



# Awareness about local anaesthetic reversal agent among dental practitioners in MMR(Mumbai metropolitan region)-A Questionnaire Based cross-sectional survey

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## Abstract

Local anaesthetic drugs are one of the effective drugs in pain management procedures. Administration of local anaesthetic drugs is responsible for prevention of pain that arises during dental procedures. With the indispensable use of local anaesthetic agents, it is learned that its effect stays more than the time required for the dental procedure to be completed. Sometimes this prolonged soft tissue anaesthesia can be unnecessary. Local anaesthesia reversal agent is the drug of choice in cases where prolonged anaesthesia after a dental procedure is not needed.

Phentolamine mesylate essentially serves the purpose of quicker recovery from numbness at the site of local anaesthesia. Phentolamine mesylate reduce postoperative anaesthesia as well injuries that occur because of prolonged anaesthesia. Therefore the aim of this survey to create as well as assess the level of awareness about local anaesthetic reversal agent among dental practitioners in Mumbai metropolitan region.

**Keywords:** Local anaesthetic drugs, Phentolamine mesylate.

## 1. Introduction

Local anaesthetic drugs are one of the effective drugs in pain management procedures. Administration of local anaesthetic drugs is responsible for prevention of pain that arises during dental procedures. This effective management of pain has been effective in performing the necessary dental procedures successfully. The use of local anaesthesia over the years has benefited a lot of patients. With the continuous use of local anaesthetic agents, it is been known that its effect stays more than the time required for the dental procedure to be completed. Sometimes this prolonged soft tissue anaesthesia can be unnecessary.

## 2. Literature Review

Novalar is a pharmaceutical company behind a new injectable called phentolamine mesylate, otherwise known as OraVerse. This chemical is basically a vasodilator. It's packaged in the same type of carpules that you use every day in your practice.

Novalar has tested OraVerse through 20 university and private practice research centres across the country. They did randomised controlled double-blinded studies, on patients ranging from 4 to 92. They found that the average time it took for the patient's lip sensation to return back to normal was reduced by 55% in the maxilla, and by 62% in the mandible. Paediatric patients, age 6 to 11 experienced a 47% reduction in the maxilla and a 67% reduction in the mandible by the time it took to get back to normal lip sensation.

Originally, phentolamine has been in use for the diagnosis and treatment of patients with pheochromocytoma and for the treatment and the prevention of dermal necrosis following intravenous administration or extravasation of norepinephrine in the USA since 1952.

Phentolamine mesylate, marketed under the proprietary name OraVerse, was granted FDA approval on May 12, 2008 with an indication for the reversal of STA (lip and tongue numbness) and the associated functional deficits resulting from a local dental anesthetic containing a vasoconstrictor.

An intraoral submucosal injectable formulation of phentolamine mesylate was developed by Novalar Pharmaceuticals (San Diego, Calif., USA) to help terminate the numbing action of local anaesthesia when it is no longer desired. This product contains 0.4 mg phentolamine mesylate packaged in a 1.7-mL dental cartridge. Based on the results of two phase two and two phase three randomised placebo- or sham-controlled clinical trials (see Table 1 for description of FDA clinical trial phases), 7-9 phentolamine mesylate, under the proprietary name OraVerse (Septodont Inc., Lancaster, Pa., USA) was granted FDA approval in 2008 for accelerating the return of sensation and function following nonsurgical dental procedures requiring local anaesthetic plus epinephrine in adult and paediatric dental patients as young as six years old.

## 3. Objectives of study

To assess awareness of local anaesthetic reversal agent among dental practitioners in MMR (Mumbai metropolitan region).

## 4. Methodology

Exploratory research was done by reading available literature related to the topic. Available secondary data was also read.

A structured questionnaire was prepared with 11 relevant questions to cater to all areas and aspects of the study. This was used for primary data collection. Simple random sampling technique was applied in administering the questionnaire. The sample size was 384. The study was limited to Mumbai City.

The questionnaire was created using Google Forms and was disseminated via various social media platforms over a period of two months.

