COMPARISON OF LOCAL ANESTHETIC EFFECTS OF TRAMADOL AND LIDOCAINE USED SUBCUTANEOUSLY IN MINOR SURGERIES WITH LOCAL ANESTHESIA

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Abstract

Objectives: In this study, the local anesthetic and post-operative analgesic effects of tramadol were compared to those of lidocaine in minor surgeries under local anesthesia.

Methods: This double-blind clinical trial study included 70 patients in ASA physical status I and II, aging between 20 and 50 years, undergoing minor surgery (lipoma excision and revision of scars less than 4 cm within 30 minutes or less) under local anesthesia. The patients were randomly assigned to receive either 2 mg/kg tramadol (group T, n = 35) or 1 mg/kg lidocaine 2% (group L, n = 35) subcutaneously. Scores of the pain sensation were recorded as VAS (visual analogue scale 0-10) during injection, incision and 15, 30 and 45 minutes after incision, and then 2, 4 and 6 hours post-operatively at the ward.

Results: There was no significant difference between pain scores of the two groups during injection, incision and surgery or in the post-operative period at the ward (p = 0.181). Incidence of nausea was 0% and 22.8% in group L and group T, respectively. The difference was statistically significant (p = 0.002). Furthermore, 82.9% of subjects in group L and 60% of subjects in group T needed acetaminophen to control their pain and the difference was significant (p = 0.004).

Conclusion: Tramadol 2 mg/kg has local anesthetic and post-operative analgesic effect equal to lidocaine 1 mg/kg in minor surgeries performed subcutaneously. Therefore, we concluded that tramadol can be used as an alternative drug to lidocaine in local anesthesia and has the ability to decrease the demand for post operative analgesics.

Keywords: Tramadol, Lidocaine, subcutaneous block, visual analogue scale.

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Introduction

Many distant years ago, native people of Peru sought a native plant called "Eryrthroxylum Coca" which made them euphoric and tranquilized. But it was only in 1884 when Koller made clinical use of cocaine, for the first time, to induce local anesthesia on the corneal surface, commencing a new era in the science of medicine[1]. Cocaine's ability to induce psychological dependence and its stimulating characteristics when placed on the surface or on the periphery of nerves led to a survey to find a more suitable local anesthetic. Lidocaine was made by Lofgern in 1943 and following that, various ester and amide anesthetics were invented and used[1]. This class of drugs inhibits the conduction of nerve impulses by blocking sodium channels in stimulative membranes leading to a temporary lack of sensation[2].

Tramadol, as a non-narcotic central analgesic entered the market in 1977. Its main acting mechanism is the increase in serotonergic neural conduction; therefore, its analgesic effects can be averted by simultaneous administration of a serotonin-receptor antagonist. Also, tramadol inhibits the action of epinephrine carrier and is a weak agonist for μ receptor; its structure is a methyl-morphine resembling that of codeine and it will only be partially antagonized by naloxone[3].

The analgesic effects of tramadol are mostly independent of its effects on μ receptor; for example, tramadol applies its analgesic effects via spinal and supra-spinal pathways[4] and can be useful in subsiding atypical pains such as chronic nervous pains[1]. But several studies have recently shown that tramadol also has peripheral local anesthetic effects[3,5-7]. For example, its anesthetic characteristics have been demonstrated by directly administering tramadol onto the sciatic nerve of a rabbit[5]. In similar studies, tramadol had effects similar to those of prilocaine after intra-dermal injections[7,8].

The current study has been designed with the aim of testing the local anesthetic effects of tramadol. The ability of tramadol to induce anesthetic and analgesic effects when injected subcutaneously is a phenomenon which itself can revolutionize the local anesthetics chapter, leading to a new class of medicines which can be used to induce local anesthesia.

Therefore, this study has compared tramadol with lidocaine when both injected subcutaneously in minor surgeries.

The aim of this study is to compare tramadol and lidocaine in terms of the degree of local anesthesic effect at the time of surgical incisions and during the operation, and also the degree of analgesia after minor surgeries under local anesthesia.

Materials and Methods

This experimental interventional study was done as double-blind clinical trial approved by the research council and medical ethics committee of Lorestan University of Medical Science in Shohada Ashayer hospital, Khorram Abad, IRAN in 2006. It included 70 patients between 20 and 50 years of age undergoing minor surgeries under subcutaneous block.

The minor surgeries include lipoma excision and revision of scars less than 4 cm within 30 minutes or less.

