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Original Article

Magnesium Sulfate versus Tramadol as Adjuvants to Lidocaine in Intravenous Regional Anesthesia for Carpal Tunnel Release Surgery: A Randomized Clinical Study

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ABSTRACT

Background: Intravenous regional anesthesia [IVRA] is a simple and effective anesthetic method for providing regional anesthesia of the upper limbs during carpal tunnel release surgery [CTRS]. However, the procedure is associated with significant postoperative pain and adjuvant analgesic agents are recommended.

The Aim of The Work: This study aimed to compare the analgesic effects of magnesium sulfate and tramadol when added to lidocaine for IVRA during CTRS.

Methods: In this double-blinded, randomized clinical trial, 60 ASA I-II patients eligible for elective CTRS with IVRA were randomly allocated into one of 3 groups. The first group [lidocaine group] received IVRA with 40 ml lidocaine 0.5%. The second group [lidocaine + tramadol group] received IVRA with40 ml 0.5% lidocaine and tramadol 1mg/kg. The third group [lidocaine + magnesium sulphate group] received IVRA with 40 ml 0.5% lidocaine and magnesium sulfate 10 mg/kg and normal saline. Outcome parameters included time to onset of sensory and motor block, time to onset of tourniquet pain, need of intra-operative analgesia, intraoperative consumption of fentanyl, duration of postoperative analgesia and pain intensity were noted in each patient.

Results: Comparison between the studied groups regarding the outcome parameters. The Lidocaine + Tramadol and the Lidocaine + Magnesium groups achieved better performance in all the studied parameters in comparison to the Lidocaine group. In addition, Lidocaine + Tramadol groups had significantly better performance in comparison to the Lidocaine + Magnesium group. No significant differences were reported between the studied groups regarding post-operative complications

Conclusions: Use of tramadol and magnesium sulphate as adjuvants to lidocaine achieved better performance in all the studied parameters in comparison to the lidocaine only. In addition, tramadol had significantly better performance in comparison to magnesium sulphate without significant side effects.

Keywords: Magnesium Sulfate; Tramadol; Intravenous Regional Anesthesia; Carpal Tunnel Release Surgery.

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* Main subject and any subcategories have been classified according to the research topic.

INTRODUCTION

Intravenous regional anesthesia [IVRA] entails the intravenous injection of a local anesthetic into a tourniquet-occluded limb described by August Bier in 1908 [1]. IVRA is an ideal technique of anesthesia for minor ambulatory surgical procedures performed on the extremities [2]. However, it has some disadvantages, including limited postoperative analgesia time, incidence of tourniquet pain, scanty muscle relaxation, local anesthetic toxicity and not suitable for extended operation [3]. Many adjuvant agents have been proposed to improve postoperative analgesia, including opioids [4], ketamine [5], ketorolac [6], muscle relaxants [7], non-steroidal anti-inflammatory drugs [8], clonidine [9], dexmedetomidine [10] and neostigmine [11]. Tramadol is a novel synthetic opiate agent with a distinctive dual-action through opiate receptors and, by interfering with serotonin reuptake, makes it an ideal IVRA agent [12]. Magnesium has been proven to have potent analgesic properties by inhibiting neuropathic pain [13], potentiating morphine analgesia, and attenuating morphine tolerance, most likely through regulation of intracellular calcium influx and antagonistic effect on central N-methyl-D- aspartate [NMDA] receptors [14].

AIM OF THE WORK

The current randomized study aims to compare tramadol and magnesium sulfate as an adjuvant to lidocaine in IVRA for patients undergoing elective carpal tunnel release surgery [CTRS] regarding benefits and presence of complications.