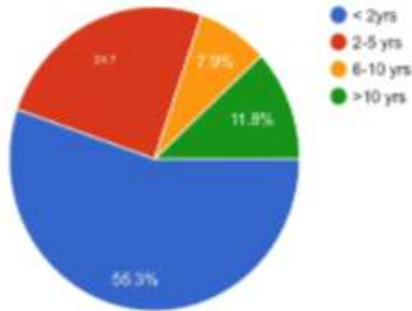
All the subjects taking part in the survey were informed about the purpose of conducting this survey and were also informed about the confidentiality of their responses.

Data obtained was compiled on a MS Office Excel Sheet. The tools used for statistical analysis include SPSS and Chi square.

**TABLE NO-2**

**How long have you been practicing dentistry?**

	Frequency	Percent
< 2yrs	214	55.7
>10 yrs	45	11.7
2-5 yrs	95	24.7
6-10 yrs	30	7.8
Total	384	100.0

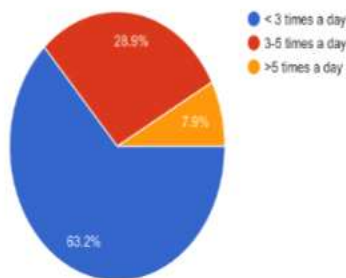


Based on the survey conducted in Mumbai city 55.7% dentists have a experience of <2 years whereas 7.8% dentists are practising since 6-10 years

**TABLE NO -3**

**How frequently do you use local anaesthetic?**

	Frequency	Percent
< 3 times a day	244	63.5
>5 times a day	30	7.8
3-5 times a day	110	28.6
Total	384	100.0

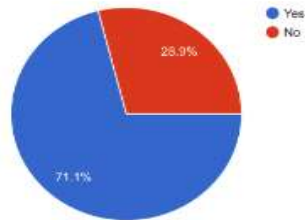


The data reveals that 63.5% dentists use LA <3 times a day whereas 28.6% dentists use LA between 3-5 times a day.

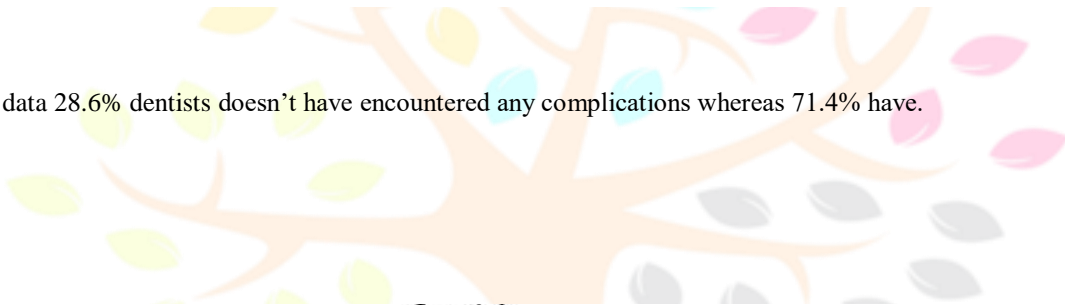
**TABLE NO -4**

Have you encountered any complications due to persistent anaesthesia?

	Frequency	Percent
No	110	28.6
Yes	274	71.4
Total	384	100.0



According to this data 28.6% dentists doesn't have encountered any complications whereas 71.4% have.



**Crosstab**

Count

		How frequently do you use local anaesthetic?			Total
		< 3 times a day	>5 times a day	3-5 times a day	
Have you encountered any complications due to persistent anaesthesia?	No	65	15	30	110
	Yes	179	15	80	274
Total		244	30	110	384

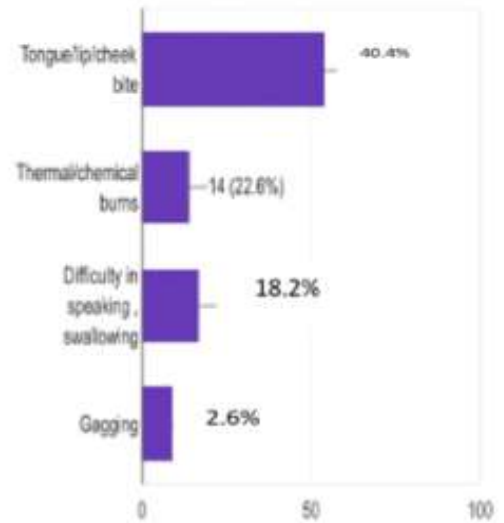
There was statistically significant difference seen for the frequencies between the groups  $p < 0.05$  with higher frequency for response yes with  $< 3/\text{day}$

