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Comparative evaluation of effectiveness of 2% lignocaine hydrochloride with 1.5% potassium chloride *versus* 2% lignocaine hydrochloride with adrenaline bitartrate *versus* 2% lignocaine hydrochloride as local anaesthetic for adult patients undergoing surgical extraction of impacted mandibular third molars: a randomized controlled clinical study

Rinku Kalra[1,2,*], Shreyas Gupte[2], Thomson D'Cruz[2], Nidhi Pandey[2], Drishti Shah[2], Ranjana Patnaik[1]

[1] School of Biological and Biomedical Sciences, Galgotias University, Greater Noida, India
[2] Department of Oral and Maxillofacial Surgery, YMT Dental College and Hospital, Kharghar, Navi Mumbai, India

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Abstract – Background and objective: Administration of some additives with local anesthetics can prolong pain free period post-operatively, thereby reducing need for post-operative analgesics and improving patient comfort. Potassium chloride was found to increase duration and quality of anesthesia in various studies on brachial plexus blockade. This study was designed to evaluate and compare the effect of 2% lignocaine with 1.5% potassium chloride, 2% lignocaine with adrenaline and 2% lignocaine (plain) in pterygomandibular nerve blocks. **Materials and methods:** A triple blind randomized controlled study was conducted on 120 adults, aged 18–45 years in ASA-I category, requiring surgical extraction of impacted mandibular third molars. The subjects were divided equally into 3 groups randomly by computer generated sequence; Group 1: 2% lignocaine plus 1.5% solution of potassium chloride, group 2: 2% lignocaine with 1:80,000 adrenaline and group 3: 2% plain lignocaine. Onset, duration, depth (pain) of anesthesia, patient satisfaction, systolic and diastolic blood pressures, heart rate and oxygen saturation, were evaluated and compared. **Results:** Onset was shortest for group1 and longest for grp3, statistically highly significant difference between the 3 groups ($p < 0.01$). Statistically significant difference ($p < 0.05$) was found in duration of surgery, duration of analgesia and VAS scores between groups 1 & 3. Duration and depth of anesthesia were comparable for groups 1 & 2. There was no statistically significant difference seen for total amount of dose used, SBP, DBP, HR and SpO_2 between the 3 groups ($p > 0.05$). **Conclusion:** Potassium chloride, a physiological salt is inert and causes no local/systemic adverse effects when injected with lignocaine in physiologically permissible amounts. The combination achieves satisfactory onset, duration, depth of anesthesia without altering hemodynamic variables. Hence, it may be considered as a safe and effective additive.

Introduction

Achieving better, prolonged and deeper regional anesthesia with prolonged post-operative pain control is one of the therapeutic goals for every clinician. Local anesthetic (LA) agents have an inherent vasodilatory effect and when used alone, provide limited duration of action, not so profound sensory block and probable risk of systemic toxicity. In an attempt to counter these, vasoconstrictors like adrenaline (Adr) are commonly added to LA. However, due to detrimental systemic effects of vasoconstrictors and limited permissible dose in patients with certain systemic conditions, many pharmacological agents like opioids, clonidine, neostigmine, hyaluronidase, dexamethasone, sodium bicarbonate, magnesium sulphate, *etc*. have been tried as additives to anesthetic agents for various regional nerve blocks [1].

Potassium salts have been shown to possess local anesthetic potency which is almost similar to that of procaine, when tested under experimental conditions [2]. It has been stated that, toxicity of LA can be reduced by adding potassium salts, since, the amount of LA required to produce a desired degree of anesthesia is reduced [2].

* Correspondence: drrinkukalra@gmail.com

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Potassium Chloride (KCl) is a physiologic salt, inert, compatible with lignocaine. Addition of KCl to LA increases the extracellular concentration of K^+, depolarizes nerve membrane and blocks the conduction of nerve impulses thereby, shortening the onset, improving quality and duration of anesthesia, without causing any adverse effect on the hemodynamic status of the individual [3].