PATIENTS AND METHODS

The present study has been conducted at Al-Azhar University Hospitals [Sayed Galal, Al-Hussein] in Cairo, Egypt, from June 2015 to November 2017. The study included 60 consecutive patients with ASA I and II, aged 20-60 years, of both sexes, and set for elective CTRS under IVRA. They were randomly assigned via closed envelopes. The research was authorized by the local ethics board, and all patients who participated provided written informed consent. Exclusion criteria; ASA III, IV, age <20 or more than 60 years, pregnant females, peripheral vascular disease or sickle cell anemia, patients with anatomical or neurological deformity, prolonged surgery more than 60 min, allergy for any component of the study, post-traumatic injuries, and history of epilepsy.

Anesthetic procedure: After complete cardiac monitoring, with patients lying in a supine position, a 20G IV cannula was secured in the non-operative hand for crystalloid fluid infusion and emergency drugs. Another 22G IV cannula was inserted in a dorsal vein of the operative hand. A double pneumatic tourniquet was then wrapped around the upper arm of the operative limb over a cotton pad. After elevating the arm for 2 min, it was stretched using an Esmarch bandage. The proximal cuff was pumped to a pressure of 100 mmHg above the systolic pressure. The loss of radial pulsation and disappearance of a pulse oximetry signal in the index finger verified the arm's vascular segregation. The study medications were then injected as described below. Five minutes on the establishment of motor and sensory block, the proximal cuff was withdrawn after the distal cuff was pumped to 250 mmHg. In tourniquet pain, 25 mcg Fentanyl was used as intraoperative rescue analgesia if visual analog scale was [VAS] more than three. This dose could be repeated up to 100 mcg Fentanyl if pain scores still more than three. The patient could be shifted to general anesthesia and excluded from the research if the pain continued. At the end of the procedure, a repetitive inflation-deflation technique was used for tourniquet deflation. In the 1st 8 hrs, if the VAS was higher than five, postoperative analgesia would be given in terms of pethidine 0.3 mg/kg IV and paracetamol 1 mg/kg.

Study interventions

The 60 patients included in the study were divided into three equal groups received IVRA. 1] Control [C] group: lidocaine 40 ml 0.5% [3 mg/kg]. 2] Tramadol [T] group: lidocaine 0.5% [3 mg/kg] 40 ml and 1mg /kg Tramadol. 3] Magnesium sulfate [M] group: lidocaine 0.5% [3 mg/kg] 40 ml and 10mg/kg magnesium sulfate.

Study outcomes

Outcome parameters included the onset of sensory and motor block, the tourniquet pain onset, Fentanyl consuming, time of postoperative analgesia and postoperative analgesia. Both the patients and surgeons were blinded to the research and questioned about the anesthetic procedure's quality at the closing of the operation. The patient classifies the quality of the anesthetic technique into 4 points numerical scale; 4= excellent, no patient complaints, 3= good, the patient has a mild problem without further analgesics, 2= moderate, a complaint requiring more analgesics, 1= unsuccessful, required repeated doses of perioperative supplemental analgesia. The surgeon graded the quality of the Anesthetic technique according to four numerical scales; 4= perfect, 3=acceptable, 2= poor, 1= unsuccessful. After 15 minutes tourniquet, pain was assessed using a typical 10-point visual analogue scale [VAS], then at 30 minutes, 45 minutes, 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 12 hours, and 24 hours after tourniquet deflation.

Statistical analysis: Collected data were analyzed using SPSS [version 26, IBM, USA]. Numerical variables were presented as Mean ± Standard Deviation [SD]. One-way ANOVA compared numerical data. Categorical variables were presented as frequency and percentage and compared between groups using the chi-square test. Ordinal data [VAS scores, patients and surgeons satisfaction] were presented as median [IQR], and Kruskal-Wallis and Mann–Whitney U tests were used in comparing between groups. P-value < 0.05 was considered statistically significant.

