
**“COMPARISON OF LOCAL ANESTHETIC
EFFICACY OF 5 % TRAMADOL HYDROCHLORIDE
(WITH ADRENALINE) AND 2 % LIGNOCAINE
HYDROCHLORIDE (WITH ADRENALINE) IN
EXTRACTION OF A TOOTH : A SPLIT MOUTH
RANDOMIZED CONTROLLED STUDY”**

By

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MASTER OF DENTAL SURGERY

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(BRANCH III)

Under the guidance of

Dr. ARATI NEELI MDS

Reader

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY

KAHER's V K INSTITUTE OF DENTAL SCIENCES

BELAGAVI, KARNATAKA

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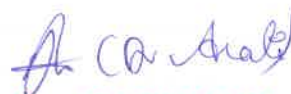
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LIST OF ABBREVIATIONS USED

RCT : ANDOMISED CONTROL TRIAL

HCL : HYDROCHLORIDE

OMFS : ORAL AND MAXILLOFACIAL SURGERY

ABSTRACT

Introduction

Local anaesthetics are widely used in dental practice for pain control while performing oral surgical procedures. Lignocaine is one of the commonly used anaesthetic and considered as gold standard. Since past two decades tramadol has also shown to have local anaesthetic effect similar to lignocaine. Tramadol can be good alternative to lignocaine if tramadol has similar anaesthetic efficacy as that of lignocaine where patients are allergic to lignocaine. In present study, we are comparing local anaesthetic efficacy of 5 % tramadol hydrochloride with adrenaline and 2 % lignocaine hydrochloride with adrenaline for extraction of maxillary tooth.

Aim of study

To compare anaesthetic efficacy of 5 % tramadol hydrochloride with adrenaline and 2% lignocaine hydrochloride with adrenaline when used as local anaesthetic by a method of infiltration.

Materials and method

Split mouth randomised controlled study done on total 32 patients, where each patient received 5 % tramadol hydrochloride infiltration on one side and 2 % lignocaine hydrochloride infiltration on another side for maxillary tooth extraction by a method of infiltration. Onset of action, duration of action and intraoperative pain were assessed and compared.

Results

There was no significant statistical difference in onset of action between 5% tramadol with adrenaline and 2 % lignocaine with adrenaline . There was no statistically significant difference in duration of action between both groups and also no significant statistical difference in VAS of intraoperative pain in both the groups.

Conclusion

Tramadol has similar anaesthetic efficacy as that of lignocaine when used with adrenaline by a method of infiltration in maxillary teeth extraction. Thus Tramadol can be a good alternative to lignocaine where patients are allergic to lignocaine.

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INTRODUCTION

Dental extraction is one of the most common procedure that dentist perform in daily practice. Most of the patients avoid visiting dentist due to fear of pain. For smoother extraction experience the procedure should be pain free to reduce anxiety or fear of procedure. Local anesthetics are being used by dental practitioner to carry out different surgical procedures. Local anesthetics drugs was been introduced to control pain during surgical procedures . Local anesthetics are the drugs which cause reversible loss of sensation as they block the sodium channels in membrane of the neurons hence reduce sodium influx and inhibit firing threshold¹.

Cocaine was the first anesthetic drug introduced, after that many anesthetic drugs were introduced such as lignocaine, mepivacaine, bupivacaine. Drugs such as antihistamines, anticonvulsants, alcohol and analgesic also shown anaesthetic effect according to bennett¹. Although many drugs were developed as local anesthetics but due to some considerable adverse effects researcher has looked for more safer anesthetic agent, so only few drugs are used presently. Lignocaine is amide and one of the most widely used anesthetic and considered to be one of the safest among others due to its low systemic toxicity that is why it is considered as a gold standard local anesthetic¹. Apart from esters and amides, opioids have also shown local anesthetic property. Tramadol belongs to synthetic opioid of samincyclohexanol group and centrally acting analgesic selective for opioid μ receptor. Studies have shown that tramadol has local anesthetic effect equivalent to lidocaine². Tramadol has neurotransmitter blocking effect on nerves (peripheral) by producing antinocieptive effect and interacting peripherally with opioid receptors.

Tramadol HCl was critically pre-reviewed by world health organisation in year 1992 and 2006 and concluded that tramadol has minimal degree of abuse, even after the considerable increase in use of the tramadol for therapeutic purpose². Since past 20 years, many researchers have documented tramadol HCl has same local anesthetic property compared to the lidocaine HCl, advantage being that it also provides post-operative analgesia³. Tramadol was first used intraorally in 2013 as local anesthetic for removal of tooth. After this very few clinical trials was done to evaluate effectiveness of tramadol HCl as intraoral anesthetic. Tramadol is easily available drug, less expensive and has minimal side effects therefore it can be a used as an alternative anesthetic drug.

In recent literature tramadol was used along with adrenaline for local anaesthetic purpose^{2,4}. Adrenaline was used as it is vasoconstrictor which confines the solution within infiltration area so duration of the action of local anesthetics also increases, adrenaline also reduces systemic toxicity of solution. Multiple local and regional anesthesia techniques are used in dental practice. One of the commonly used technique is local infiltration for maxillary teeth extraction.

Hence, in our study we are comparing local anaesthetic effectiveness of 5% tramadol HCl (with adrenaline 1: 80000) and 2% lignocaine HCl (with adrenaline) (1: 80000) for extraction of maxillary teeth using maxillary infiltration technique.

AIMS AND OBJECTIVES

Aims :

- To assess and compare anaesthetic efficacy of local infiltration of 5% tramadol HCl with adrenaline and 2% lignocaine hydrochloride with adrenaline when used as anesthetic.

Objectives of study:

- To compare and assess the onset of 5% tramadol HCl with adrenaline and 2% lignocaine HCl with adrenaline
- To assess and compare the duration of 5% tramadol HCl with adrenaline and 2% lignocaine HCl with adrenaline.
- To assess and compare the intraoperative pain after infiltration of tramadol and lignocaine.
- To assess and compare side effect after administration of tramadol HCl and lignocaine HCl.

NULL HYPOTHESIS:

There is no significant difference in efficacy of 5% tramadol hydrochloride when compared with 2% lignocaine hydrochloride when used as an anesthetic

ALTERNATIVE HYPOTHESIS:

There is significant difference in efficacy of 5% tramadol hydrochloride when compared with 2% lignocaine hydrochloride when used as an anesthetic .