Several authors have reported use of KCl as an additive with various LAs for brachial plexus blockade [4–6]. Not many studies have reported the use of KCL as an additive with lignocaine for anesthesia in the maxillofacial region. Tainter *et al.* [2] studied and compared the effects of adding potassium sulphate and sodium chloride to 2 per cent procaine hydrochloride with 1:50,000 epinephrine. Sidon *et al.* [7] studied mandibular nerve blocks as well as supra periosteal injection techniques in surgical patients as well as volunteers [7]. However, the variables assessed were onset, duration and depth.

Hence, this study, was designed and conducted to evaluate and compare onset, duration, pain control and hemodynamic effects, using 2% lignocaine hydrochloride with 1.5% KCl, 2% lignocaine hydrochloride with 1:80,000 Adrenaline bitartrate and 2% lignocaine hydrochloride (plain) in pterygomandibular nerve blocks for surgical extractions of impacted mandibular third molars. The study tested the null hypothesis, which stated that there is no difference in the effectiveness of 2% lignocaine with 1.5% KCl, 2% lignocaine with 1:80,000 Adrenaline and 2% lignocaine in pterygomandibular nerve blocks for the outcome variables, quality of anesthesia, hemodynamic response and pain control.

Materials and methods

A triple blinded (operator, observer, subject) randomized controlled trial was designed including patients who visited the department of Oral and Maxillofacial Surgery of recognized dental college for extraction of impacted mandibular third molars.

The sample size was calculated using the formula, $n = 2 (Z\alpha + Z\beta)^2 [s]^2/d^2$, where $Z\alpha$ is the z variate of alpha error *i.e.* a constant with value 1.96, $Z\beta$ having a value of 0.84, considering the mean and standard deviation from the literature, that concluded approximately 40 subjects per group. Approval from Institutional Ethics Committee was obtained (n°. YMTDCH /IEC/OUT/072/2017).

The study included ASA-I category (American Society of Anesthesiologists) subjects of both sexes, aged between 18 and 45 years, requiring surgical extraction of mandibular third molars (with moderate Pederson's difficulty index [8] *i.e.*, 5–7) and willing to consent for the study. Patients with any known medical condition, h/o previous resistance to LA, known drug/food allergy, pregnant or lactating mothers, mentally challenged, uncooperative or apprehensive were excluded from the study. It was ascertained that none of the subjects was suffering from any form of active infection nor consuming any medication one week prior to the procedure.

Thus, a total of 120 patients, who fulfilled the inclusion criteria were randomly selected for this study and divided randomly into three groups (40/per group) using computer generated random numbers. Pterygomandibular nerve blocks were used in all groups. In group 1: 2% lignocaine hydrochloride with 1.5% potassium chloride in the ratio 2:1, in group 2: 2% lignocaine hydrochloride with 1:80,000 adrenaline bitartrate, in group 3: plain 2% lignocaine hydrochloride were used.

The basic protocol followed for every case included a detailed case history, explanation of the procedure to the patient, routine X-rays and blood investigations. A well-informed written consent was obtained from all subjects. All subjects underwent surgical extractions of impacted mandibular third molars under similar conditions by same operating surgeon using standard aseptic and surgical protocol under pterygomandibular nerve blocks. No pre-medications were used in any group. Care was taken to avoid any intra-vascular injection. In the event of a positive aspiration, the solution and the syringe were discarded and a new solution from the same group was used. Neither the subject, nor the operating surgeon was aware of the contents of the solution used for nerve blocks. Routine post-operative medications were prescribed and postoperative instructions were explained. The subjects were kept under observation post-operatively and discharged after all study variables were recorded. All subjects were advised to use prescribed analgesic as required. The time of first rescue analgesic postoperatively was also recorded. Patients were recalled on the next day for follow-up. Postoperative pain and rescue analgesic requirement were noted.