Subjects were randomly divided into two groups either receiving tramadol 2 mg/kg (Group T) (Tramadol made by Krewel Meuselbach factory) or lidocaine 1 mg/kg (Group L) (Lidocaine made by Kingdom factory). The injection mixture volumes were increased to 5cc and then were injected by a needle no. 25 to induce local anesthesia by subcutaneous block.

Subjects did not receive any anesthesia pre-medications. The surgeon and the patient were unaware of the identity of the drugs. The amount of pain was measured and documented via VAS (Visual Analogue Scale) at the time of the injection and during the surgical incisions and every 15 minutes (at the 15^{th}, 30^{th} and 45^{th} minute of the surgery) till the end of the operation and after that, every 2 hours until 6 hours past the operation.

During the operation, the anesthetic would be subcutaneously injected once again as much as 0.5 mg/kg if VAS was equal to or greater than 4.

The surgical incision was made 5 minutes after the subcutaneous injection of the drug and blood pressure, heart rate, respiratory rate and SaO_2 were monitored and registered during the surgery. Incidence of nausea, vomiting, dermal reaction (on a scale of 0-3 [0: without reaction, 1:mild rash, 2:erythema, 3:wheals])

and bleeding (on a 0-3 scale [0: without bleeding, 1: bleeding less than 50cc, 2: bleeding between 50cc and 100cc, 3: bleeding more than 100cc]) were evaluated. After the operation, acetaminophen 325 mg tablets were prescribed in case of a VAS≥4. The interval between two tablets of acetaminophen was not allowed to be less than 2 hours. The patients were discharged the same day of operation.

Data analysis

The data were analyzed using repeated measures model, student t distribution and chi-square test and p values less than 0.05 were finally considered as to be statistically significant.

Results

The mean pain intensity was not significantly different between the two studied groups (L and T) during the drug administration as well as the surgical incision or after 15, 30 and 45 minutes post the injection (p = 0.181).

These results show that the subcutaneous injection of tramadol is not more painful than that of lidocaine and that tramadol (with a dosage of 2 mg/kg) can have local anesthetic effects as much as lidocaine and provide desirable anesthesia during an operation.

Furthermore, after 2, 4 and 6 hours post operation, the two groups did not have significant difference in the pain scores (p = 0.05) meaning that the anesthesia induced by tramadol is as efficient as that induced by lidocaine.

When comparing the need of patients to an extra medicine dosage during the operation, 17.1% of subjects in group L and 8.6% of subjects in group T needed an extra dosage of medicine, making no significant difference in this matter between the two groups (p = 0.48).

Table 3 shows that tramadol 2 mg/kg can compete with lidocaine 1 mg/kg in terms of anesthetic effects when injected subcutaneously.

As for the amount of acetaminophen used by subjects in the first 6 hours after the operation, 54.3% of subjects needed one tablet of acetaminophen, 28.6% needed two tablets and 17.1% did not need any tablets in lidocaine group, while 48.6% of subjects needed one tablet, 11.4% needed two tablets and 40% did not need any tablets in the tramadol group; the two groups had statistically significant difference in this matter (p

Table 1
The mean and the standard deviation of pain intensity score at different times in tramadol and lidocaine groups

Medicine \ Time		Administration	Surgical incision	15 minutes after the block	30 minutes after the block	45 minutes after the block	2 hours after the block	4 hours after the block	6 hours after the block
Lidocaine	Number	35	35	35	35	35	35	35	35
	Mean pain intensity score	2.54	0.57	0.05	0.05	0.60	2.37	2.62	1.85
	Standard deviation of pain intensity score	1.59	0.55	0.23	0.23	0.97	1.69	1.55	1.68
Tramadol	Number	35	35	35	35	35	35	35	35
	Mean pain intensity score	2.65	0.74	0.48	0.14	0.11	2.02	1.60	1.45
	Standard deviation of pain intensity score	1.55	0.61	0.98	0.35	0.32	1.75	1.68	
Total	Number	70	70	70	70	70	70	70	70
	Mean pain intensity score	2.60	0.65	0.27	0.10	0.35	2.20	2.11	1.65
	Standard deviation of pain intensity score	1.56	0.58	0.74	0.30	0.76	1.72	1.69	1.66

= 0.04), meaning that tramadol group had significantly less need to analgesics in the first 6 hours after the operation.