REVIEW OF LITERATURE

Dr. Madhumita et al, conducted study in 2018 on comparison of anesthetic effectiveness tramadol HCl with lidocaine locally in complicated tooth extraction. In this double blinded study in patient required maxillary teeth extraction bilaterally by close technique, they divided patient in tramadol group and lignocaine group. Each group received infiltration with 5% tramadol and 2% lignocaine with 1: 80000 adrenaline respectively. In conclusion they found tramadol HCl may be substitute for lidocaine in terms of onset, total duration, intra op pain and post op complication. It also showed several advantages like slight shorter duration of action and negligible need of post op analgesia².

U sivakalyan et al in 2019 conducted study on effectiveness of tramadol HCl as local anaesthetic and analgesic agent for maxillary teeth extraction. Over 90 patients between October 2017 to August 2019. In conclusion they found that one ml of 50 mg tramadol when used for infiltration was effective as anaesthetic for maxillary teeth removal. Also it has provided good post op analgesia for 24 hours post extraction³.

- Yahya Alhaideri in 2010 conducted study where they compared effectiveness of plain tramadol HCl versus tramadol along (with adrenaline) for removal of teeth in the maxilla. In conclusion it was found that there was significant difference between both groups in terms of volume of local anaesthesia solution used as anaesthetic also in level of intra op pain on vas. Tramadol HCl with adrenaline provided better anaesthesia and extraction was less painful for maxillary teeth. Plain tramadol produced weak local anaesthesia whereas tramadol along with adrenaline anaesthesia was more

effective for maxillary teeth removal . They concluded that tramadol along with adrenaline may be a very good substitute to the other local anaesthetic drugs used in oral and maxillofacial surgery⁴.

- Manu goel et al in 2020 checked local anaesthetic effectiveness of lignocaine hydrochloride and tramadol in removal of firm teeth. In study intraop pain was assessed in tramadol and lignocaine group using vas .in study, both groups received infiltration of 1.8 millilitre of tramadol and lignocaine HCl respectively.VAS score for lignocaine group was 0.71 and vas score for tramadol group was 1.21. In conclusion they found that lignocaine HCl has more potent anesthetic effect than tramadol HCl .higher volume of tramadol is necessary to obtain desired anaesthesia . Also tramadol may be used as alternative where patient are allergic to lignocaine¹.
- Dr.madhumita et al in 2019 did study on tramadol HCl: a prospective local anesthetic drug. They checked anaesthetic effectiveness of tramadol HCl along with adrenaline. Study was done on thirty nine patients undergoing several maxillofacial surgical treatments.

They evaluated pain on injection, total onset of action, post op analgesia and total duration of anesthesia . They concluded that tramadol HCl is good substitute for local anaesthesia in oral and maxillofacial surgery when used along with adrenaline. Tramadol's both anesthetic and analgesic property could be "beneficial" for prolonged surgical procedures. Petardanic et al in 2017 did study on new findings of local tramadol use in oral surgery. They evaluated local effect of tramadol in study .they found in study that tramadol has anaesthetic as well as analgesic effect when administered locally⁵.

- H. Altunkaya et al. have done research in 2003. In which they assessed the anesthetic effectiveness of tramadol. Tramadol HCl was compared with prilocaine for minor surgeries under local. Study was done on 60 patients for cutaneous lesions removal under local anesthesia. Patients were randomly allotted to two groups, group a received 5% tramadol HCl and group b received 2% prilocaine intradermally. Burning sensation and tenderness over injection site was evaluated during treatment, and they have found that there is no major difference in the side effects of tramadol and prilocaine HCl. And also tramadol showed very similar anesthetic effect as that of prilocaine⁶.
- Dr. Darshalkumar et al. have done prospective randomized controlled trial in 2020. They compared anaesthetic effectiveness of tramadol HCl and lignocaine HCl for surgical removal of impacted 3rd molar. Total 40 patients were included and divided in two equal groups. First group received 2.5ml tramadol with adrenaline and in 2nd group lignocaine with adrenaline given. Onset and total duration of anesthesia, allergic effects, side effects, need of post op painkillers, total amount of anesthetic agents, time of the surgery and intra op pain was assessed in both the groups and they noticed there was no difference between lignocaine and tramadol as an anesthetic agents. So tramadol HCl can be used as another choice of anesthetic agents when patient is allergic to xylocaine⁸.
- Tahani et al. also did comparative study on local anesthetic effectiveness of lidocaine and tramadol along with epinephrine. Study was done on 124 patients undergoing minor oral surgical procedures. Patients were divided in two groups i.e. Tramadol and lidocaine group. They checked onset of action, total cartridges used, duration and degree of pain. In conclusion they

mentioned that anaesthetic effectiveness of tramadol were similar to lidocaine in term of onset, total cartridges and intraoperative pain, although duration of anaesthesia was significantly longer in lignocaine group⁹.

MATERIALS AND METHODS

STUDY DESIGN:

An In-Vivo Comparative Study (A randomized control trial)

This study will be conducted in KAHER'S KLE V. K. Institute of Dental Sciences, Belagavi.

In Department of Oral & Maxillofacial surgery.

INCLUSION CRITERIA:

Patients requiring extraction of multiple teeth in either side of maxilla.

Patient willing to undergo extraction of teeth.

EXCLUSION CRITERIA:

Teeth with periapical infections.

Patient on anti-depressant drug.

Patients with allergy to tramadol or lignocaine.

Patients on antiepileptic drug.

INVESTIGATIONS:

Hemoglobin

Bleeding time

Clotting time

Random blood sugar

Blood pressure

ARMAMENTARIUM:

2% Lignocaine hydrochloride

5% Tramadol hydrochloride .

Adrenaline ampule

Syringes

Extraction forceps

Gloves

Periosteal elevator

STUDY DESIGN:

An in-vivo split mouth randomized controlled study

Methodology

Patients requiring bilateral maxillary teeth extraction were selected for study.

Study was done on total 32 patients.

It was split mouth randomised controlled study, so all 32 patients were supposed to receive tramadol HCl (5 % with adrenaline) on one side and Lignocaine HCl (2 % with adrenaline) on other side .

On basis of computerised generated randomisation it was decided wheather patient will receive lignocaine first or tramadol first.

After randomization, patient was selected and test dose of tramadol and lignocaine was given.

After test dose, patients received lignocaine or tramadol infiltration depending on randomised generated list.

After infiltration, onset of action was checked using stopwatch and by using sharp probe every 5 seconds at injection site on attached gingiva by asking patients that whether they experienced pain. After checking onset, duration of action was checked by using sharp probe every 5 minutes till reversal of anaesthesia. After infiltration tooth extraction was performed and intraoperative pain was recorded on visual analogue scale. After checking all the parameters , post operative instruction was given to patient and recalled after 3 days for extraction of remaining opposite quadrant maxillary tooth and same procedure was repeated on another side . (If patient had received lignocaine infiltration on first appointment then he will receive tramadol infiltration on next appointment on the another side.)