The outcome variables measured were, cardiovascular variables (SBP, DBP, MABP and HR and SPO_2) and quality of anesthesia assessed by onset, duration and its depth. The cardiovascular variables were measured using a multiparameter monitor (Intellivue MX 400, Philips, with more than 95% accuracy), just prior to LA injection and repeated at intervals of 5 min, 10 min, 15 min, 30 min and 45 min after injection. Onset of anesthesia (in seconds) was measured from the time of injection to the onset of first tingling sensation on the lower lip. Duration (in minutes) was recorded from the onset of first tingling sensation on the lower lip till the first prescribed rescue analgesic used by the subject. Clinical signs and symptoms of hyperkalemia like paresthesia of the extremities, listlessness, mental confusion, weakness or heaviness of the legs, flaccid paralysis, cold skin, grey pallor, fall in blood pressure if any, were also specifically looked for. Any other symptoms like nausea, vomiting, sedation, itching, shivering, headache, accidental soft tissue injury was also mentioned in the case file. The duration of surgery (time of injection to the last suture taken) and total amount of dose used were also recorded. Depth of anesthesia was assessed with VAS score which was specifically recorded for pain during extraction.

Data obtained was compiled on a MS Office Excel Sheet (v 2019, Microsoft Redmond Campus, Redmond, Washington, United States). Data was subjected to statistical analysis using Statistical package for social sciences (SPSS v 26.0, IBM).

Descriptive statistics like frequencies and percentage for categorical data, Mean & SD for numerical data has been depicted. Inter group comparison (>2 groups) was done using one way ANOVA followed by pair wise comparison using post hoc test. Intra group comparison was done using repeated measures ANOVA (for >2 observations) followed by post Hoc test. Comparison of frequencies of categories of variables with groups was done using chi square test. For all the statistical tests, $p < 0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

Results

The mean age of the subjects was 32.31 ± 4.902 (Min − 21 years, Max − 45 years). There were 57 (47.5%) females, 63 (52.5%), male subjects. Inter group comparison of mean age of the subjects showed a statistically non-significant difference ($p > 0.05$) which ruled out age as a confounding factor. Also inter group comparison of frequencies of sex of the subjects showed a statistically non-significant difference ($p > 0.05$).

Table I shows Inter group comparison of Onset, duration, total amount/dose used, duration of surgery, number of injections and depth of anesthesia using VAS scale.

Table II shows Inter group pair wise comparison using Post Hoc Tests for Onset, duration, total amount/dose used, duration of surgery, number of injections and depth of anesthesia using VAS scale.

Table III shows Inter group pairwise comparison of SBP. DBP, Pulse, SpO_2 using Post Hoc Tests.

There was a highly statistically significant difference in the onset of action between 3 groups, grp 3 (mean = 246.65 s) > grp 2 (102.60 s) > grp 1 (44.20 s) (Tabs. I and II). Duration of analgesia was least for group 3 (100.28 min) as compared to Group 1 (205.20 min) and group 2 (222.43 min) (highly statistically significant, Tabs. I and II). Depth of anesthesia (VAS scores) showed statistically significant difference between groups 1 and 3 and non-significant difference between 1 and 2 (Tabs. I and II). There was a statistically non-significant difference seen for SBP. DBP, Pulse and SpO_2 at all the time intervals between all pairs of groups *i.e.* group 1 *versus* 2, 1 *versus* 3 and 2 *versus* 3 (Tab. III). There was no statistically significant difference in the amount of Lignocaine injected and number of injections used in the 3 groups ($p > 0.05$, Tabs. I and II).

Discussion

A physiologic concentration of potassium, similar to that in extracellular fluid, when added to isotonic solutions of LA, potentiates their effect [9]. Systemic and local toxicity studies conducted by Aldrete *et al.* on animals and volunteers injected with KCl-LA, established its safety [3]. Aldrete *et al.* also showed that there were no consistent or significant alterations in serum potassium levels of patients undergoing bronchoscopies, anesthetized with bilateral superior laryngeal nerve block and trans-cricoid injection, using 8 ml. of 1 percent lidocaine plus KCl [10]. This suggested that when small amount of KC1 is used, there is no change in normal balance of the extracellular potassium pool [3]. A proposed mode of action of potassium ions when added to LA, has been given by Sidon *et al.* [7] and Huxley *et al.* [11].

