior to lignocaine as far as quality of anesthesia was concerned. The comparison of mean VAS scores showed that ropivacaine has better anesthetic and analgesic effect when compared to the control group.

CONCLUSION: Ropivacaine 0.75% provides significantly longer duration of anesthesia than lignocaine 2% with adrenaline. Ropivacaine 0.75% decreases the intraoperative and postoperative analgesia compared to lignocaine 2% with adrenaline. Thus, efficacy of ropivacaine 0.75% is superior to lignocaine 2% with 1:200,000 adrenaline in terms of duration of anesthesia and analgesia. Hence, ropivacaine 0.75% can be used as an alternative to lignocaine in implant surgeries and other surgical procedures which require longer duration of anesthesia and analgesia intraorally.

INTRODUCTION

Local anesthesia has been defined as a loss of sensation in a circumscribed area of the body caused by depression of excitation in nerve endings or inhibition of conduction process in peripheral nerves. Local anesthetics (LA's) are used clinically for anesthesia and analgesia either following surgery or for management of other acute and chronic pain conditions; they only last a few hours. Lignocaine is perhaps the most commonly used local anesthetic agent: it is used either in local or regional anesthesia, or in epidural or spinal blockade.[1]

For many years, anesthesiologists and pharmacologists have been searching for an ideal local anesthetic solution with prolonged action and low toxicity. Experiments with the piperidine ring of cocaine combined with the xylidine component of lidocaine resulted in the pipecoloxylidine family of local anesthetics which included the long acting local anesthetics; mepivacaine, bupivacaine and ropivacaine. These drugs possess enhanced lipid solubility characteristics (making them extremely potent) and display an increased affinity for protein binding which dramatically increases the duration of achievable anesthesia. This biochemical trait makes this group of drugs far more superior than their short acting analogues.[2]

Long acting local anesthetics not only produce localized sensory and motor anesthesia, but also provide effective postoperative pain relief and analgesia. Therefore, there are 2 primary indications for utilization of long acting local anesthetics in dentistry: (1) lengthy dental procedures for which pulpal anesthesia in excess of 90 minutes is necessary and (2) management of postoperative pain.[2]Long acting local anesthetics available are bupivacaine and etidocaine. Bupivacaine has more tissue toxicity, neurotoxicity and cardiotoxicity. Etidocaine is less cardiotoxic but increased intra operative bleeding is observed.[3]

Ropivacaine is a local anesthetic of the amide type that chemically is homologous to bupivacaine and mepivacaine. It is available in various concentrations (0.75%, 0.5%, 0.375%, or 0.25%) and is said to have inherent vasoconstrictive properties at low concentrations. Ropivacaine has 75% greater margin of safety than bupivacaine. Cardiovascular electrophysiology effects of ropivacaine were also found to be intermediate between those of lidocaine and bupivacaine. Ropivacaine is suitable local anesthetic without vasoconstrictor for nerve block anesthesia in dental practice.[4]

Ropivacaine is equivalent in potency and efficacy to bupivacaine. Due to its long duration of both pulpal and soft tissue anesthesia after mandibular nerve block and a lower CNS and cardiovascular toxicity, ropivacaine can be a good alternative to bupivacaine as a local anaesthetic in dental implant surgery.[5]Thus this study has been undertaken to compare the efficacy of ropivacaine to lignocaine with adrenaline for prolonged anesthesia and postoperative analgesia in implant surgery.

AIMS AND OBJECTIVES

1. To evaluate and compare the anesthetic efficacy of ropivacaine 0.75% and lignocaine 2% with 1:200,000 adrenaline during implant surgery.

2. To evaluate the influence of two anesthetic agents on patients' postoperative paiperception after implant surgery.

MATERIALS AND METHODS :-

This study will be done on patients who reported to Department of Implantology, Rajarajeswari Dental college and Hospital, Mysore Road, Bangalore, requiring implant placement. General information including name, age, sex and address will be recorded. Patient's medical and dental history will be assessed.

15 healthy patients (ASA I) with bilateral partial edentulism indicated for implant placement, will be randomly selected of both sexes (male and female) between the age group of 20-60 years.

Group I –15 implant surgeries in which lignocaine with adrenaline will be used on one side (control group)

Group II –15 implant surgeries in which ropivacaine will be used on the other side (test group).