EVALUATION CRITERIA

- Onset of anesthesia was checked by clinical examination and stop watch.
- Duration of anesthesia was checked by clinical examination and stop watch.
- Intraoperative pain was assessed by visual analogue scale.

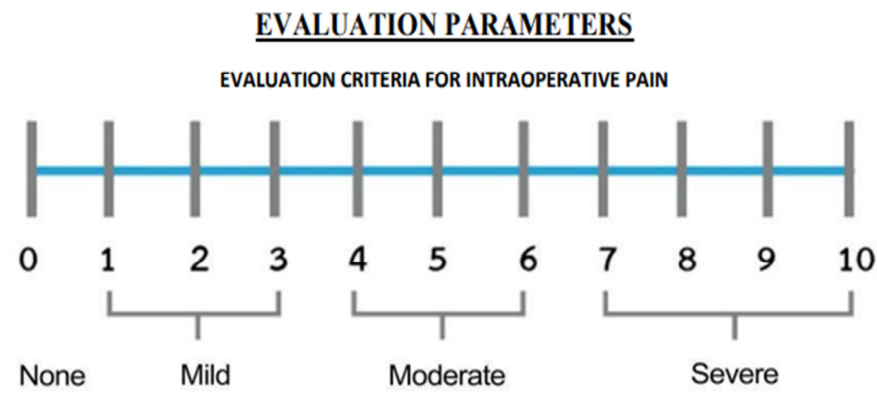


FIGURE 1: VISUAL ANALOGUE SCALE



FIGURE 2: ARMAMENTARIUM



FIGURE 3: TRAMADOL HCL WITH ADRENALINE INFILTRATION



FIGURE 4 LIGNOCAINE HCL WITH ADRENALINE INFILTRATION



FIGURE 5: LIGNOCAINE HCL WITH ADRENALIN INFILTRATION



FIGURE 6: TRAMADOL HCL WITH ADRENALINE INFILTRATION

RESULTS

This study was done on total 32 patients, it was split mouth study where each patient received 5% tramadol HCl (with adrenaline) on one side and 2 % lignocaine HCl (along with adrenaline) on another side for maxillary teeth extraction using infiltration technique.

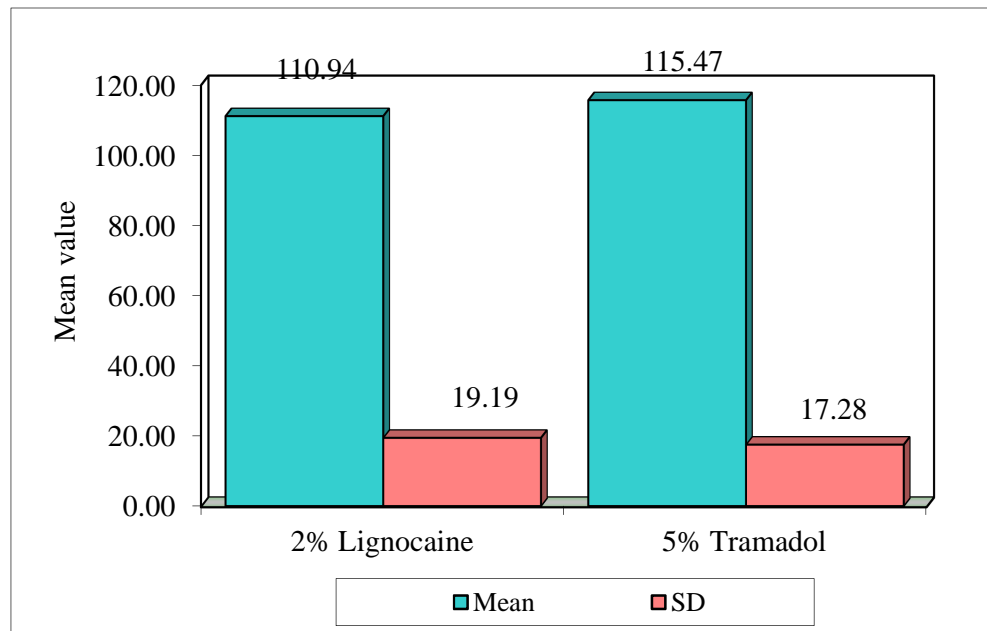
Onset of action, pain intraoperatively and duration of action were noted in both tramadol and lignocaine groups and compared and subjected to statistical analysis. Results after statistical analysis of our study were obtained as following.

Table 1: Comparison of onset of action (seconds) of lignocaine HCl (2% with adrenaline) and tramadol HCl (5% with adrenaline) by dependent t test.

Drugs	Mean	Sd	Mean diff.	Sd diff.	% of change	Paired t	P-value
2% lignocaine	110.94	19.19					
5% tramadol	115.47	17.28	-4.53	10.49	-4.08	-2.4433	0.204

Mean onset of action of lignocaine was 110.94 seconds while that of tramadol was 115.47 seconds.

In term of onset of action, difference was statistically non significant between tramadol group and lignocaine group .

