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Comparison of efficacy of intraarticular application of magnesium, levobupivacaine and lornoxicam with placebo in arthroscopic surgery

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Abstract
Purpose Arthroscopic knee surgery is done in outpatient settings; however, postoperative pain is a major barrier for discharge and limits early rehabilitation. The efficacy of intraarticular application of magnesium sulphate, levobupivacaine and lornoxicam, with placebo on postoperative pain after arthroscopic meniscectomy was evaluated.
Methods One hundred and twenty ASA status I-II patients undergoing elective arthroscopic meniscectomy were included in this randomized, single blind, prospective study. Group-M (GM) patients had intraarticular 500 mg of magnesium sulphate in 20 ml saline; group-P (GP) patients had intraarticular 20 ml saline; group-LB (GLB) patients had 100 mg levobupivacaine in 20 ml (0.5%); group-L (GL) patients had intraarticular 8 mg of lornoxicam in 20 ml saline before tourniquet deflation. Postoperative analgesia was maintained by iv tramadol PCA 0.3 mg kg^{-1} bolus dose and 5 min lockout time during the first 4 h and later with paracetamol 500 mg. The NRS values at rest and at exercise and analgesic consumptions were evaluated at the end of the first, second and 4th hours and at the 12th, 24th and 48th hours by an anaesthesiologist who was blind to the solutions administered.
Results All study groups provided analgesia when compared with GP. The first request of oral analgesic time was shorter in GP. Analgesic consumptions of GP were higher than other groups. Pain scores during 1, 2 and 4 h postoperatively were lower in all study groups than the GP.
Conclusion Administration of all the drugs provided better analgesia than placebo and the most effective one was lornoxicam.
Level of evidence Prospective, randomized study with placebo, Level I.

Keywords Intraarticular · Magnesium sulphate · Levobupivacaine · Lornoxicam · Arthroscopy

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Introduction

Arthroscopic knee surgery is one of the most common surgeries done on outpatient settings. However, postoperative pain is one of the major barriers for discharge and limits early rehabilitation. Systemic opioid and non-opioid analgesics, central and peripheral nerve blockades, preemptive analgesia and intraarticular drug administration have been tried to prevent or treat pain due to arthroscopic knee surgery [23].

Adequate analgesia has been provided by intraarticular bupivacaine, however, the analgesic effect is only short lived [2, 14, 22, 25, 26]. To prolong analgesia, many drugs are added to bupivacaine including ketamine, morphine, clonidine or non-steroidal analgesics [4]. Non-steroidal analgesics provide adequate analgesia after arthroscopic knee surgery, but the optimal route is not clear yet [6].

A variety of drugs including opioids [1, 2, 17], local anaesthetics [1, 2, 8, 14, 16, 22], non-steroidal anti-inflammatory drugs [1, 6, 8, 26], α-2 agonists[1] or magnesium [3, 7] have been used for pain relief after arthroscopic knee surgery with conflicting results. Bupivacaine 0.25% is one of the drugs most frequently used [1, 2, 5, 9, 17, 26] and generally compared with morphine [1, 9, 17]. Postoperative analgesic effects of intraarticular levobupivacaine 0.5% have been compared with other local anaesthetics [16]; however, the analgesics effects of intraarticular

0.5% levobupivacaine have not been compared with lornoxicam and magnesium in a placebo-controlled study.

The aim of this randomized and placebo-controlled study was to compare the analgesic efficacy of intraarticular application of magnesium, levobupivacaine and lornoxicam with placebo on postoperative pain and analgesic requirement after arthroscopic meniscal resection knee surgery.

Materials and methods

With the approval of the Istanbul Faculty of Medicine's ethics committee (No: 1716 and file no: 2008/1621) and signed informed consent of the patients, 120 American Society of Anaesthesiologists (ASA) I–II patients aged between 18 and 65 years planned to undergo elective arthroscopic meniscectomy for symptomatic isolated irreparable tears were included in the study. All patients were evaluated with respect to their systemic problems prior to inclusion in the study. If arthroscopic meniscectomy was not performed and meniscal repair or another intervention was made, these patients took the same pain protocol but were not included to the statistical analysis.