Patients will be informed about the drug and its possible complications. And also, about the surgical procedure that will be carried out on the patient, the sequelae of the treatment and possible complications of the procedure. Informed consent will be taken before the procedure.

Patients will be anesthetized with 3ml of 2% Lignocaine with adrenaline in the control group and 3ml of 0.75% plain ropivacaine (Ropin 0.75%, Neon Laboratories Ltd) in the test group.

Pain experiences will be measured by Numerical rating scale(NRS), visual analog scale (VAS) and Verbal descriptive scale(VDS).

INCLUSION CRITERIA-

- Patients in the age group 20 to 60 years.
- Systemically healthy patients under the classification of ASA1.
- Patients requiring the replacement the missing teeth by means of implant placement.

EXCLUSION CRITERIA-

- Patients with history of allergic reactions to LA of amide group and sulfides.
- Patients with acute infections.
- Patients taking medications like MAO inhibitors, tricyclic antidepressants, phenothiazine vasodepressor drugs and ergot type oxytocic drugs.
- Chronic smokers and alcoholics.
- Pregnant and lactating females.

EVALUATION OF PAIN SCORES AND OTHER PARAMETERS: -

Pain assessment was done using the pain scales such as visual analog scale, Numerical rating scale and verbal descriptive scale at the following times - before anesthesia, after anesthesia, post operatively at 1,3,6,9 and 12 hours respectively after surgery ,late post operatively(at first and second day).The quality of anesthesia was assessed according to the patient response during implant surgery. (Sharrawy et al 2006) (Table 1). All the hemodynamic parameters such as pulse rate, blood pressure, respiratory rate, SPO_2temperature will be recorded.

PROCEDURE:

The same surgeon will be operating on all the patients. The choice of local anaesthetic for the first operation was randomised (by toss of a coin) and they were given the other local anesthetic for the second side.0.5 ml of 0.75% ropivacaine will be infiltrated intradermally as test solution.. The Numerical rating scale(NRS),

visual analog scale (VAS) and Verbal descriptive scale(VDS) will be explained preoperatively and patients will be asked to notify as soon as the lip and tongue becomes numb. Desired area will be then anaesthetised and a standard surgical technique will be used for implant placement. In all cases, the incisions were mid-crestal with no vertical releasing incisions, and the incisions were extended mesially and distally to assure accessibility. The incisions were extended as needed to expose at least 5 mm of bone.

Vital parameters were monitored and pain score assessment were recorded before injecting the drugs, on injecting and same parameters were recorded after injection at intervals of 30 minutes,1,3,6,9 hours on the day of surgery(D1),first (D2) and second day after surgery(D3).

All the patients were assessed for level of comfort and depth of anaesthesia intra-operatively via VAS, VDS, NRS scales immediately after implant surgery, for both the agents to assess the depth of anesthesia achieved.

Postoperative assessment

Patients were instructed to palpate the lower lip every 15 minutes to determine at what time numbness of lip completely disappeared and was there a return to normal sensation (absence of pins-and-needles sensations).The time from onset of anesthesia to when numbness of the lip and tongue receded as assessed by pricking was taken as the duration of anesthesia Patients were instructed not to take any analgesics until numbness of lip and tongue receded. The time from the start of numbness to when the subject first requested a dose of oral analgesic was taken as duration of analgesia. Patients were instructed to rate the extent of their pain at 3, 6, 9, and 12 h on the day of surgery (D1), on the first day after surgery (D2) and second day after surgery (D3) using the same VCS Post-operative analgesic consumption was based on the number of tablets used on a daily basis; on the day of surgery (D1), first day after surgery (D2) and second day after surgery (D3) .

Post operatively patients will be given a treatment regimen of antibiotics and analgesics. They should be instructed not to take any analgesics until the lip and tongue were no longer numb All patients were contacted by telephone the day after surgery and encouraged to complete their questionnaires. All subjects were reviewed for adverse events the next day after surgery and again 7 days after surgery to remove sutures.