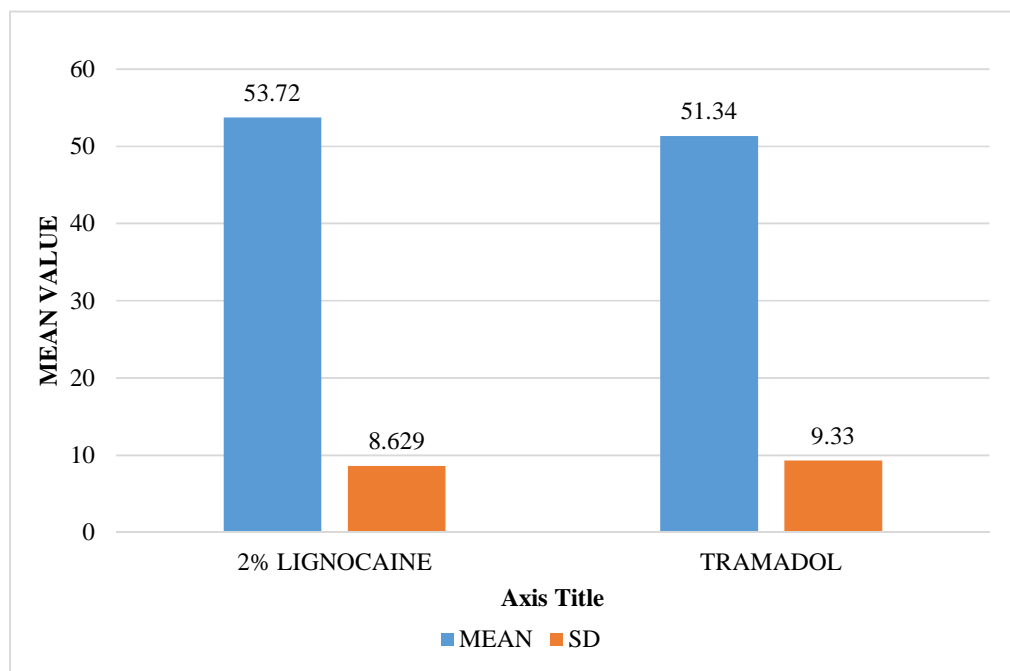


Graph 1: Comparison of 2% lignocaine HCl and 5% tramadol HCl with onset (sec)

Table 2: Comparison of duration of action (minutes) of 2% lignocaine HCl and 5% tramadol HCl with adrenaline (min) by dependent t test

Drugs	Mean Mins	Sd	Mean diff.	Sd diff.	% of change	Paired t	P-value
2% lignocaine	53.72	8.629					
5% tramadol	51.34	9.33	2.38	0.71	4.43%	1.057	0.294

Mean duration of action of lignocaine was 53.72 minutes while mean duration of action of tramadol was 51.34 minutes. Difference in terms of duration of action was statistically not significant between tramadol and lignocaine groups .

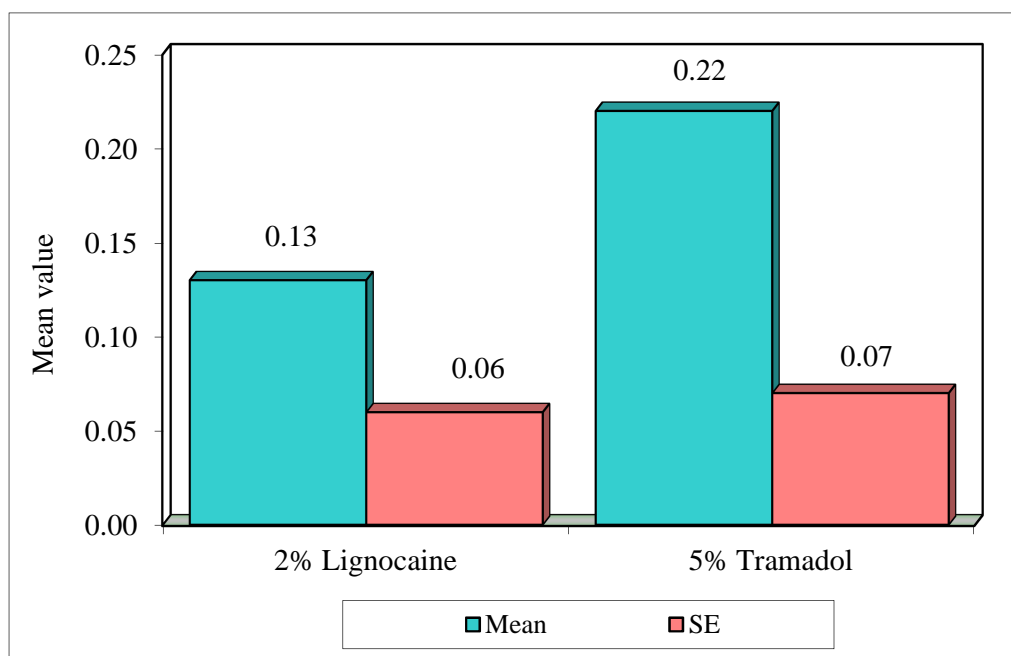


Graph 2: Comparison of “duration of action of 2% lignocaine hydrochloride” and 5% tramadol HCl

Table 3: Comparison of pain (VAS) 2% lignocaine hydrochloride and 5% tramadol hydrochloride by wilcoxon matched pair test

Drugs	Mean	Sd	Mean diff.	Sd diff.	% of change	Z-value	P-value
2% lignocaine	0.13	0.34					
5% tramadol	0.22	0.42	-0.09	0.47	-75.00	1.0142	0.3105

Mean VAS score of intraoperative pain for lignocaine was 0.13 while that for tramadol was 0.22 . In term of VAS of pain, there was no significant statistical difference between tramadol and lignocaine groups.



Graph 3: Comparison of vas of intraoperative pain of 2% lignocaine HCl and 5% tramadol HCl .

DISCUSSION

Use of effective anesthetic drug to carry out painless oral surgical procedures is very important as many patients avoid visiting dentist due to the fear of pain or any previous painful experience. Proper use of anaesthetic drug and technique provides good anaesthesia. Ideal anaesthetic drugs should have good duration of action, it should be non toxic or non irritant, it should have least systemic or local complications and anaesthetic drugs should be reversible.

Many anaesthetic drugs have been discovered since last decade such as amide or ester group of local anaesthetics, but none of the anaesthetic drug have post operative analgesic effect, also anaesthetic drugs has shown some amount of systemic toxicity and allergic reaction. Anaesthetic drugs having post operative analgesic property will be beneficial for managing post operative pain and discomfort. Since many decades opioid analgesics have been used as one of the first choice drugs for moderate to severe pain management.

In recent studies opioids have shown local anaesthetic effect and tramadol additionally has low addiction rate³. Many researchers have shown that tramadol has shown local anesthetic efficacy similar to lidocaine for more than 20 years because of its neurotransmitter blocking effect on peripheral nerves by interacting with the peripheral opioid receptors and it produces antinociceptive effect². Studies have shown that adding adrenaline to tramadol increases its effectiveness and duration of action. Tramadol alone has reported to be slight weaker anaesthetic if compared to lignocaine. 5 % tramadol with adrenaline has almost equal duration of action and local anaesthetic effect as of 2 % lignocaine with adrenaline. Tramadol also has

analgesic property which makes it beneficial for extraction of simple mobile tooth³. In comparative study between tramadol and lignocaine by manu goel et al mentioned that tramadol HCl is weaker local anaesthetic compared to lignocaine. Drugs with higher pka values are comparatively weaker anaesthetic¹

In our study, mean onset of action of lignocaine was 110.94 seconds while that of tramadol was 115.47 seconds. Difference in onset was statistically insignificant between both tramadol and lignocaine groups. In siva kalyans study, they found that mean onset of action of plain tramadol without adrenaline was 4.5 minutes. Al-haideri ya in his study found that mean onset of action of tramadol hydrochloride was 3.41 minutes. Jendi sk and talathi in study found that mean onset of tramadol was 2.86 minutes⁴.