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TABLE NO-5

**If yes, what are the complications you have encountered?**

	Frequency	Percent
	70	18.2
Difficulty in speaking , swallowing	15	3.9
Difficulty in speaking , swallowing, Gagging	10	2.6
Gagging	10	2.6
Thermal/chemical burns	5	1.3
Tongue/lip/cheek bite	155	40.4
Tongue/lip/cheek bite, Difficulty in speaking , swallowing	35	9.1
Tongue/lip/cheek bite, Difficulty in speaking , swallowing, Gagging	10	2.6
Tongue/lip/cheek bite, Gagging	10	2.6
Tongue/lip/cheek bite, Thermal/chemical burns	49	12.8
Tongue/lip/cheek bite, Thermal/chemical burns, Difficulty in speaking , swallowing	10	2.6
Tongue/lip/cheek bite, Thermal/chemical burns, Difficulty in speaking , swallowing, Gagging	5	1.3
Total	384	100.0



This data reveals that 3.9% dentists have seen complications like difficulty in speaking ,swallowing.2.6% dentists have seen gagging in patients.1.3% dentists have seen that patients suffered from thermal and chemical burns whereas 40.4% dentists have seen tongue/lip/cheek bite.

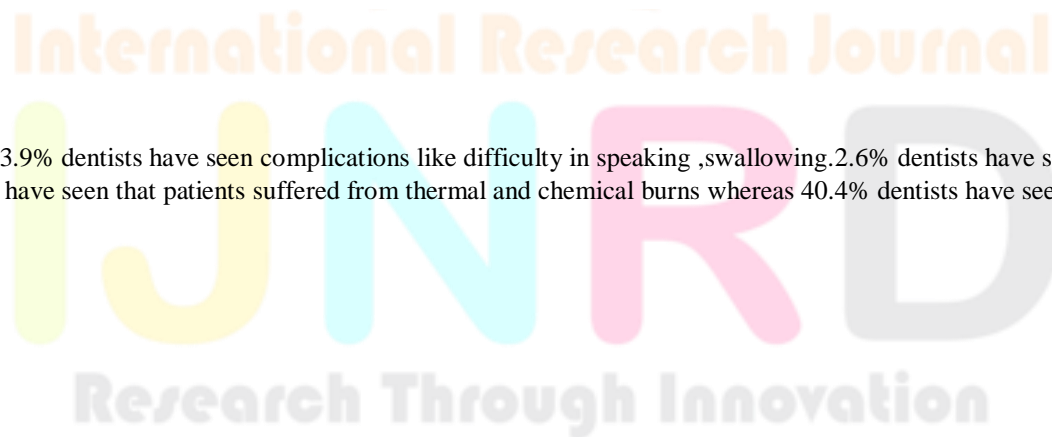
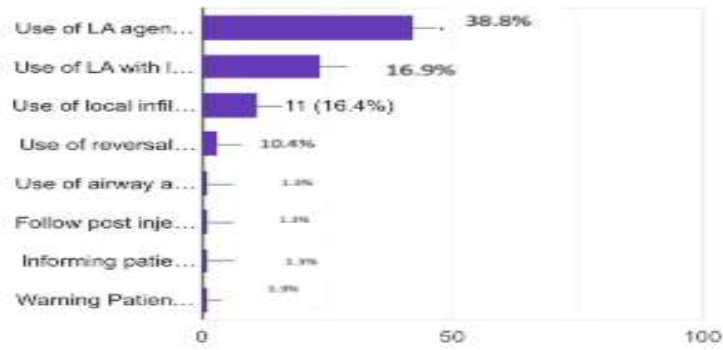


TABLE NO-6

What are the measures you have undertaken to prevent above mentioned complications?