STATISTICAL ANALYSIS

Statistical Package for Social Sciences [SPSS] for Windows, Version 22.0. Released in 2013. Armonk, NY: IBM Corp., was used to perform statistical analyses. Student Paired t Test was used to compare the mean Volume of LA, Duration of Anaesthesia & Surgery between Test and Control sites. McNemar's Test was used to compare the Quality of Anaesthesia between Test and Control sites. Wilcoxon Signed Rank Test was used to compare the mean Pain scores between Test and Control sites at different time intervals. Friedman's Test was used to compare the mean Pain Scores between different time intervals in Test and Control Site. The level of significance [P-Value] was set at $P<0.05$.

RESULTS

Following the assessment of subjective and objective parameters, the values obtained were subjected to statistical analysis.

Table 1 shows Comparison of mean LA Volume (in ml) & Duration of Anaesthesia & Surgery (in Mins) between Test & Control sites using Student Paired t Test. The duration of anesthesia was significantly greater ($p<0.001$) in the ropivacaine group when compared to the lignocaine group with a mean difference of 193.33.

Table 2 shows the quality of anesthesia obtained at test and control sites and was assessed using a rating scale. In all the surgical sites treated, areas anesthetized with ropivacaine patients reported a score of 3 or lesser while only 70% in the lignocaine group reported a score of 3 or lesser. The above observations infer that ropivacaine was superior to lignocaine as far as quality of anesthesia was concerned.

Table 3 shows the comparison of VAS scores at different time intervals/points between two groups.The

scores in the ropivacaine group were consistently lower than the lignocaine group.The difference in scores were statistically significant in favour of the ropivacaine group.

DISCUSSION

Ropivacaine is a long duration local anesthetic agent (upto 90min/more of pulpal anesthesia) that ultimately needs to be more used in case of surgical procedures as well as in dentistry practice. It has inherent vasoconstrictive properties, less/fewer cardiac and CNS adverse effects. Ropivacaine provides a concentration-dependent separation of sensory and motor effects. Several studies have found that sensory blockade is obtained with lower concentrations. Although ropivacaine at low concentrations may be suitable for providing postoperative analgesia.

According to Vikhram K et al, the results of their randomized double-blinded study in terms of quality of anesthesia **s** howed that ropivacaine 0.75% with 1:200,000 adrenaline was clinically and statistically significant when compared with lignocaine 2% with1:200,000 adrenaline in terms of latency duration, duration of anesthesia, Visual Analog Scale and Faces Pain Scale. Mean time duration of anesthetic effect for the ropivacaine group was 311.67 minutes, while for the lignocaine group, it was 163.58 minutes which was statistically significant. The mean visual analog scale score for ropivacaine group was 1.37 and for lignocaine group was 3.62.

In our study, the quality of anesthesia was assessed using a rating scale with scores ranging from 1 to 7. Evaluation revealed that the ropivacaine group exhibited a mean score of 2.4 while the lignocaine group reflected a mean score of 3.06.Subjects in the ropivacaine group reported a score of 3 or lesser (score 2=60%, score 3=40%) while only 70% in the lignocaine group reported a score of 3 or lesser score 2=20%, score 3 = 60%). In the remainder 30% of the lignocaine sites, the subjects reported a score of 4 and 5 respectively. Ropivacaine was found to have a better quality of anesthesia than lignocaine with adrenaline. There was a statistically significant difference in the duration of anesthesia between ropivacaine group and the lignocaine group, which was significantly greater ($p<0.001$) in the ropivacaine group (392) when compared to the lignocaine group (198.67). Additionally, in our study, comparison of VAS scores at different time points between the 2 groups demonstrated that the scores in the ropivacaine group were consistently lower than the lignocaine group. Further, the difference in the scores were statistically significant at all the time points

Studies by Knudsen et al 1997, Danielsson et al 1997, Feldman et al 1994, Szlark et al 1998 reported that ropivacaine has less effect on CNS and shows less cardiovascular activity. Ropivacaine was found to have rapid onset of action as well as longer duration of action in comparison with bupivacaine (Akerman et al 1988, Cederholm al 1991, Stojanovic et al 2001)

From our study, we found that ropivacaine has a moderate onset of action with longer duration of anesthesia and postoperative analgesia when compared to lignocaine with epinephrine. In dental practice, long duration of local anesthesia is useful as it reduces the postoperative discomfort and the need of analgesics to control the pain. Due to its long duration of action, ropivacaine 0.75% without vasoconstrictor may be considered as a suitable local anesthetic for soft tissue anesthesia and adequate control of postoperative analgesia during periodontal surgical procedures. ne required for effective surgical anesthesia.