RESULTS

This study included 60 patients randomly assigned to three groups; 20 patients each. The demographic data [age, gender, height, and weight] were comparable among the study groups and ASA types. No significant differences were found between the study groups regarding the baseline characteristics [Table 1]. In terms of outcome characteristics, the investigated groups [Tramadol and Magnesium] achieved better performance in all study parameters than the control group. In addition, [T] group had significantly better performance in comparison with [M] group except for the onset of sensory and motor block [Table-2]. Table [3] shows significantly reduced pain VAS in the [T] group than the other two groups in the first 15 minutes. However, no substantial changes in pain VAS were discovered between the investigated groups at further assessments.

There was a significant difference in the patients and surgeon satisfaction [Table-2, Figures 1 and 2] in-group [T] and group [M] compared to group [C].

No significant differences were reported between the study groups regarding postoperative complications [Table-4].

Table [1]: Baseline characteristics of the studied patients

	C Group n=20	T Group n=20	M Group n=20	*P-value*
Age [years]	38.0 ± 11.0	37.6 ± 9.8	39.2 ± 10.6	0.89
Female/Male	18/2	17/3	19/1	0.57
Height [cm]	165.7 ± 4.1	166.3 ± 5.0	166.5 ± 2.9	0.61
Weight [kg]	78.0 ± 6.9	76.9 ± 3.76	76.3 ± 5.3	0.89
ASA [I/II]	18/2	15/5	16/4	0.46
Duration of surgery [minutes]	31.6 ± 4.1	34.2 ± 3.5	32.3 ± 3.8	0.11

Data are presented as numbers, mean ± standard deviation [SD].

Table [2]: Outcome parameters in the study groups

	C Group n=20	T Group n=20	M Group n=20	p-value
Sensory block onset [min.]	4.4±1.1 *#	3.9 ± 1.3 #	3.1 ± 0.7	0.001
Motor block onset [min.]	6.0 ±1.53*#	5.5±1.4 #	4.3±1.2	0.001
Tourniquet pain onset [min.]	32.1±11.0 *#	51.0 ±22.0#	41.0±13.0	0.001
Fentanyl consumption [mcg]	73.8±29.4 *#	39.0 ±22.0 #	49.0 ±16.0	0.001
Postoperative analgesia [min]	95.5 ± 55.4 *#	185.9 ± 95.4 #	122.0 ± 87.2	0.001
Dose of pethidine [mg]	33.0 ±9.1 *#	11.0 ±22.0 #	19.0 ±33.0	0.01
Patient satisfaction	1.9±1.2 *#	3.8±2.1 #	3.2±1.7	0.002
Surgeons satisfaction	1.9±1.5 *#	3.9±2.3 #	3.1±1.9	0.006

Data presented as mean ± standard deviation [SD]. * Significant differences C Group Vs. T Group. # Significant differences C Group Vs. M Group.

Table [3]: Postoperative VAS scores in the study groups

VAS	C Group Median [IQR]	T Group Median [IQR]	M Group Median [IQR]	*P-value*
15 min	4 [3-5]	3 [2-3] *	4 [3-5]	0.03*
30 min	3 [1.25- 7]	1.50 [1-3.50]	2 [1- 4]	0.49
45 min	3 [1.25-4.75]	1.50 [1-3.50]	2 [1- 4]	0.091
1h	2 [1.25-2.75]	2 [2- 2]	2 [1.25- 2.75]	0.968
2h	2 [1.25-2.75]	2 [1- 2]	2 [1.25- 2.75]	0.698
3h	2 [1-2]	2 [1- 2]	2 [1- 2]	0.841
4h	2 [1-2]	2 [1- 2]	2 [1- 2]	0.678
5h	1.5 [1-2]	1 [1- 2]	1.50 [1-2]	0.698
6h	2 [1-2]	1 [1- 2]	2 [1- 2]	0.314
12h	1 [1-1]	1 [1-1]	1 [1-1]	0.820
24h	1 [1-1]	1 [1-1]	1 [1-1]	0.620

Data are presented as median [IQR], VAS =visual analog scale. *: Significant at P ≤ 0.05