	Frequency	Percent
	45	11.7
Follow post injection instruction	1	.3
Follow post injection instructions	9	2.3
Informing patient to avoid lip biting	5	1.3
Use of airway and laryngoscopy	5	1.3
Use of LA agent having short duration of action	149	38.8
Use of LA agent having short duration of action, Use of LA with lesser concentration of adrenaline	40	10.4
Use of LA agent having short duration of action, Use of LA with lesser concentration of adrenaline, Use of local infiltration or intraligamentary injection	10	2.6
Use of LA agent having short duration of action, Use of local infiltration or intraligamentary injection	5	1.3
Use of LA agent having short duration of action, Use of reversal agent	5	1.3
Use of LA with lesser concentration of adrenaline	65	16.9
Use of LA with lesser concentration of adrenaline, Use of local infiltration or intraligamentary injection	5	1.3
Use of LA with lesser concentration of adrenaline, Use of reversal agent	5	1.3
Use of local infiltration or intraligamentary injection	30	7.8
Use of local infiltration or intraligamentary injection, Use of reversal agent	5	1.3
Total	384	100.0



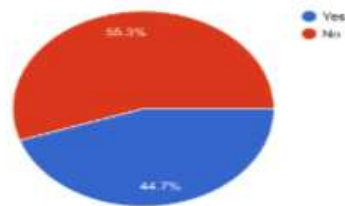


This data reveals that 2.3% dentists had given post injection instructions and 1.3% used airway and laryngoscope. 38.8% dentists used LA of short duration of action.

TABLE NO 7

Have you heard of phentolamine mesylate?

	Frequency	Percent
No	215	56.0
Yes	169	44.0
Total	384	100.0



This data reveals 56% dentists haven't heard of phentolamine mesylate whereas 44% have heard of it.

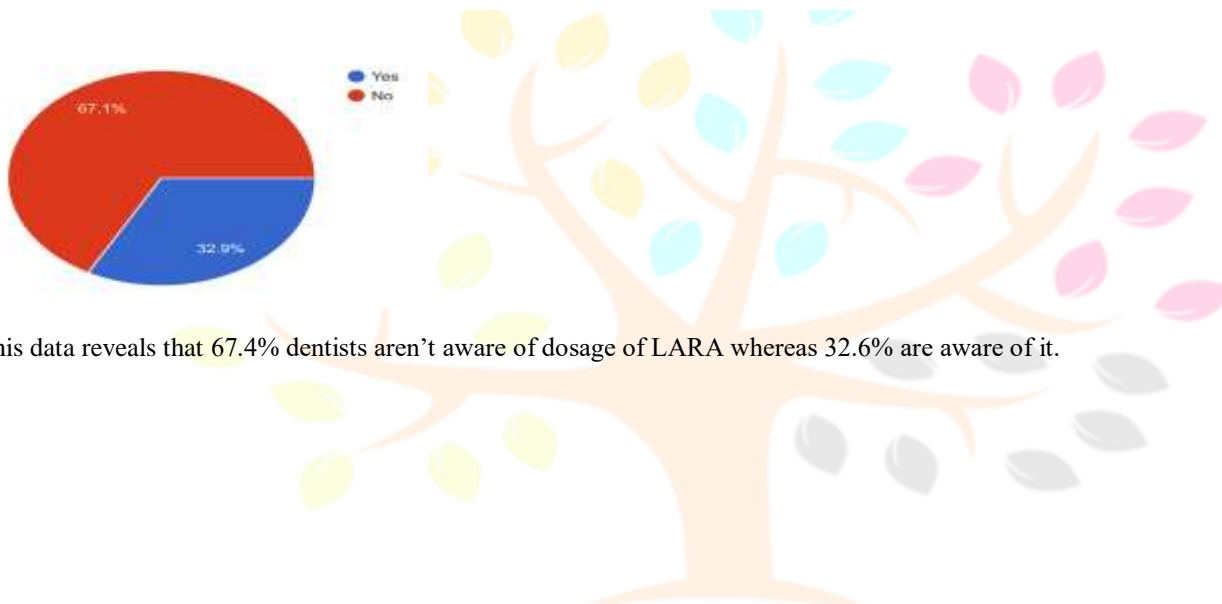
Count		How frequently do you use local anaesthetic?			Total
		< 3 times a day	>5 times a day	3-5 times a day	
Have you heard of phentolamine mesylate?	No	145	20	50	215
	Yes	99	10	60	169
Total		244	30	110	384

