Microcurrent skin patches for postoperative pain control in total knee arthroplasty: A pilot study

Authors: Timour El-Husseini[*] and Mahmoud El-Sebai[**]

*, ** Professor of Orthopaedics, Ain Shams University, Cairo, Egypt.

Abstract:

Pain control following painful orthopedic procedures such as total knee arthroplasty is an ongoing challenge, as current pain management techniques often result in undermedication and/or complications, clinical research investigating alternative or hybrid methods becomes a major interest for the orthopaedic surgeon.
This pilot study included 24 patients who underwent Total Knee Arthroplasty (TKA). Patients were randomly allocated into 2 groups of 12 patients each. Group 1 used micro-current skin patch (MCT) with tramadol hydrochloride SOS for pain relief (MCT Group). Group 2 received tramadol hydrochloride SOS without application of MCT which served as a control group. tramadol was given IM in increment doses of 100 mg and both groups were observed for 10 days postoperatively.
The main endpoint was pain assessment using a Visual Analog Score (VAS) that was measured daily. Other endpoints included dose of tramadol needed for pain relief, degree of wound healing measured at he end of the follow up period and categorized into grade 1, 2, and 3; and total drain fluid volume in ml.
Results showed progressive decrease in pain VAS. MCT group showed lower VAS throughout the observation period, most marked at follow-up days with highest pain scores in control group. This effect was achieved using a lower dose of tramadol that averaged 200.0$\pm$7.0 mg/day in control group and 63.3$\pm$15.8 mg/day in MCT group. Wound healing was better with MCT patch application. Grade 1 was observed in 50% of patients of MCT group as compared to 8.3% in control group. The total drain volume was lower in MCT group compared to controls (1020.8$\pm$211.6 and 1170.8$\pm$243.5 in the 2 groups respectively). None of the patients showed and indication for discontinuation of patch application.

Key words:
Micro current therapy, pain assessment, total knee artroplasty

Introduction:

Postoperative pain management is critical for optimal care of orthopaedic surgery patients especially after operations that cause considerable pain like total knee arthroplasty. Opioids, administered intramuscularly, as epidurals, or IV as patient-controlled analgesia, are effective for severe pain[1.]

Adjunctive therapy and preemptive analgesia such as nerve blocks, and methods of delivery such as infusion pumps are recognised but are not used as standard practice. Oral opioids are effective for moderate to severe pain, and tramadol, with efficacy comparable to morphine but with fewer severe side effects, is selected for moderate to moderately severe pain [2]. Opioid-sparing NSAIDs, such as ketorolac, and COX-2-specific NSAIDS are also widely used. These current current pain management techniques often result in undermedication and/or complications[3,4].

Nonpharmacologic treatments and alternative approaches are less widely accepted, they span over physical therapy, cryotherapy, continuous passive motion, transcutaneous electrical nerve stimulation (TENS) and patient education, an individualised approach of one or more of the above mentioned approaches[2,5].

Reports on the effectiveness of microcurrent therapy (MCT) in the management of pain[6] may offer a new nonpharmacologic approach which, to our knowledge, has not been investigated for postoperative pain following total knee arthroplasty

Aim of work:

Main objective of the study was postoperative pain assessment after total knee arthroplasty, with and without MCT patch application. Secondary objectives included dose of tramadol hydrochloride needed for pain relief, degree of wound healing, and total drain fluid volume.

Patients and method:

This pilot case-control study included 24 patients who underwent Total Knee Arthroplasty (TKA). Patients were randomly allocated into 2 groups of 12 patients each. Group 1 used micro-current therapy (MCT) applied through the Painmaster™ electrodes –which did not interfere with the wound or its dressing (figure 1), with tramadol SOS for pain relief (MCT Group). Group 2 received tramadol SOS without application of MCT and served as a control group. tramadol was given IM in increment doses of 100 mg to a maximum of 400 mg/day and both groups were observed for 10 days postoperatively. All patients gave an informed consent to participate in the study.

The main endpoint was pain assessment using a Visual Analog Score (VAS) that was measured daily. Other endpoints included dose of tramadol needed for pain relief, degree of wound healing measured at he end of the follow up period and categorized into grade 1, 2, and 3 (grade 1: dry suture line, no redness around suture line, normal skin texture around suture line, grade 2: wet suture line, no or minimal redness, normal skin, grade 3: wet or draining suture line, redness and surrounding skin changes of oedema or bullae); and total drain fluid volume in ml.