All patients were given an explanation about pain evaluation with numeric rating scale (NRS), and instructions for active–passive motion (isometric quadriceps exercises and flexion–extension beyond 90°) before surgery. One hundred and twenty patients were randomly assigned, using sealed numbered and opaque envelopes to one of the four groups of 30 patients.

Anaesthetic technique

All patients had 0.01 mg/kg intravenous midazolam for premedication. Heart rate (HR), peripheral oxygen saturation (SpO_2) and non-invasive blood pressures were monitored by Horizon XL during the surgery and for 4 h postoperatively. During induction 1–2 mcg kg^{-1} fentanyl, 2–3 mg kg^{-1} propofol were given, and a laryngeal mask was inserted. During maintenance of anaesthesia 1–2% sevoflurane was applied in 40% O_2, and 60% N_2O and no supplemental opioid was given during surgery.

Pneumatic tourniquet between 250 and 300 mmHg pressures was applied to all patients after induction of anaesthesia and before surgery. The same surgeon performed all surgical procedures and intraarticular injections. The injections were performed through the same main arthroscopic portal after the completion of the surgical procedure and irrigation before application of dressing and deflation of the pneumatic tourniquet.

Group I: Patients ($n = 30$) had 500 mg magnesium sulphate intraarticular in 20 ml normal saline.

Group II: Patients ($n = 30$) had intraarticular 20 ml normal saline.

Group III: Patients ($n = 30$) had 100 mg levobupivacaine (0.5%) of 20 ml local anaesthetic.

Group IV: Patients ($n = 30$) had intraarticular 8 mg of lornoxicam in 20 ml normal saline.

Postoperative analgesia

Postoperative analgesia was maintained by iv tramadol PCA 0.3 mg/kg bolus dose and 5 min lockout time during the first 4 h and paracetamol 500 mg as needed (maximum six/day) during the rest of the study period.

Evaluation parameters

The numeric rating scale (NRS) was used, where 0 = no pain and 10 = worst pain imaginable. Values at rest and active–passive motion at 1, 2, 4, 12, 24 and 48 h, amount of total tramadol consumption for tramadol hydrochloride (THCL) at the fourth postoperative hour, amount of total oral analgesic (paracetamol) consumption at the end of 24 and 48 h were evaluated and recorded by an anaesthesiologist who was blinded to the solution administered.

Statistical analysis

Based on a previous study assuming a SD of 1 cm, we calculated a group size of 27 patients would be sufficient to detect a difference of 1 cm on the VAS at an α threshold of 0.05 with power of analysis 95%.

Statistical analyses used an ordinary ANOVA test for intragroup differences with Dunn's post hoc test when $P < 0.05$ and Mann–Whitney U test for intergroup differences. Differences in group demographic characteristics were tested by Student's *t*-test or contingency table chi-square test for categorical measures. A level of $P < 0.05$ was considered statistically significant.

Results

The demographic features of the patients, anaesthesia length and tourniquet times were found to be similar between the groups (Table 1).

The total amount of tramadol hydrochloride used in GII in the first postoperative 4 h was significantly higher than the other 3 groups. The total amount of tramadol hydrochloride used in other groups was comparable between the other groups (Table 2).