In the present study, 1ml of 1.5% KCl (2mEq) was safely added to 2ml of 2% lignocaine (grp1) and its effects were evaluated and compared with 2% lignocaine with 1:80,000 adrenaline (grp2) and 2% lignocaine (grp3) in pterygomandibular nerve blocks for surgical extraction of mandibular third molars.

There was a highly statistically significant difference in the onset of action between 3 groups, grp 3 ((mean = 246.65 s) > grp 2 (102.60 s) > grp 1 (44.20 s) (Tabs. I and II). Thus, the onset was fastest in grp1.

Similarly, in other studies, shorter onset of action was obtained for brachial plexus [4], and epidural blockade [1]. The addition of KCl renders additional extracellular potassium ions, leading to depolarization of nerve membrane and blocks conduction of impulses [4,7,11].

As regards duration of surgery, a statistically significant difference was obtained between groups 1 and 3 ($p < 0.05$, Tab. II), which can be explained by the delayed onset in group 3 as compared to earlier onset in group 1.

Duration of analgesia was least for group 3 (100.28 min) as compared to Group 1 (205.20 min) and group 2 (222.43 min) (highly statistically significant, Tabs. I and II). However, the duration of LA with KCl was comparable to LA-Adr and statistically non-significant (Tab. II). Prolonged duration of action with KCl is consistent with previous studies with mandibular nerve blocks and supra-periosteal injections [7], brachial plexus [4] and epidural blockade [12].

Shorter onset and prolonged duration for both sensory and motor nerve blocks were also obtained when KCl was used with bupivacaine [13,14].

Depth of anesthesia, measured by pain experienced during extraction by the subjects using VAS scale showed statistically significant difference between groups 1 and 3 and non-significant difference between 1 and 2 (Tabs. I and II), indicating that pain control with LA-KCl was comparable to the standard LA-Adr.

There was a statistically non-significant difference seen for SBP. DBP, Pulse and SpO_2 at all the time intervals between all pairs of groups *i.e.* group 1 *versus* 2, 1 *versus* 3 and 2 *versus* 3 (Tab. III). Thus, there were no differences in hemodynamic effects in the 3 groups.

There was no statistically significant difference in the amount of Lignocaine injected and number of injections used in the 3 groups ($p > 0.05$, Tabs. I and II). There was no need for additional injection and/or alternate technique to be used in any of the subjects in the 3 groups. Thus, the Lignocaine-KCl combination was comparable to the standard Lignocaine-Adr as regards LA dose required.

Table I. Inter group comparison of Onset, duration, total amount/dose used, duration of surgery, number of injections and depth of anesthesia using VAS scale.

	Groups	Mean	Std. deviation	Std. error	95% confidence interval for mean		Minimum	Maximum	*F* value	*P* value of one way ANOVA
					Lower bound	Upper bound				
Onset of analgesia (sec)	1	44.20	5.450	0.862	42.46	45.94	34	55	470.702	0.000**
	2	102.60	9.803	1.550	99.46	105.74	76	120		
	3	246.65	51.403	8.128	230.21	263.09	27	301		
Duration of analgesia (min)	1	205.20	28.399	4.490	196.12	214.28	167	271	110.759	0.000**
	2	222.43	61.369	9.703	202.80	242.05	154	456		
	3	100.28	12.770	2.019	96.19	104.36	79	132		
Total amount of dose used	1	2.20	0.608	0.096	2.01	2.39	2	4	2.079	0.130#
	2	2.35	0.770	0.122	2.10	2.60	2	4		
	3	2.55	0.904	0.143	2.26	2.84	2	4		
Duration of surgery (min)	1	15.10	4.460	0.705	13.67	16.53	5	26	2.869	0.061#
	2	18.18	6.201	0.981	16.19	20.16	9	29		
	3	21.25	18.361	2.903	15.38	27.12	10	131		
Number of injections required	1	1.10	0.304	0.048	1.00	1.20	1	2	2.079	0.130#
	2	1.18	0.385	0.061	1.05	1.30	1	2		
	3	1.28	0.452	0.071	1.13	1.42	1	2		
VAS	1	3.50	0.480	0.076	3.28	3.72	2	5	6.452	0.002**
	2	3.73	0.599	0.095	3.53	3.92	2	4		
	3	3.98	0.679	0.107	3.82	4.13	2	5		

* statistically significant difference ($p < 0.05$).
**statistically highly significant difference ($p < 0.01$).
non significant difference ($p > 0.05$).