Data are summarized using means $\pm$ standard deviations for quantitative variables and percentages for categorical variables. Nonparametric tests were used for analysis due to the limited number of patients in this pilot study. The threshold of significance was fixed at the 5% level.

Results:

Effect on pain control:

The VAS was lower under MCT throughout the 10 days of the study. This lower VAS was achieved starting first day postoperatively. (Table 1 and Figure 2).

Effect on dose of tramadol hydrochloride:

The lower pain VAS in MCT group was achieved using a significantly lower dose of tramadol as compared to controls. The average daily dose was 200.0±7.0 mg/day in control group and 63.3±15.8 mg/day in MCT group; a difference proved to be significant at $p<0.001$ (Table 2 and Figure 3). All through the observation period, patients of MCT group needed lower doses of tramadol (Table 3 and Figure 4).

The need for lower dose of tramadol was evident in MCT group. Throughout the observation period, there was no need for the drug in almost 60% of patients at day 1 in MCT group. In control group, about 80% of patients were in need of 300 mg of tramadol. In day 10, more than 90% of patients were not in need of the drug in MCT group as compared to 40% in control group (Tables 4 and 5)

Effect on wound healing:

As shown in table 6, wound healing was better in MCT group. They had higher frequency of grade 1 (50.0% compared to 8.3%). Grades 2 and 3 were more frequent in control group. Ridit analysis proved significance of higher frequency of lower grades under MCT ($p<0.001$). This was accompanied by less drain volume in MCT group

Effect on drain volume:

The lower pain VAS and better wound healing in MCT group were accompanied by a less drain volume compared to controls. The drain volume was 1020.8+211.6 in MCT group and 1170.8±243.5 in control group (Table 2). The difference was proved to be statistically significant ($p <0.05$).

Side effects and discontinuation of treatment:

During the entire observation period, none of the patients had any side effects from patch application. None of them requested discontinuation of MCT treatment.

Discussion

Pain control following painful orthopedic procedures such as total knee arthroplasty is an ongoing challenge, as current pain management techniques often result in undermedication and/or complications[1,2]. The standard approach depends on systemic opioids given in bolus IV or IM or in patient controlled analgesia (PCA) self administration pumps. Preemptive analgesia in the form of epidural pumps, several techniques of regional nerve blocks also depend on opioids and local anaesthetic agents. Oral pharmacologic postoperative pain therapy similarly depends on opioids, but non opioid agents as tramadol hydrochloride are widely used due to their relative safety and known potency. The use of NSAIDs and the new COX-2-specifics is widely practiced despite the scope of side effects associated with its administration in higher doses required in such operations [1,2,4].

Nonpharmacologic methods are less widely accepted in the management of sever pain induced by this group of operations, they include physical therapy, cryotherapy, continuous passive motion (CPM), transcutaneous electrical nerve stimulation (TENS) and patient education[4]. Reports on the efficacy of cryotherapy[7,8,9] and TENS[10] are generally disappointing, while the use of CPM to control pain is controversial[11].

Several reports support a favourable effect of MCT as related to pain control and tissue healing through the modification and recruitment of cell membrane ATP (adenosine triphosphate)[6,12,13,14,15], but this was mostly reported in chronic painful conditions.

If MCT can proves to be a reliable and effective method to control pain postoperatively while avoiding the side effects associated with pharmacologically based methods, a new approach for postoperative pain management would be available to the orthopaedic surgeon.

This pilot study was designed to investigate such an approach, in our small number of patients it was evident that in the group which used the MCT the need for tramadol to control pain has markedly decreased indicating better pain control. Their was also evidence that the use of MCT may improve local wound healing which may be of major importance in total knee arthroplasty, and other operations with major surgical approaches.

Conclusion:

1. This pilot study showed that MCT led to better pain control with markedly lower need for tramadol as compared to control group.
2. This better pain control was accompanied by better wound healing and lesser drain volume.
3. There were no adverse effects or need for discontinuation of MCT application.