Dr. Madhumita srivastava, found that difference was statistically insignificant between tramadol and lignocaine in term of onset of action⁵. Edge et al in their comparative study found that mean onset of tramadol was 43.26 second while that for lignocaine was 32.34 seconds⁹. Difference was statistically not significant between tramadol and lignocaine in term of onset. Onset of action was less than other studies because of use of adrenaline in tramadol which is vasoconstrictor that confines the solution in the area of infiltration⁴.

Use of vasoconstrictor along with tramadol lowers the onset of action⁴. Most of the studies in literature shown that tramadol has slight lower onset of action^{2,3,4,1}.

In our study, the mean duration of action of lignocaine was 53.72 minutes while mean duration of action of tramadol was 51.34 minutes. Duration of action was similar in tramadol and lignocaine group. Difference was statistically not significant

between both tramadol and lignocaine groups in terms of duration of action. Lignocaine group experienced slight longer duration of anaesthesia .

Dr. Madhumita srivastava, et al found that, there was notable statistical difference in between tramadol and lignocaine group in term of duration of action, lignocaine group patients have experienced longer duration of action than tramadol. They have also mentioned that mean time taken by tramadol group (169.8 minute) to experience pain was higher than lignocaine group (26.7 minute) which shows tramadol has post op analgesic property⁵.

Study done by U siva kalyan et al mentioned mean duration of action of tramadol in maxillary infiltration was 40.14 minutes³. Edge at al stated in his study that, tramadol and lignocaine groups showed similar results in term of duration of action. They also checked soft tissue anaesthesia after giving infiltration anesthesia , reference points on the attached gingiva were checked by probe *in the soft tissue* at the infiltration site.

They found significant *difference in the effectiveness for gingival anesthesia (sensory innervation) at 10 minutes between both the groups*⁹. There was a statistically significant difference between tramadol and lignocaine group at 15 and 30 minutes when study was done on skin and tramadol was more effective at these times. Alsandook and al-haideri ya and et al., conducted study where they compared the duration of the action of tramadol along with adrenaline to lignocaine along with adrenaline and found that, the mean duration of tramadol was 117.38 minutes and 153.14 minutes for lignocaine⁴. Shoeb kasim jend found that 55.60 mins the average duration of time for tramadol and that for lignocaine found to be 57.50 mins which was statistically insignificant.

In our study, mean VAS score of intraoperative pain for lignocaine was 0.13 while that for tramadol was 0.22, which was statistically insignificant. Out of 32 patients who received tramadol infiltration, 5 patients experienced mild pain during procedure and out of 32 patients who received lignocaine infiltration, 4 patients experienced mild pain. Overall both the drugs provided good anaesthesia in our study with slight better pain free experience in lignocaine group.

In Siva Kalyans study on tramadol as anaesthetic agent, mean vas of pain score for anterior extraction was 0.41 while that of posterior was 2.54 which shows patient undergoing extraction of posterior maxillary tooth, experienced more pain than anterior in tramadol group³.

Shoeb Kasim Jend mentioned in his study that, the difference between 2 groups for pain were considerable i.e. Tramadol and lignocaine group. Tramadol group experienced more intraop pain as compared to lignocaine group and difference in pain was significant.

Dr. Madhumita srivastava, in their study found there was no statistically significant difference between both the groups (i.e. Tramadol group and the lignocaine group) in terms of VAS of pain⁵. 7 patients of tramadol group and 9 patients of lignocaine group had mild pain.

In our study, none of the patients showed any complications in tramadol group except for one patient who complained nausea 10 minutes after tramadol injection. Sensation of nausea cannot be directly attributed to the effect of tramadol but could be because of stress.

Tramadol HCl was critically pre-reviewed by world health organisation in 1992 and 2006 and concluded that tramadol has minimal degree of abuse, even after the considerable increase in the use of tramadol for therapeutic purpose (a). Some literature has shown overdosing or some systemic toxicity of opioids, but opioids overdose can be reversed by nalaxone (a).

CONCLUSION:

In our study, we have found that ,there was no significant difference between 5% tramadol HCl along with adrenaline as that of 2% lignocaine HCl along with adrenaline when used as infiltration anaesthesia in maxillary teeth extraction for onset of action . When VAS of intraoperative pain and duration of action were compared between both the groups,,lignocaine has slight longer duration of action as compared to tramadol. Also depth of anaesthesia was almost equal in both the group as most of the extraction were painless .

It concludes that tramadol HCl can be a good alternative to lignocaine HCl for maxillary teeth extraction where patients are allergic to lignocaine .


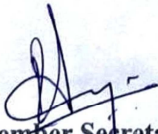

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ANNEXURE – II

BIOSTATISTIC CLEARANCE CERTIFICATE

Scientific Correspondence and Review Committee	
KLE VK Institute of Dental Sciences	
	A Constituent Unit of KLE Academy of Higher Education and Research (Deemed-to-be-University u/s 3 of the UGC Act, 1956) Nehru Nagar, Belagavi - 590 010, Karnataka State Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
☎: 0831-2470362 FAX: 0831-2470640	Web: http://www.kledental-bgm.edu.in E-mail: principal@kledental-bgm.edu.in
Date : 3.3.2022	Serial No. : 102
PLAGIARISM CHECK REPORT	
Name of the Applicant : DR. AJIT. POWAR UG / PG / Ph.D / Staff : POSTGRADUATE Batch & Year : 2019-22 Department : ORAL AND MAXILLO FACIAL SURGERY	
The soft copy of Research Work / Manuscript by DR. AJIT. POWAR entitled "COMPARISON OF LOCAL ANESTHETIC EFFICACY OF 5% TRAMADOL HYDROCHLORIDE (WITH ADRENALINE) AND 2% LIGNOCAINE HYDROCHLORIDE (WITH ADRENALINE) IN EXTRACTION OF TROTH. ASPLIT MOUTH. RANDOMIZED CONTROLLED STUDY."	
under the guidance of ...DR. ARATI. NEELI.....has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.	
The scan has been carried out and the scanned output reveals a Similarity Index of3.....%, which is <u>within</u> / not within the acceptable limits of 10% as per the UGC guidelines.	
 Member Secretary Scientific Correspondence and Review Committee KLEVK Institute of Dental Sciences KAHER-Belagavi	 Chairman Scientific Correspondence and Review Committee KLEVK Institute of Dental Sciences KAHER - Belagavi