The length of first oral analgesic request was significantly longer in Group III and Group IV than Group II

Table 1 The demographic features of the patients, anaesthesia and tourniquet times

	G I (MG)	G II (SF)	G III (L-Bupi)	G IV (Lor)
Age (years)	48.4 ± 11	46 ± 15.6	50.6 ± 12	42.5 ± 9.7
Body weight (kg)	77.7 ± 11.1	76.9 ± 11.1	80.9 ± 12.8	75.4 ± 11.7
M/F	9/21	11/19	10/20	8/22
Anaesthesia time (min)	60 ± 21	59.5 ± 15.3	69 ± 19	65 ± 15
Tourniquet time (min)	49 ± 19	49.7 ± 14.9	57 ± 23	56.4 ± 22.5

Table 2 Analgesic consumption of groups (Mean ± SD)

	G I (MG)	G II (SF)	G III (L-Bupi)	G IV (Lor)
Tramadol consumption (mg)	113.7 ± 92.7***	300 ± 127.5	104.4 ± 87.3***	139.1 ± 119.1**
First oral analgesic taking time (h)	8 ± 1.9	6.3 ± 1.8	10.6 ± 5.1*	14.6 ± 7.2***
No of pills in 24 h	2.3 ± 0.67	2.8 ± 1.2	2 ± 1.2	1.1 ± 0.86[&,**]
No of pills in 48 h	3.2 ± 1.2	4.4 ± 2.1	3 ± 2.1	2 ± 1.6**

[&] $P < 0.05$ when compared with G I

* $P < 0.05$ when compared with G II

** $P < 0.01$ when compared with G II

*** $P < 0.001$ when compared with G II

($P < 0.05$ and 0.001, respectively). There was no statistically significant difference between the other groups in terms of first oral analgesic request time (Table 2). Group IV used significantly less analgesic than GI and GII during the first 24 h. There was no statistically significant difference between the other groups in terms of oral analgesic consumption in the first 24 h of the study period (Table 2). And also Group IV patients used significantly less oral analgesic than Group II patients during the first 48 h. There was no statistically significant difference between the other groups in terms of oral analgesic consumption throughout the study period (Table 2).

Numeric rating scale (NRS) at rest

The preoperative and postoperative NRS values of the groups at the 1st hour at rest of were comparable with each other. Group III and Group IV had significantly lower NRS values than Group II at 2 h postoperatively at rest. Also, the NRS values of Group II patients were significantly higher than Group I, III and IV patients at 4 h at rest. There was no other significant difference between the groups at other times, but the NRS values of Group II patients were always higher (except NRS values of Group III at 24 h) than the NRS values of the patients in other groups (Table 3).

Numeric rating scale (NRS) at active motion

When the groups were compared on their NRS values at active motion Group I and III had significantly lower NRS values than Group II at 2 h.

Also, the NRS values of Group II patients were significantly higher than Group I, III and IV patients at 4 h at rest. There was no other significant difference between the groups at other times (Table 4).

Numeric rating scale (NRS) at passive motion

When the groups were evaluated on their NRS values at passive motion Group II had significantly higher NRS values ($P < 0.01$, 0.001 and 0.01) than Group I, Group III and Group IV at 4 h. There was no other significant difference between the groups at other times (Table 5).

Discussion

The most important finding of the present study was that intraarticular injection of 500 mg magnesium, or 20 ml of 0.5% levobupivacaine, or 8 mg lornoxicam at the end of surgery provided a better pain relief than placebo after outpatient arthroscopic meniscectomy under general anaesthesia and lornoxicam was superior to 0.5% levobupivacaine and 500 mg magnesium.

Pain after arthroscopic surgery varies considerably and depends, among other factors, on the type of the procedure, with diagnostic procedures producing mild pain, whereas invasive procedures such as anterior cruciate ligament repair produce moderate to severe pain. For patients who underwent arthroscopic meniscal repair surgery, the expected pain intensity could be considered to be mild to moderate. This was true only during rest when the mean

Table 3 NRS values at rest (Mean ± SD)

	Preop VAS	Postop 1st h VAS	Postop 2nd h VAS	Postop 4th h VAS	Postop 12th h VAS	Postop 24th h VAS	Postop 48th h VAS
G I (MG)	0 (0–7)	2 (0–4)	2 (0–6)	0 (0–4)***	1 (0–3)	1 (0–2)	0 (0–4)
G II (SF)	1 (0–6)	3 (0–6)	3 (0–8)	4 (0–6)	2 (0–4)	1 (0–3)	1 (0–3)
GIII (LBupi)	0 (0–5)	1 (0–6)	1 (0–4)*	0 (0–3)***	0 (0–7)	1 (0–6)	0 (0–5)
G IV (Lor)	2 (0–7)	1 (0–7)	1 (0–4)**	1 (0–4)***	1 (0–3)	1 (0–5)	0 (0–4)