The mean amount of bleeding within the first 45 minutes after the block (on a 0-3 scale) was 0.26 and 0.18 in L and T groups, respectively showing no significant difference between the two groups (p = 0.104).

Table 2
Comparison of the mean and the standard deviation of pain intensity score in the two therapeutic groups of tramadol and lidocaine

Medicine	Number	Mean	Standard deviation	Mean deviation
Lidocaine	35	1.33	0.55	0.18
Tramadol	35	1.15	0.57	

p = 0.181

The mean skin reaction severity (on a 0-3 scale), 15, 30 and 45 minutes after the block was 0.09 and 0.19 in L and T groups, respectively, showing no significant difference between the two groups (p = 0.104).

In the first 6 hours after the operation, the mean systolic blood pressure, heart rate, respiratory rate and the mean SaO_2 did not show any significant difference in the two groups (p = 0.167).

Table 3
Number and frequency of patients in tramadol and lidocaine groups in need of extra dosages of anesthesia medicine during the operation

Medicine		Without a need of an extra dosage	With a need of an extra dosage
Lidocaine	**Number**	29	6
	Percentage	82.9	17.1
Tramadol	**Number**	32	3
	Percentage	91.4	8.6
Total	**Number**	61	9
	Percentage	87.1	12.9

p = 0.48

There was no incidence of nausea in lidocaine group in the first 6 hours while there was one incidence of nausea in 17.1% of subjects and two in 5.7% of subjects in tramadol group which made a significant difference between the two groups in this matter (p = 0.002). It can be concluded that tramadol induces nausea in more patients compared to lidocaine.

There was no incidence of vomiting in the first 6 hours after the operation in group L whereas 11.4% of subjects in group T had one occasion of vomiting; the difference was not significant (p = 0.114).

Discussion

In this study, subcutaneous injection of tramadol led to local anesthesia effects similar to those of lidocaine. Such a result was also achieved in similar studies conducted by Al tunkaya H. et al in Turkey, where they compared tramadol with prilocaine and lidocaine[2,7]. In our study, tramadol resulted in longer duration of analgesia, reducing the need for analgesics after the operation, which is in accordance with the results of Al tunkaya's study[8].

At first, tramadol was thought to apply its analgesic effects through spinal and supraspinal pathways[4], but several clinical studies showed that tramadol can also have local anesthetic function[3,5-7].

It has been demonstrated that tramadol bears anesthetic characteristics when injected in sciatic nerves of the rats[5].

When sodium concentration declines in the extracellular fluid, the nerve becomes sensitized to the local anesthetic[9].

In 2003, Jou et al suggested that tramadol, like lidocaine, disrupts the sensory and motor nerves by blocking axons by affecting the voltage-dependent sodium channels[10].

In 2002, Mert et al showed that tramadol might have a different mechanism from lidocaine in blocking the nerve conduction; for example, a different calcium concentration in the medium outside would increase the activity of tramadol but decrease that of lidocaine[11].

After intramuscular injection of tramadol, it will be absorbed quickly and thoroughly and reaches its maximum serum level within 45 minutes[12,13]. The desired serum level to control mild pains will be achieved in a average time of 7 minutes[13]. The recommended daily intramuscular dosage is 50-100 mg

every 4-6 hours[13,14]. The pharmacokinetics of tramadol removal is described based on a double-compartment model. The half-life of tramadol is 5.1±0.8 hours and the half-life of its derivatives is 9 hours for a 100-mg single dose[14].

In our study, the total acetaminophen used in tramadol group was less, which is in accordance with Al tunkaya's study. The only difference was that they had used paracetamol as the analgesic[8].

There was no difference between the two groups in terms of blood pressure, heart rate and respiratory rate; these results are comparable to those of studies where tramadol was injected in intramuscular or intravenous approaches or when it was used in patient-controlled analgesia method[12] or in subcutaneous form.

Nausea and vomiting are among the more important complications of tramadol when it is used to control pain after the operation[14]. The prevalence of these complications seem to depend on the serum concentration peak of the drug; for instance, these symptoms are more evident in a 3 mg/kg intravenous dosage of the drug compared to when it is infused or used in patient-controlled analgesia method[8].

In our study, nausea and vomiting were only detected in tramadol group which is similar to the results of the study by Al tunkaya[8].

Finally, we evaluated the anesthetic and analgesic effects of subcutaneous tramadol after the operation and concluded that tramadol can be a good choice in minor surgeries.

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