ANNEXURE – III

PLAGIARISM CHECK CERTIFICATE



KLE V.K. Institute of Dental Sciences

(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi-590 010 INDIA

Re-Accredited 'A' grade by NAAC (2nd Cycle) & Placed in Category 'A' by MHRD (GoI)

Phone : 0831-2470362
FAX: 0831-2470640

Web: <http://www.kledental-bgm.edu.in>
E-mail: principal@kledental-bgm.edu.in



Biostatistics Clearance Certificate

This is to certify that the Biostatistics aspect of the Dissertation / Research work of Dr. Ajit kashinath powar , Post Graduate Student, Department of oral and maxillofacial surgery under the guidance of Dr. Arati neeli M.D.S, Reader, Department of oral and maxillofacial surgery , entitled “COMPARISON OF LOCAL ANESTHETIC EFFICACY OF 5% TRAMADOL HYDROCHLORIDE (WITH ADRENALINE) and 2% LIGNOCAINE HYDROCHLORIDE (WITH ADRENALINE) IN EXTRACTION OF TOOTH : SPLIT MOUTH RANDOMIZED CONTROLLED STUDY” has been done under my guidance and considered satisfactory.

Place: Belagavi

Date: 4-1-22

Name & Signature of Biostatistician

CDR. S. B. Javali

ANNEXURE IV

PATIENT INSTRUCTION PERFORMA

DEPARTMENT OF ORAL & MAXILLOFACIAL SURGERY.

KLE V.K INSTITUTE OF DENTAL SCIENCES, BELAGAVI.

**COMPARISON OF LOCAL ANESTHETIC EFFICACY OF 5% TRAMADOL
HYDROCHLORIDE (WITH ADRENALINE) AND 2% LIGNOCAINE
HYDROCHLORIDE (WITH ADRENALINE) IN EXTRACTION OF A TOOTH
: A SPLIT MOUTH RANDOMIZED CONTROLLED STUDY**

My name is Dr. Ajit Powar. I am Post Graduate student in the Department of Oral & Maxillofacial Surgery, KLE V.K. Institute of Dental Sciences, KAHER, Belagavi. I am doing this study to evaluate the efficacy of tramadol hydrochloride as a local anesthetic agent with lignocaine hydrochloride . Adrenaline will be added to both tramadol hydrochloride & lignocaine hydrochloride for extraction of teeth.

Signature of the Participant _____ Date _____

Signature of Investigator _____ Date _____

रुग्णसूचनापरफॉर्म

ओरल आणि मॅक्सिलॉफोसेकल सर्जरी विभाग

के. एलईव्ही. के. दंत विज्ञान विज्ञान संस्था, बेलागावी.

दूध एक्सट्रॅक्शनमध्ये २% टरॅमाडॉल पायडर ओक्लोराइड (एड्डर नलाइनस) आडि

२% इलप्रोकार्बिन पायडर ओक्लोराइड (एड्डर नलाइनस) लोकल एनेस्टेटिक

एफकॉक्सी

माझे नाव डॉ. [] इति पोवार आहे. मी ओरल एंड मॅक्सिलोफेडिसयल सर्जरी, के. एलईव्ही. के. मधील पदव्युत्तर इवद्याथी आहे. दंत इवज्ञान संस्था, के. ए. आर., बेलागावी. इलप्रोकेन पायडर ओक्लोराइड [] सलेल्या स्थाइनक भूल देणारा एट म्हीन टर [] माडॉल पायडर ओक्लोराइडच्या कायजक्षमतेचे मूल्यांकन करण्यासाठी मी [] अभ्यास करत आहे. दात काढण्यासाठी टरॅमाडॉल पायडर ओक्लोराइड आडि इलप्रोकेन पायडर ओक्लोराइड या दोघांमध्ये रेनडरेनालाईन िोडली िाईल.

संभागीची संपी _____ तारीख _____

[] न्वेषकांची स्वाक्षरी _____ तारीख _____

ANNEXURE-III

CONSENT FORM:

DEPARTMENT OF ORAL & MAXILLOFACIAL SURGERY

K.L.E.S. INSTITUTE OF DENTAL SCIENCES, Belgaum.

I, _____

Address: _____

Doctor's name: _____

The doctor has informed me about the suturing procedure and my involvement in it.

1. I agree to give my personal details like name, age, sex, address, medical history, previous dental history and the details required for the study to the best of my knowledge.

2. I will cooperate with the dentist for my internal and external examination.

3. I will follow the instructions given by the doctor during the treatment and take medications prescribed.

4. If the prognosis is poor, because of my tissue condition, I will not hold the dentist responsible. Anyhow the dentist can make alternative treatment plan to improve the prognosis.

5. I will pay the treatment charges to K.L.E.S. Institute of Dental Sciences, Belgaum at the reception counter and collect receipt of the same.

6. I will visit the dentist as and when required for the treatment, as the given appointments (date and time).

7. I permit the operator to utilize the information given by me and result obtained from this study for presentation and publication.

8. I permit the doctor to take my intraoral extraoral photographs to utilize for the study purpose, if required.

9. I will not claim any returns for my cooperation in the study, even if it is being sponsored by an agency. I am participating with my own will and wish for the betterment of the community.

10. If for any reason I am unable to participate in the study, for reasons unknown, I can withdraw from, the study. I have read, gone through and understood the above information given by the doctor. I have entered & signed this application.

Dentist's name: _____

Address: _____

Phone No: _____ Mobile No. _____

Dentist's signature:

Patient signature

Witness: _____

Date:

Place:

ಒಪ್ಪಿ ಗೆಪತ್ರ:

ಮೌಖಿಕ ಮತ್ತು ಮಾಸ್ಕಿ ಲೋಫೇಶಿಯಲ್ ಯೋಜನಾ ಅಧಿಕಾರಿ

ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಇನ್ಸ್ಟಿಟ್ಯೂಟ್ ಆಫ್ ಟೆಕ್ನಾಲಜಿ, ಬೆಂಗಳೂರು

ನಾನು,

ವೆಳಾಸ:

ವ್ಯವಸ್ಥಾಪಕರು:

ಹಲಿಗವಿಧಾನಮತತು ಅದರಲಿಲ ನನನ ಪಾಲೊಲೊ ಳಳಳ ವೆಕೆಯಬಗೊ ವ್ಯವಸ್ಥಾಪಕರು ರುನನಗೆಮಾಹಿತತನಸೋಡರ ದಯದ ರೆ.