CONCLUSION

The following conclusions can be drawn from the results obtained from our study. Ropivacaine 0.75% provides significantly longer duration of anesthesia than lignocaine 2% with adrenaline. Ropivacaine 0.75% decreases the intraoperative and postoperative analgesia compared to lignocaine 2% with adrenaline. Thus, efficacy of ropivacaine 0.75% is superior to lignocaine 2% with 1:200,000 adrenaline in terms of duration of anesthesia and analgesia. Hence, ropivacaine 0.75% can be used as an alternative to lignocaine in implant surgeries and other surgical procedures which require longer duration of anesthesia and analgesia intraorally. Moreover, ropivacaine 0.75% can be used safely in patients in whom adrenaline use has to be minimized. No adverse effects were reported with ropivacaine in our study. Further studies are required to evaluate the safety and efficacy of ropivacaine in medically compromised patients undergoing implant and periodontal

surgeries.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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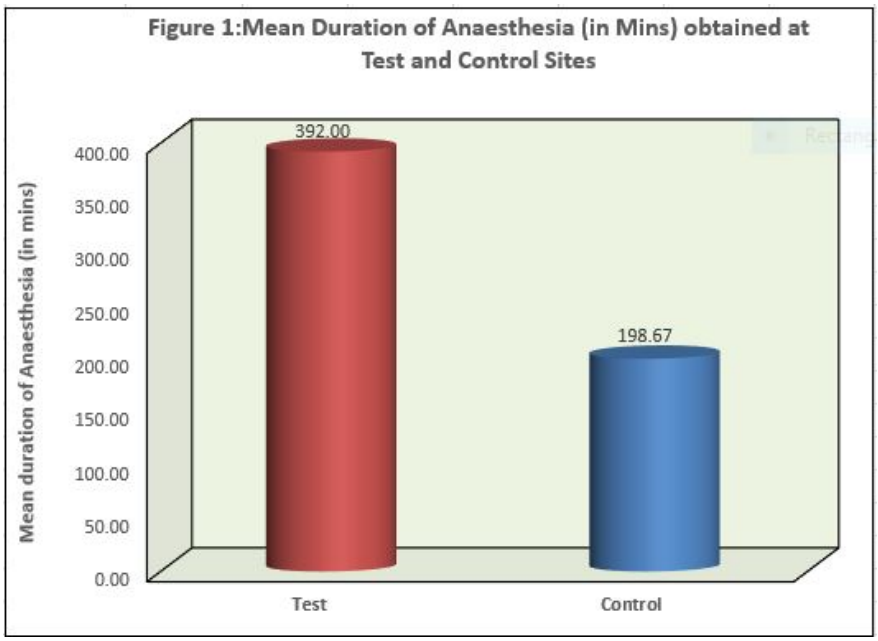