Table [4]: Postoperative complications in the studied groups

	C Group [n = 20]	T Group [n = 20]	M Group [n = 20]	P-value
Hematoma	1 [5.0]	1 [5.0]	1 [5.0]	-
Pain with injection	3 [15.0]	2 [10.0]	1 [5.0]	0.57
Skin rash	4 [20.0]	4 [20.0]	3 [15.0]	0.9
Postoperative sedation	-	2 [10.0]	-	0.13
Neurological complications	-	-	-	-
Hallucination	-	1 [5.0]	-	0.36
Nausea and vomiting	2 [10.0]	3 [15.0]	3 [15.0]	0.87

Data are presented as number and per cent.

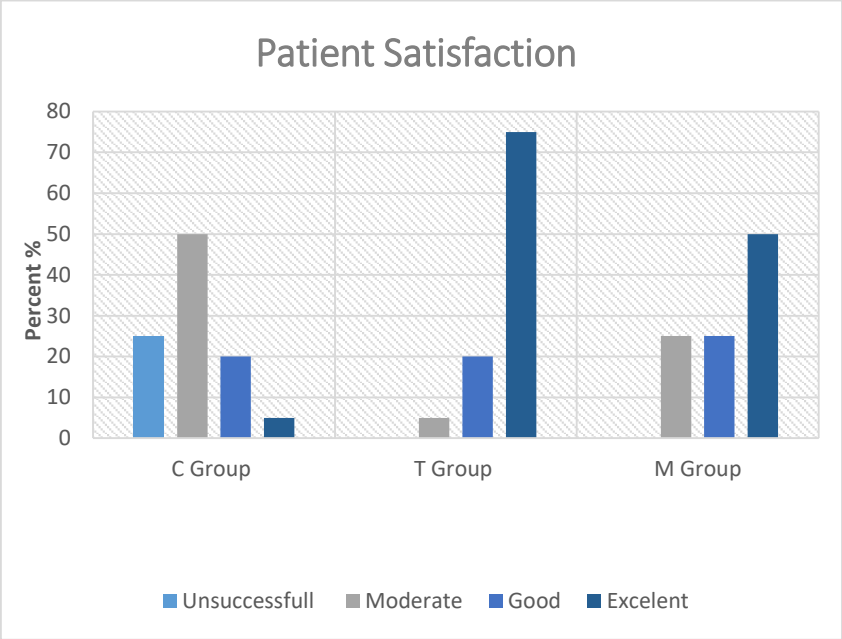

Figure [1]: Patient Satisfaction

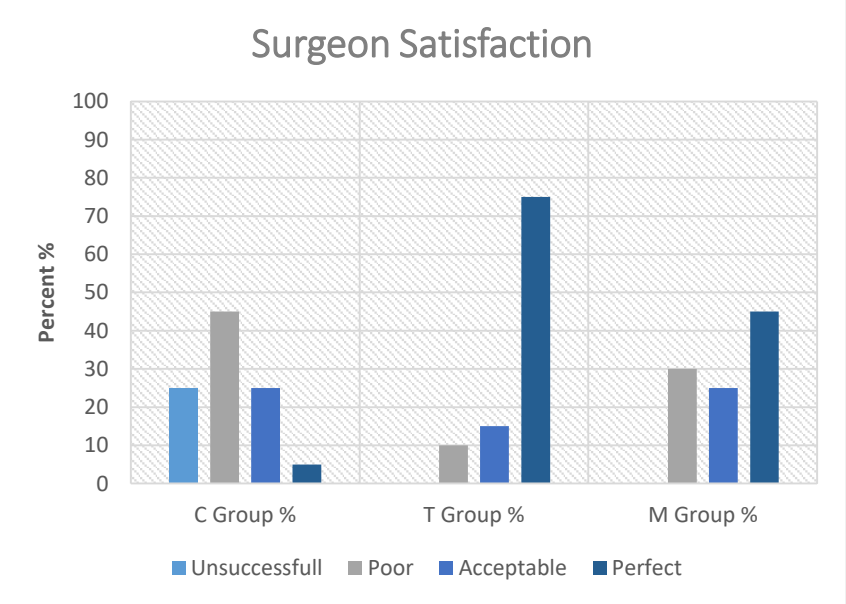

Figure [2]: Surgeon Satisfaction

DISCUSSION

The present study showed that tramadol and magnesium sulfate which is adjuvant to IVRA in carpal tunnel release surgery, is more effective than lidocaine alone. Still, tramadol outperforms magnesium sulfate as an adjuvant in terms of decreasing postoperative pain level.

For patients who underwent IVRA for carpal tunnel release surgery, the procedure was found to restrains tourniquet pain and reduce intraoperative and postoperative analgesic requirement, without increasing incidence of postoperative complications, and with a high percentage of patients and surgeons satisfaction.

Many studies discuss using IVRA for upper limb sugary as an effective method easy applicable safe for patients with a high degree of patients and surgery satisfaction [1].

Many studies show the effect of adding opioids as an adjuvant to local Anesthetic in IVR, which shows significant improvement in both the sensory and motor block [15].

Other studies suggest that tramadol can be used as a local anesthetic and can be used alone [16].

On the other side, some studies suggest using tramadol as an adjuvant to lidocaine, not as a solo local anesthetic agent [17]. However, many studies [18] agree with our research that tramadol is an effective and safe adjuvant to lidocaine in the local, intravenous regional block regarding opioid consumption and postoperative analgesia and patients and surgeon satisfaction [19].

Turan *et al*. [20] concluded that Mg sulfate might be an effective adjuvant to IVRA compared to placebo, effectively controls post-operative pain in a small trial.

However, in contrast to our findings, El-Tahawy *et al.* [21] found that Mg sulfate was not an efficient adjuvant to IVRA since dexmedetomidine was superior at suppressing the tourniquet pain minimizing postoperative one.