* $P < 0.05$ when compared with G II

** $P < 0.01$ when compared with G II

*** $P < 0.001$ when compared with G II

Table 4 NRS values at active motion (Median, range)

	Preop VAS	Postop 1st h VAS	Postop 2nd h VAS	Postop 4th h VAS	Postop 12th h VAS	Postop 24th h VAS	Postop 48th h VAS
G I (MG)	5 (0–8)	4 (1–6)	3 (1–5)*	2 (0–4)***	3 (0–3)	3 (0–5)	2 (0–5)
G II (SF)	4 (0–8)	5 (2–8)	5 (2–8)	5 (2–6)	4 (0–5)	4 (1–6)	2 (0–5)
GIII (L-Bupi)	5 (0–8)	3 (0–7)	3 (0–6)*	2 (0–4)***	3 (1–8)	3 (0–8)	2 (0–8)
G IV (Lor)	6 (0–10)	3 (0–8)	3 (0–6)	3 (0–5)**	2 (1–6)	2 (0–7)	1 (0–4)

* $P < 0.05$ when compared with G II

** $P < 0.01$ when compared with G II

*** $P < 0.001$ when compared with G II

Table 5 NRS values at passive motion (Median, range)

	Preop VAS	Postop 1st h VAS	Postop 2nd h VAS	Postop 4th h VAS	Postop 12th h VAS	Postop 24th h VAS	Postop 48th h VAS
G I (MG)	6 (0–9)	5 (1–7)	3 (1–6)	3 (1–5)**	3 (0–4)	2 (2–4)	2 (0–5)
G II (SF)	4 (0–8)	5 (2–8)	5 (2–8)	5 (2–7)	4 (0–6)	4 (1–6)	2 (0–5)
G III (L-Bupi)	3 (0–8)	3 (0–7)	2 (0–8)	2 (0–5)***	2 (0–7)	2 (0–8)	2 (0–8)
G IV (Lor)	6 (0–9)	3 (0–8)	3 (0–6)	3 (0–5)***	2 (1–6)	1.5 (0–5)	1.5 (0–5)

** $P < 0.01$ when compared with G II

*** $P < 0.001$ when compared with G II

VAS pain scores were <3 up to 4 h postoperatively except the control group. In two groups (Group I and Group III), pain intensity increased from 4 h postoperatively, peaking between 12 and 24 h especially during active mobilization.

In several studies, comparing bupivacaine with placebo either no effect or only a very short effect was found [14, 17, 20]. However, in several other studies bupivacaine was found to be a safe and effective analgesic in the early postoperative period [5, 25].

The levo form of the racemic mixture bupivacaine named levobupivacaine is also a long-acting local anaesthetic with a clinical profile very closely similar to that of bupivacaine; its main advantage is its safer cardiotoxicity profile [11, 13].

In general, levobupivacaine is accepted as equally effective as bupivacaine and this has been shown in several studies [15, 24]. There are only a few studies in the literature using levobupivacaine in knee arthroscopy [16], and there is no study in the literature comparing levobupivacaine with magnesium and lornoxicam in knee arthroscopy.

In the present study, it was found out that 20 ml 0.5% levobupivacaine was more effective than placebo in the early postoperative period; but these analgesic effects vanished after 4 h. This is similar to the findings in Moiniche's review [21].

Magnesium can be considered as a physiological blocker of N-methyl-D-aspartate (NMDA) receptors [10]. In addition, it has been demonstrated that magnesium reduces postoperative analgesic requirements [18, 19].