1. ನನನ ವ್ಯವಸ್ಥಾಪಕರು ಕವೆವರಗಳಾದಹಸರು, ವಯಸಿ, ಲಿಂಗ, ವೆಳಾಸ, ವ್ಯವಸ್ಥಾಪಕರೊಯಇತತಹಾಸ, ಹೊಂದೆನಹಲಿಲ ನಇತತಹಾಸಮತತು ಅಧಿ ಯನಕೊ ಬೇಕಾದವೆವರಗಳನುನ ನನನ ಜಿಜಾ ನದಅತತು ತು ಮವಾಗೆನಸೋಡಲುನಾನುಒಪಪತು ಲೋನೆ.
2. ನನನ ಆಲೊಂತರಿಕಮತತು ಬಾಹಾ ಪರೊಲೊಕೆ ಗೆನಾನುದಂತವ್ಯವಸ್ಥಾಪಕರು ರೊಂದೆಗಿಸಹಕರಿಸುತು ಲೋನೆ.
3. ಚಿಕಸತಿ ಯಸಮಯದಲಿಲ ವ್ಯವಸ್ಥಾಪಕರು ರುನಸೋಡರದಸೂಚನೆಗಳನುನ ನಾನುಅನುಸರಿಸುತು ಲೋನೆಮತತು ಸೂ ಚಿಕಸತಿ ಅಧಿಗಳನುನ ತೆಗೆದುಕಳಳ ತು ಲೋನೆ.
4. ಮುನನ ರಿಮಕಳಪೆಯಾಗಿದದ ರೆ, ನನನ ಅಲೊಂಗೊಂಶದಸೆಧ ತತಯಕಾರಣ, ನಾನುದಂತವ್ಯವಸ್ಥಾಪಕರು ನನನ ಹಣಿಗರನನನ ಗೆಮಾಡುಮದೆಲಲ. ಹೇಗದರೂದಂತವ್ಯವಸ್ಥಾಪಕರು ಮುನನ ರಿವನುನ ಸುಧಾರಿಸಲುಪಯುಜಯಸಂಸೂ ರಣಾಘಟಕವ ನುನ ಮಾಡಬಹುದು.
5. ನಾನುಚಿಕಸತಿ ಯಶುಲೂ ವನುನ ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಇನ ಸೆ ಟಿಯು ಟಿಆಫಡ ಲೊಂಟಲಿ ಡೈನಿ ಸೆ, ಸತವ ಗತಕೊಂಟಲ ನಲಿಲ ಬೆಲೊ ಮಮ ತತು ಅದರರಶೊಡಿಯನುನ ಸಂಗಾ ಹೆಸೆ.

6. ನಸದಿಜಜಿ ನೇಮಕಾತಗಳಂತೆ (ದಿನಾಂಕಮತತು ಸಮಯ) ನಾನುದಂತವೈದಾ ರನುನ ಚಿಕಿತ್ಸೆ ಗೆಅಗತಾ ವಾದಯಗಭೇಟಿಮಾಡುತು ಲೋನೆ.
7. ನಾನುನಸೋಡರದಮಾಹಿತತಯನುನ ಮತತು ಈಅಧಾ ಯನದೇಂದಪಡದಫಲಿತೇಂಶವನುನ ಪಾ ಸುು ತತಮ ತತು ಪಾ ಕಟಣಿಗಿಬಳಸಿಕಳಲ ಲುಆಪರೇಟರ ಗೆನಾನುಅನುಮತತನಸೋಡುತು ಲೋನೆ.
8. ಅಗತಾ ವೆದದ ರೆ, ಅಧಾ ಯನದಲುಡದ ಲೋಶಕೂ ಗಿಬಳಸಿಕಳಲ ಲುನನನ ಇಲೊಂಟೆರಾ ರಲವಕೆ ಟೆರಾ ರಲ s ಾ ಯಾಚಿತಾ ಗಳನುನ ತೆಗೆದುಕಳಲ ಲುನಾನುವೈದಾ ರೆಗೆಅನುಮತತನಸೋಡುತು ಲೋನೆ.
9. ಅಧಾ ಯನದಲಿಲ ನನನ ಸಹಕಾರಕೂ ಗಿನಾನುಯಾಮದೇಆಡಯಯವನುನ ಪಡಯುಮದೆಲಲ , ಅದನುನ ಏಜನಸೆ ಪಾ ಯಲೋಜಿಸುತತು ದದ ರೂಸಹ. ನಾನುನನನ ಸವ ಲೊಂತಇಚಾ ಯಲೊಂದೆಗೆಭಾಗವಹಿಸುತತು ದದ ಲೋನೆಮತತು ಸಮುದಯಯದಸುಧಾರಣೆಗೆ ಗಿಬಯಸುತು ಲೋನೆ.
10. ಯಾಮದೇಕಾರಣಕೂ ಗಿನಾನುಅಧಾ ಯನದಲಿಲ ಭಾಗವಹಿಸಲುಸತಧಾ ವಾಗದೆದದ ರೆ, ಅಪರಿಚಿತಕಾರಣಗಳಗಿ, ನಾನುಅಧಾ ಯನದೇಂದಹೇಂದೆಸರಿಯಬಹುದು. ವೈದಾ ರುನಸೋಡರದಮೇಲಿನಮಾಹಿತತಯನುನ ನಾನುಓದೆಡದ ಲೋನೆ, ಹಲೋಗಿಡದ ಲೋನೆಮತತು ಅಶಜಮಾಡರಕೊಂಡರಡದ ಲೋನೆ. ನಾನುಈಅಪಲಲ ಕೇಶನಅನುನ ನಮೂದಿಸಿದದ ಲೋನೆಮತತು ಸಹಮಾಡರಡದ ಲೋನೆ. ದಂತವೈದಾ ರಹೆಸರು:

ವೆಳಾಸ: _____

ದೂರವಾಣಿಸಂಖಯಾ: _____ ಮೂಲಬೈಲಿ ಲೊಂಖಯಾ

ದಂತವೈದಾ ರಸಹೆ: ರಲೋಗಿಯಸಹೆ

ಸತಕಸೆ: _____

ದಿನಾಂಕ: ಸಧ ಳ:

संरमतीपत्र:

ओरल आणरिर्मॅक्सलिॅफोसेकल सर्जरीणभागा

के.एल.ई.एस. दंतणजिज्ञानसंस्था, बेळगा

मी,

पत्ता: _____

डॉक्टरचेनाव: _____

डॉक्टरांनीमलाटाके डचप्रड्याआडित्यामध्येमाझासंभागयाबद्दलमाड्तीडदलीआपे.