There was statistically significant difference seen for the frequencies between the groups  $p < 0.01$  with higher frequency for response yes with  $< 2/\text{day}$

**TABLE NO-8**

**Are aware about the dosage given for reversal of anaesthesia after completion of dental procedure?**

	Frequency	Percent
No	259	67.4
Yes	125	32.6
Total	384	100.0



This data reveals that 67.4% dentists aren't aware of dosage of LARA whereas 32.6% are aware of it.

**Crosstab**

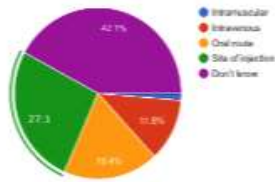
Count		How long have you been practicing dentistry?				Total
		< 2yrs	>10 yrs	2-5 yrs	6-10 yrs	
Are aware about the dosage given for reversal of anaesthesia after completion of dental procedure?	No	149	40	55	15	259
	Yes	65	5	40	15	125
Total		214	45	95	30	384

There was statistically significant difference seen for the frequencies between the groups  $p < 0.01$  with higher frequency for response yes with <2/day

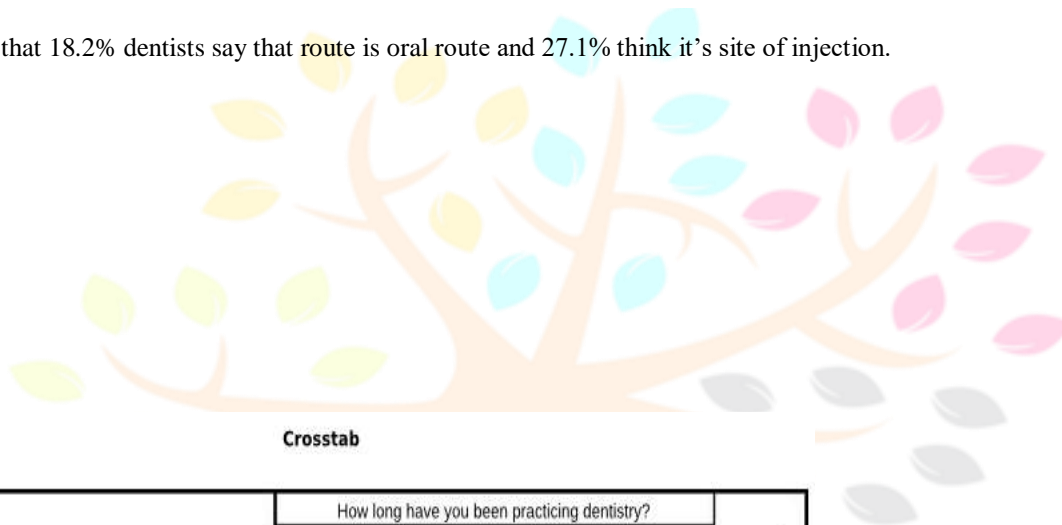
**TABLE NO-9**

Are you aware of route of administration of Local anaesthetic reversal agent (LARA)?

	Frequency	Percent
Don't know	160	41.7
Intramuscular	5	1.3
Intravenous	45	11.7
Oral route	70	18.2
Site of injection	104	27.1
Total	384	100.0



This data reveals that 18.2% dentists say that route is oral route and 27.1% think it's site of injection.