Table II. Inter group pair wise comparison using post hoc tests.

Dependent variable	(I) group	(J) group	Mean difference (I–J)	Std. Error	*p* value
Onset of analgesia (sec)	1	2	–58.400*	6.792	0.000**
	1	3	–202.450*	6.792	0.000**
	2	3	–144.050*	6.792	0.000**
Duration of analgesia (min)	1	2	–17.225	8.884	0.132#
	1	3	104.925*	8.884	0.000**
	2	3	122.150*	8.884	0.000**
Total amount of dose used	1	2	–0.150	0.172	0.660#
	1	3	–0.350	0.172	0.109#
	2	3	–0.200	0.172	0.479#
Duration of surgery (min)	1	2	–3.075	2.567	0.457#
	1	3	–6.150*	2.567	0.047*
	2	3	–3.075	2.567	0.457#
Number of injections required	1	2	–0.075	0.086	0.660#
	1	3	–0.175	0.086	0.109#
	2	3	–0.100	0.086	0.479#
VAS	1	2	0.250	0.132	0.146#
	1	3	0.475*	0.132	0.001**
	2	3	0.225	0.132	0.209#

* statistically significant difference ($p < 0.05$).
** statistically highly significant difference ($p < 0.01$).
# non significant difference ($p > 0.05$).

Table III. Inter group pairwise comparison of SBP. DBP, Pulse, SpO_2 using Post Hoc Tests.

Dependent variable	(I) group	(J) group	Mean difference (*I–J*)	Std. error	*p* value
SBP preop	1	2	1.000	1.038	0.601#
	1	3	–0.150	1.038	0.989#
	2	1	–1.000	1.038	0.601#
	2	3	–1.150	1.038	0.511#
DBP preop	1	2	0.000	0.554	1.000#
	1	3	0.550	0.554	0.583#
	2	1	0.000	0.554	1.000#
	2	3	0.550	0.554	0.583#
SBP 5 min	1	2	0.300	0.903	0.941#
	1	3	–0.200	0.903	0.973#
	2	1	–0.300	0.903	0.941#
	2	3	–0.500	0.903	0.845#
DBP 5 min	1	2	0.350	0.457	0.725#
	1	3	–0.250	0.457	0.848#
	2	1	–0.350	0.457	0.725#
	2	3	–0.600	0.457	0.391#
SBP 10 min	1	2	1.050	0.877	0.457#
	1	3	–0.350	0.877	0.916#
	2	1	–1.050	0.877	0.457#
	2	3	–1.400	0.877	0.251#
DBP 10 min	1	2	–0.400	0.445	0.642#
	1	3	0.350	0.445	0.712#
	2	1	0.400	0.445	0.642#
	2	3	0.750	0.445	0.215#

Table III. (continued).