१. माझेवैयक्सिकतपशीलिसेकीनाव, वय, डलंग, पत्ता, वैद्यकीयइडतपास,

मागीलदंतइडतपासआडिं भ्यासासाठीआवश्यक सलेल्यातपशीलांनामाझ्यामाड्तीनुसारमी देण्याससंमतआपे.

२. मीतंगजतआडिंबाह्यपरीक्षेसाठीदंतडचडकत्सकांनासंकायजकरीन.

मीउपचारादरम्यानडॉक्टरांनीडदलेल्यासूचनांचेपालनकरेनवडलहूनडदलींिंिरीऔषधेघेईन.

The.

रिरोगडनदानकमकु वत संसेलतरमाझ्याऊतकांच्याक्सस्थतीमुळे

मीदंतडचडकत्सकांनािंबाबदारधरिरानापी.

रोगडनदानसुधारण्यासाठीदंतडचडकत्सकवैक्सिकउपचारपांंटबनवूशकतात.

I.

मीके.एल.ई.एस.लाउपचारशुल्कदेईन. इक्सिट्यूटऑफडेंटलसायन्सेस,

बेळगावररसेप्शनकाउंटरवरआडित्याचीपावतीगोळाकरते.

The.

डदलेल्यानेमिका (तारीखवेळ)

प्रमािंचेआडिंिंेव्हाउपचारआवश्यक सतीलतेव्हादंतडचडकत्सकांनाभेटदेऊ.

I.

मीऑपरेटरलामाझ्याद्वारेडदलेलीमाड्तीवापरण्यासआडिया भ्यासामधूनप्राप्तझालेल्यासादरी करिसाठी आडिंप्रकाशनासाठीवापरण्यासपरवानगीदेतो.

I.

आवश्यक सल्यास, मी भ्यासाच्या उद्देशासाठी माझे इंटर
ऑरल एक्स्टोरल फोटो काढण्यासाठी डॉक्टरांना परवानगी देतो.
मी भ्यासाच्या माझ्या संप्रकायजसाठी मी परताव्याचा दावा करारिनापी,
िरीती एखाद्या एन्सीने प्रायोडितके ली सेल. मी माझ्या इच्छे
नुसार संप्रभागी पोत आणे आडिसमा िाच्या उन्नतीसाठी शुभेच्छा देतो.

१०.

कोित्यापी कारिस्तवमी भ्यासामध्ये भाग घेण्यास संध ज सल्यास, ज्ञात कारिंमुळे
मी भ्यासातून माघार घेऊ शकतो. मी डॉक्टरांनी इदलेली वरील माडपीती मी वाचली आहे,
ती समिून घेतली आहे. मी ा नुप्रयोग प्रडवष्टके ला आणे आडित्यावर सपीके ली आहे.
दंतवैद्याचे नाव: _____

पत्ता: _____

फोन नंबर: _____ मोबाईल नंबर: _____

_____ दंतवैद्याची स्वाक्षरी: रुग्ंची सपी

उत्तर: _____

तारीख:

डठकाि:

ANNEXURE-IV
MASTER CHART

S NO	NAME	Age	Sex	ONSET (SEC)		DURATION (MIN)		VAS (VISUAL ANALOG SCALE)	
1	RAMESH PATIL	38	M	L-108	T-113	L - 70	T-66	L-0	T-0
2	SADA SHETKE	41	M	L-95	T-108	L - 66	T-70	L-0	T-0
3	NANDA GURAV	43	F	L-116	T-125	L - 61	T-56	L-0	T-1
4	PRATIDNYA K	28	F	L-110	T-98	L - 80	T-77	L-0	T-0
5	SAVITA SABLE	43	F	L-138	T-147	L - 48	T-45	L-0	T-0
6	VINAYAK PATIL	25	M	L-115	T-125	L - 48	T-51	L-1	T-0
7	ASHWINI SHINDE	33	F	L-87	T-98	L - 61	T-66	L-0	T-0
8	S. HIREMATH	52	M	L - 118	T-130	L - 52	T-40	L-0	T-0
9	RAMAPPA S	58	M	L-133	T-141	L - 58	T-55	L-0	T-1
10	BASU KAMBLE	47	M	L-178	T-156	L - 55	T- 52	L-0	T-0
11	SAGAR HATKAR	27	M	L-106	T-119	L - 57	T-49	L-0	T-0
12	LAKAPPA G	33	M	L-128	T-130	L - 63	T - 66	L-0	T-0
13	PRAVIN TANKATTI	38	M	L-137	T-146	L - 48	T-53	L-0	T-0
14	SURESH TIPPE	40	M	L - 95	T-101	L - 63	T - 53	L-1	T-1
15	BASALINGAPPA	56	M	L-122	T-110	L - 50	T-46	L-0	T-0
16	Siddhesh m	23	M	L - 119	T - 132	L - 53	T - 55	L - 0	T - 1
17	Dhanaji sutar	45	M	L - 122	T - 116	L - 55	T - 58	L - 0	T - 0
18	sumayya h	26	F	L - 88	T - 100	L - 41	T - 43	L - 0	T - 1
19	Rudrapa	39	M	L - 102	T - 110	L - 47	T - 41	L - 0	T - 0
20	Sarojini hiremath	48	F	L - 119	T - 113	L - 53	T - 49	L - 0	T - 0
21	Akash chavan	33	M	L - 101	T - 118	L - 59	T - 51	L - 0	T - 0
22	viramma hanchikatti	51	F	L - 108	T - 123	L - 47	T - 39	L - 0	T - 0
23	shivanand katti	51	M	L - 109	T - 116	L - 45	T - 42	L - 0	T - 0
24	Vishal gujjar	30	M	L - 113	T - 116	L - 43	T - 48	L - 1	T - 1
25	Aradhana dhenge	39	F	L - 100	T - 106	L - 52	T - 55	L - 0	T - 0
26	Kavita s	36	F	L - 112	T - 103	L - 47	T - 41	L - 0	T - 0
27	Jagdish h	43	M	L - 96	T - 101	L - 45	T - 43	L - 0	T - 0
28	Maruti g	41	M	L - 70	T - 88	L - 42	T - 46	L - 0	T - 0
29	Appana p	55	M	L - 99	T - 76	L - 50	T - 45	L - 0	T - 1
30	Satish gavkar	29	M	L - 103	T - 108	L - 56	T - 47	L - 1	T - 0
31	Virendra s	41	M	L - 105	T - 115	L - 55	T - 49	L - 0	T - 0
32	Dodappa mandakki	50	M	L - 98	T - 107	L - 49	T - 46	L - 0	L - 0