**Crosstab**

Count		How long have you been practicing dentistry?				Total
		< 2yrs	>10 yrs	2-5 yrs	6-10 yrs	
Are you aware of route of administration of Local anaesthetic reversal agent (LARA)?	Don't know	65	40	50	5	160
	Intramuscular	0	0	0	5	5
	Intravenous	40	0	5	0	45
	Oral route	50	5	10	5	70
	Site of injection	59	0	30	15	104
Total		214	45	95	30	384

There was statistically significant difference seen for the frequencies between the groups  $p < 0.01$  with higher frequency for response yes with  $< 2/day$

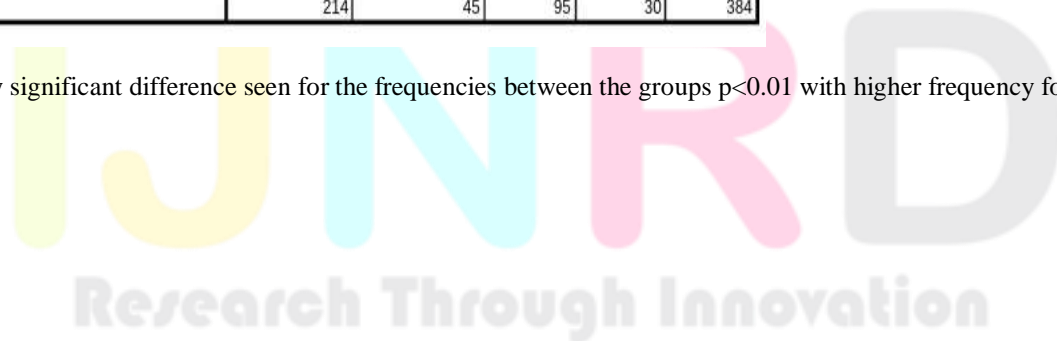
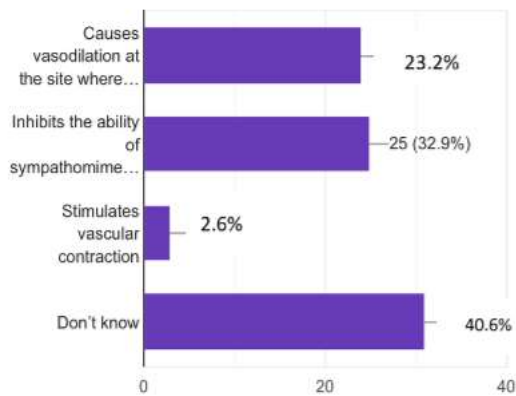


TABLE NO -10

Are you aware of mechanism of action of LARA

	Frequency	Percent
Causes vasodilation at the site where LA is injected.	89	23.2
Causes vasodilation at the site where LA is injected., Inhibits the ability of sympathomimetic amines like norepinephrine and epinephrine	30	7.8
Causes vasodilation at the site where LA is injected., Inhibits the ability of sympathomimetic amines like norepinephrine and epinephrine, Stimulates vascular contraction	5	1.3
Don't know	156	40.6
Inhibits the ability of sympathomimetic amines like norepinephrine and epinephrine	94	24.5
Stimulates vascular contraction	10	2.6
Total	384	100.0



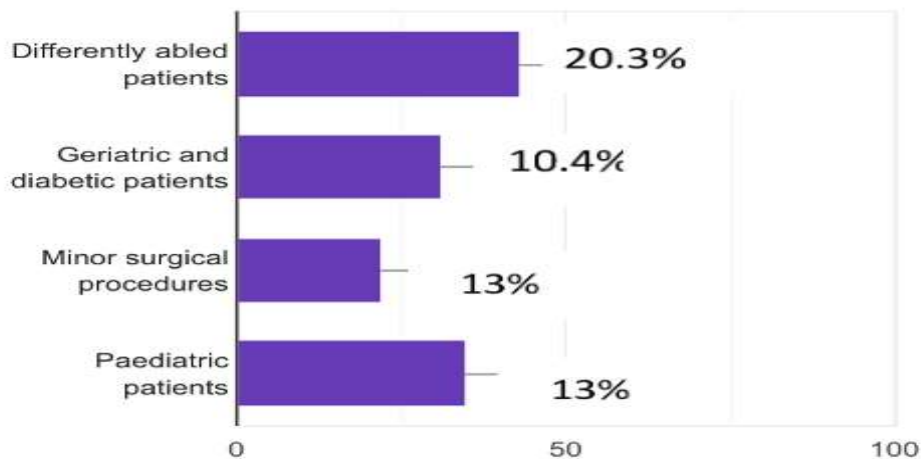
This data reveals 24.5% dentists believe that mechanism of action as inhibition of the ability of sympathomimetic amines whereas 1.3% think it's causes vasodilation at the site where LA is injected.