Dependent variable	(I) group	(J) group	Mean difference (*I–J*)	Std. error	*p* value
SBP 15 min	1	2	0.550	0.946	0.830#
	1	3	–0.050	0.946	0.998#
	2	1	–0.550	0.946	0.830#
	2	3	–0.600	0.946	0.802#
DBP 15 min	1	2	–0.400	0.493	0.697#
	1	3	–0.350	0.493	0.758#
	2	1	0.400	0.493	0.697#
	2	3	0.050	0.493	0.994#
SBP 30 min	1	2	0.450	21.900	1.000#
	1	3	–26.900	21.900	0.439#
	2	1	–0.450	21.900	1.000#
	2	3	–27.350	21.900	0.427#
DBP 30 min	1	2	–0.400	0.451	0.649#
	1	3	–0.400	0.451	0.649#
	2	1	0.400	0.451	0.649#
	2	3	0.000	0.451	1.000#
SBP 45 min	1	2	0.400	0.913	0.900#
	1	3	–0.150	0.913	0.985#
	2	1	–0.400	0.913	0.900#
	2	3	–0.550	0.913	0.819#
DBP 45 min	1	2	–0.550	0.464	0.464#
	1	3	–0.150	0.464	0.944#
	2	1	0.550	0.464	0.464#
	2	3	0.400	0.464	0.665#
Pulse preop	1	2	0.200	0.958	0.976#
	1	3	1.975	0.958	0.103#
	2	1	–0.200	0.958	0.976#
	2	3	1.775	0.958	0.157#
Pulse 5 min	1	2	0.025	0.937	1.000#
	1	3	0.675	0.937	0.752#
	2	1	–0.025	0.937	1.000#
	2	3	0.650	0.937	0.768#
Pulse 10 min	1	2	0.350	0.959	0.929#
	1	3	0.500	0.959	0.861#
	2	1	–0.350	0.959	0.929#
	2	3	0.150	0.959	0.987#
Pulse 15 min	1	2	0.550	0.956	0.833#
	1	3	0.925	0.956	0.599#
	2	1	–0.550	0.956	0.833#
	2	3	0.375	0.956	0.919#
Pulse 30 min	1	2	–0.050	0.935	0.998#
	1	3	–1.475	0.935	0.259#
	2	1	0.050	0.935	0.998#
	2	3	–1.425	0.935	0.283#
Pulse 45 min	1	2	–1.400	0.985	0.334#
	1	3	–0.925	0.985	0.617#
	2	1	1.400	0.985	0.334#
	2	3	0.475	0.985	0.880#

Table III. (continued).

Dependent variable	(I) group	(J) group	Mean difference (*I*–*J*)	Std. error	*p* value
SpO_2 preop	1	2	0.075	0.235	0.946#
	1	3	0.150	0.235	0.800#
	2	1	–0.075	0.235	0.946#
	2	3	0.075	0.235	0.946#
SpO_2 5 min	1	2	0.200	0.218	0.631#
	1	3	0.000	0.218	1.000#
	2	1	–0.200	0.218	0.631#
	2	3	–0.200	0.218	0.631#
SpO_2 10 min	1	2	0.225	0.238	0.612#
	1	3	0.200	0.238	0.678#
	2	1	–0.225	0.238	0.612#
	2	3	–0.025	0.238	0.994#
SpO_2 15 min	1	2	0.000	0.202	1.000#
	1	3	–0.125	0.202	0.810#
	2	1	0.000	0.202	1.000#
	2	3	–0.125	0.202	0.810#
SpO_2 30 min	1	2	0.350	0.218	0.247#
	1	3	0.150	0.218	0.771#
	2	1	–0.350	0.218	0.247#
	2	3	–0.200	0.218	0.630#
SpO_2 45 min	1	2	–0.450	0.229	0.126#
	1	3	–0.150	0.229	0.790#
	2	1	0.450	0.229	0.126#
	2	3	0.300	0.229	0.393#

* statistically significant difference ($p < 0.05$).
** statistically highly significant difference ($p < 0.01$).
# non significant difference ($p > 0.05$).

In this study, none of the subjects experienced any untoward reaction, local and/or systemic in the immediate and late post-operative periods. None of the grp1 subjects developed any sign of hyperkalemia.

Conclusion

It can thus be concluded that KCl is inert, causes no local &/or systemic adverse effects when injected with lignocaine in physiologically acceptable amounts. The effectiveness of KCl-lignocaine is comparable to Lignocaine-Adr and causes no hemodynamic alterations. However, significant advantage of KCl-lignocaine over Lignocaine-Adr is shorter onset of action.

Future scope

In this study, freshly prepared KCl-Lignocaine solution was used. In future, clinical studies may be designed to evaluate stability and shelf-life of the mixture.

Keeping in view that physiological amounts of KCl used doesn't cause any hemodynamic changes, clinical studies with ASA-2,3 AND 4 patients may be designed to further establish its safety.

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Ethical Approval

Ethical Approval was not required.

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