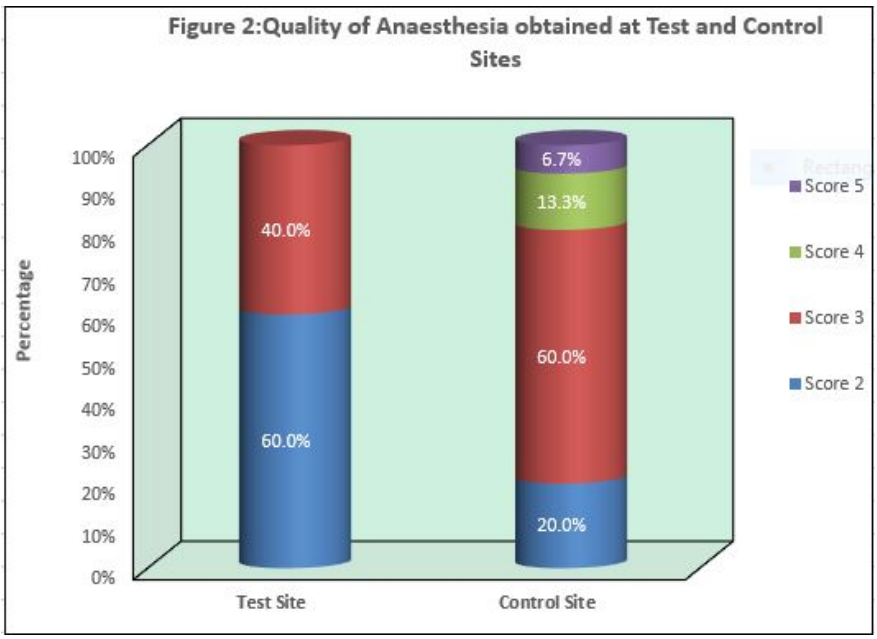

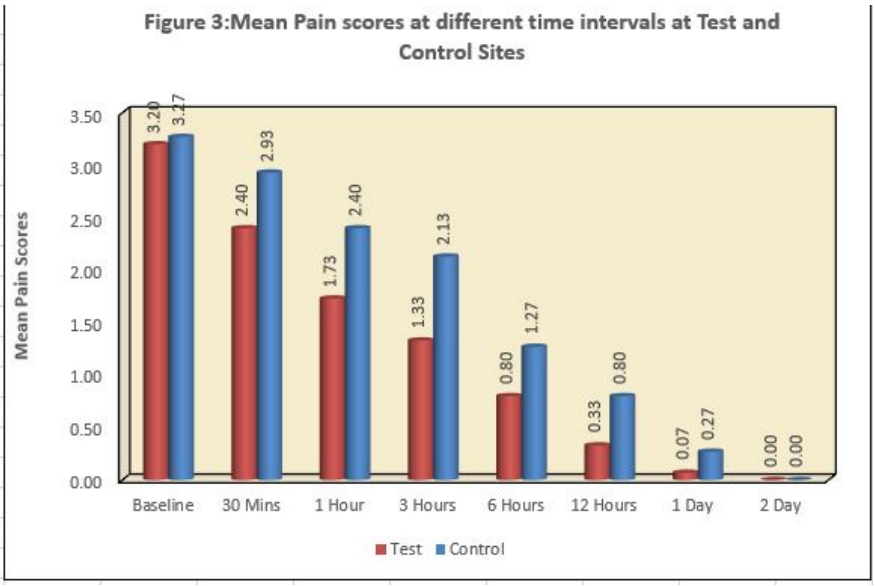

Comparison of mean LA Volume (in ml) & Duration of Anaesthesia & Surgery (in Mins) between Test & Control sites using Student Paired t Test						
Variables	Sites	N	Mean	SD	Mean Diff	P-Value
LA Volume (in ml)	Test	15	3.17	0.31	0.00	..
	Control	15	3.17	0.31		
Dur. Anasthesia	Test	15	392.00	40.96	193.33	<0.001*
	Control	15	198.67	30.15		
Dur. Surgery	Test	15	71.00	19.38	0.67	0.33
	Control	15	70.33	18.47		

Comparison of Quality of Anaesthesia between Test & Control Sites using McNemar's Test						
		Test Site		Control Site		
Variables	Category	n	%	n	%	P-Value
Quality of Anaes-thesia	Score 2	9	60.0%	3	20.0%	0.001*
	Score 3	6	40.0%	9	60.0%	
	Score 4	0	0.0%	2	13.3%	
	Score 5	0	0.0%	1	6.7%	

Comparison of mean Pain scores between Test & Control Sites at different time intervals using Wilcoxon Signed Rank Test						
Time	Sites	N	Mean	SD	Mean Diff	P-Value
Baseline	Test	15	3.20	0.56	-0.07	0.56
	Control	15	3.27	0.59		
30 Mins	Test	15	2.40	0.51	-0.53	0.01*
	Control	15	2.93	0.70		
1 Hour	Test	15	1.73	0.46	-0.67	0.008*
	Control	15	2.40	0.63		
3 Hours	Test	15	1.33	0.49	-0.80	0.006*
	Control	15	2.13	0.64		
6 Hours	Test	15	0.80	0.56	-0.47	0.04*
	Control	15	1.27	0.59		
12 Hours	Test	15	0.33	0.49	-0.47	0.04*
	Control	15	0.80	0.68		
1 Day	Test	15	0.07	0.26	-0.20	0.18
	Control	15	0.27	0.46		
2 Days	Test	15	0.00	0.00	0.00	1.00
	Control	15	0.00	0.00		