In the present study, it was shown that intraarticular administration of $MgSO_4$ (500 mg ml) at the end of arthroscopic knee surgery improves postoperative pain scores when compared with placebo (a longer time to first analgesic requirement and NRS values in the postoperative period were always lower than placebo except 48th h); but these analgesic effects showed no statistically significance after 4 h.

Bondok and Abd El-Hady proved the efficacy of intra-articular application of magnesium in knee arthroscopy [3]. They stated that 'It seems likely that a local effect is at least partly responsible for this, as we did not observe the side-effects usually described after systemic administration of magnesium' [3]. We do not agree with this statement, because in a study Tramèr and Glynn used 4 mg intravenous magnesium which is much higher than the doses used in the present study and they found no impact on postoperative pain and analgesic consumption; it is still impossible to exclude the role of systemic absorption of magnesium in the analgesic efficacy [27].

However, in the present study, it was found out that even low concentration of intraarticular magnesium has analgesic properties. In a study comparing intraarticular magnesium–bupivacaine combination with bupivacaine alone, magnesium alone and placebo, it was found out that magnesium–bupivacaine combination produced a reduction in postoperative pain and bupivacaine alone and magnesium alone had also analgesic properties [7]. More studies comparing higher concentrations of magnesium sulphate using different routes of application are needed in order to find out the optimal dose and best way of application of magnesium without serious side effects.

The postoperative pain after arthroscopic knee surgery may be due to the site of surgery, like patellar tendon graft taking, and inflammation, oedema and the hyperalgesic substances produced; anti-inflammatory agents such as NSAIDs and steroids, either applied systemically or locally, may help to reduce inflammation and swelling which may occur and reduce pain and consequent analgesic consumption. Eren et al. [8] reported a study on postoperative efficacy of intraarticular lornoxicam application. They had better results in lornoxicam group when compared with other groups. Talu et al. [26] reported a similar study on postoperative efficacy of intraarticular tenoxicam application. They had better results in tenoxicam added group when compared with other groups. In a study, that compared the analgesic effects of intraarticular neostigmine, morphine, tenoxicam, clonidine and bupivacaine Alagol et al. [1] found out that the most effective drugs were neostigmine and clonidine, and also tenoxicam provided a longer postoperative analgesia than morphine and bupivacaine. These studies support the hypothesis that the intraarticular application of oxicam group NSAIDs are effective in treating postarthroscopy pain.

In the present study, it was shown that intraarticular administration of magnesium, levobupivacaine and lornoxicam have comparable analgesic efficacy after arthroscopic meniscectomy. Tramadol consumption, first oral analgesic requirement time, total oral analgesic consumptions at 24 and 48 h postoperatively and VAS values were similar between the groups with best results in lornoxicam administered groups (generally but not always).

There are several limitations of the present study. First of all, the plasma concentrations of the drugs were not measured and chondrotoxic effects of the drugs were not evaluated. Secondly, the VAS values of the patients were evaluated just for 48 h and no long-term data about pain and analgesic requirements or complications were given. Also, the protocol which was used mandated the use of general anaesthesia and a 4 h period of iv tramadol PCA use, and no comment could be made about pain relief and its effects on discharge times.

The clinical relevance of the present study may be argued. Local anaesthetic toxicity in knee arthroscopy may not be a major risk, but risk minimization is important especially in outpatient surgery when patients are discharged as early as possible. None of the patients in the present study used oral or iv non-steroidal anti-inflammatory drugs and one may also question whether avoidance of non-steroidal anti-inflammatory drug is of major importance, but non-steroidal anti-inflammatory drugs have serious side effects. In a survey of drug-related side effects, non-steroidal anti-inflammatory drugs were the third most common drug after selective serotonin-reuptake inhibitors and beta-blockers in outpatient setting [12].

Conclusion

The results of this study show that intraarticular administration of 500 mg magnesium sulphate, 20 ml 0.5% levobupivacaine and 8 mg lornoxicam provide better pain relief and less analgesic requirements for outpatient arthroscopic meniscectomy under general anaesthesia than placebo.

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