  
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TABLE NO-11

**In what situation do you think this drug will be useful?**

	Frequency	Percent
Differently abled patients	78	20.3
Differently abled patients, Geriatric and diabetic patients	25	6.5
Differently abled patients, Geriatric and diabetic patients, Minor surgical procedures	10	2.6
Differently abled patients, Geriatric and diabetic patients, Minor surgical procedures, Paediatric patients	35	9.1
Differently abled patients, Geriatric and diabetic patients, Paediatric patients	35	9.1
Differently abled patients, Paediatric patients	35	9.1
Geriatric and diabetic patients	40	10.4
Geriatric and diabetic patients, Minor surgical procedures	5	1.3
Geriatric and diabetic patients, Paediatric patients	11	2.9
Minor surgical procedures	50	13.0
Minor surgical procedures, Paediatric patients	10	2.6
Paediatric patients	50	13.0
Total	384	100.0

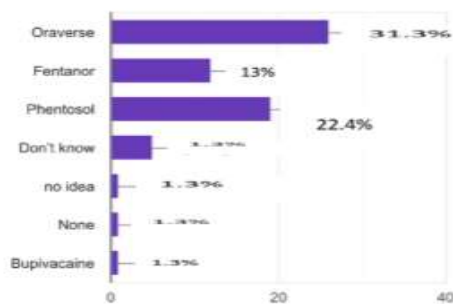


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TABLE NO-12

Which are the common brand names that you are aware of?

	Frequency	Percent
Bupivacaine	5	1.3
Don't know	9	2.3
Don't know	23	6.0
Fentanor	50	13.0
no idea	1	.3
Oraverse	120	31.3
Oraverse, Fentanor	5	1.3
Oraverse, Fentanor, Phentosol	5	1.3
Oraverse, Phentosol	5	1.3
Phentosol	86	22.4
Total	384	100.0

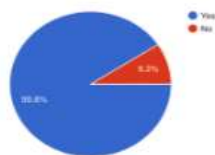


This data reveals that 31.3% dentists are aware of oraverse whereas 1.3% are aware of bupivacaine.

TABLE NO-13

Would you like to use it if it's readily available?

	Frequency	Percent
No	35	9.1
Yes	349	90.9
Total	384	100.0



This data reveals that 90.9% dentists are ready to use if it's readily available whereas 9.1% aren't interested

Crosstab

Count		How long have you been practicing dentistry?				Total
		< 2yrs	>10 yrs	2-5 yrs	6-10 yrs	
Would you like to use it if it's readily available?	No	20	10	5	0	35
	Yes	194	35	90	30	349
Total		214	45	95	30	384

There was statistically significant difference seen for the frequencies between the groups  $p < 0.01$  with higher frequency for response yes with  $< 2/day$

## 6. Conclusion

There are several conclusions that can be drawn from the results of the study. The results of the study show that majority of dentists less frequently use LA but majority of them have encountered complications due to persistent anaesthesia.

Mainly the complications that were encountered by dentists in their daily practice due to LA was tongue/lip/cheek bite but whereas thermal/chemical burns were less frequently encountered by them. The results have shown that majority of dentists preferred using LA with shorter duration of action to prevent these complications while few of them preferred giving post injection instructions.

The results of the data analysis reveal that majority of dentists aren't aware of phentolamine mesylate neither they are aware of dosage given for reversal of anaesthesia after completion of procedure. When asked about route of administration of local anaesthetic reversal agent majority weren't aware about it whereas few said it can be oral route or site of injection.

The results of this survey reveal that majority of dentists think that this drug will be useful in case of differently abled patients as these patients are prone to self-inflicted injury in case of prolonged soft tissue anaesthesia. This survey also reveals that majority of dentists are willing to use LARA (Local anaesthetic reversal agent) if it's readily available in the market.

### Limitations:-

There are several limitations which were found in the study. The sample size used for primary data collection was very limited. Therefore, the results cannot be scaled to depict the entire population.

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