In addition, Nasr *et al*. [22] reported that tramadol could delay the time of the first analgesic request and reduce postoperative usage of supplemental analgesia when added to IVRA.

In our research, Mg sulfate was shown to be more effective than lidocaine at decreasing postoperative pain severity and delaying the start of postoperative pain. Nonetheless, Mg sulfate was ineffective in delaying the onset of postoperative pain and reducing its severity compared to Tramadol.

This study shows that magnesium sulfate is a good choice as an adjuvant to lidocaine in IVRA for carpal tunnel release surgery as the onset of sensory and motor block and postoperative analgesia without increase incidence of postoperative complications, but it is less effective than tramadol [21].

Bansal *et al*. [23] reported that common complications, if opioid is used as an adjuvant to lidocaine in IVRA, are sedation, nausea, vomiting and skin rash. This research concurred again with Altunkaya *et al*. [12], which found that integrating tramadol with magnesium sulfate was effective, and has no significant increase in postoperative complications such as skin rash, pain during injection, nausea and vomiting, and other neurological complications.

The major restriction of the study was the medication dosage, which was determined by prior research. A serial dosage of tramadol or Mg sulfate should thus be used to obtain the appropriate dosage that offers superior intraoperative and after operative analgesia. Additional research is recommended with a larger sample sizes to demonstrate the systemic and local effects of tramadol and magnesium sulfate in different surgeries.

Conclusion

Tramadol prolongs postoperative analgesia duration and reduces intraoperative and postoperative analgesic intake, increasing patients and surgeons satisfaction. However, magnesium sulfate improves sensory and motor onset compared to tramadol and boosts patients and surgeons' satisfaction but less than tramadol and does not improve postoperative analgesia. Both adjuvants are safe in usage without significant adverse events. Tramadol may be a better supplemental drug than magnesium sulfate for carpal tunnel release surgery.

Declarations

All authors equally contributed to this work. Authors of this manuscript declare no conflict of interests.

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