Further formal clinical trials with larger numbers are required to establish the validity of this pilot study

References

1- Skinner HB, Shintani EY. Results of a multimodal analgesic trial involving patients with total hip or total knee arthroplasty. Am J Orthop 2004; 33(2):85-92.

2- Bourne MH. Analgesics for orthopedic postoperative pain. Am J Orthop 2004; 33(3):128-135.

3- Singelyn FJ, Deyaert M, Joris D, Pendeville E, Gouverneur JM. Effects of intravenous patient-controlled analgesia with morphine, continuous epidural analgesia, and continuous three-in-one block on postoperative pain and knee rehabilitation after unilateral total knee arthroplasty. Anesth Analg 1998; 87(1):88-92.

4- Colwell CW, Jr. The use of the pain pump and patient-controlled analgesia in joint reconstruction. Am J Orthop 2004; 33(5 Suppl):10-12

5- Scarcella JB, Cohn BT. The effect of cold therapy on the postoperative course of total hip and knee arthroplasty patients. Am J Orthop 1995; 24(11):847-852.

6- Mercola JM. Kirsch DL. The basis of microcurrent electrical therapy in conventional medical practice, J of Advancement in Medicine, Volume 8, No.8, 1995.

7- Healy WL, Seidman J, Pfeifer BA, Brown DG. Cold compressive dressing after total knee arthroplasty. Clin Orthop 1994;(299):143-146.

8- Ivey M, Johnston RV, Uchida T. Cryotherapy for postoperative pain relief following knee arthroplasty. J Arthroplasty 1994; 9(3):285-290.

9- Scarcella JB, Cohn BT. The effect of cold therapy on the postoperative course of total hip and knee arthroplasty patients. Am J Orthop 1995; 24(11):847-852.

10- Breit R, Van der WH. Transcutaneous electrical nerve stimulation for postoperative pain relief after total knee arthroplasty. J Arthroplasty 2004; 19(1):45-48.

11- Walker RH, Morris BA, Angulo DL, Schneider J, Colwell CW, Jr. Postoperative use of continuous passive motion, transcutaneous electrical nerve stimulation, and continuous cooling pad following total knee arthroplasty. J Arthroplasty 1991; 6(2):151-156.

12- Cheng N, Van Hoff H, Bockx E, et al. The effect of electric currents on ATP generation, protein synthesis, and membrane transport in rat skin. Clin Orthop 1982. 171:264-72.

13- Jaffe LF, Venable JW. Electric fields and wound healing. Clin Dermatol 1984; 2:34-44

14- Kirsch D, Lerner F. Innovations in pain management: a practical guide for clinicians. In: Weiner RL (ed) Electromedicine 1990; Deutsche Press; 23:1-29

15- Kulig K, Jarski R, Drewek E, et al, The effect pf microcurrent stimulation on CPK and delayed onset muscle soreness. Phys ther 1991; 71:6 (suppl).

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Tables and figures

Table 1: Pain visual analog score (mean ± Standard Deviation) during the 10-day observation period in the 2 groups.

Days	Control Group	MCT Group
1	84.2±4.2	63.7±19.4
2	86.3±4.8	81.3±14.6
3	82.1±7.2	55.8±18.3
4	77.1±9.6	77.5±17.4
5	76.7±8.1	78.8±26.8
6	68.8±7.4	62.1±15.9
7	60.0±12.1	46.1±19.8
8	55.4±10.9	35.4±11.9
9	43.8±7.4	37.9±17.8
10	38.8±10.9	34.2±13.8

Table 2: Total dose of tramodol in mg/patient and average drain volume

Grade	Control Group	MCT Group
Dose	200.0±7.0	63.3±15.8
Drain	1170.8±243.5	1020.8±211.6

Table 3: Daily dose of tramadol (mean ± standard deviation) in the 2 groups during the 10-day observation period.

Days	Control Group	MCT Group
1	291.7±66.9	50.0±67.4
2	325.0±45.2	125.0±75.4
3	283.3±71.8	41.7±66.9
4	250.0±67.4	15.0±90.5
5	258.3±108.4	133.3±49.2
6	183.3±71.8	66.7±65.1
7	158.3±90.0	25.0±45.2
8	125.0±86.6	8.3±28.9
9	66.7±65.1	25.0±45.2
10	58.3±51.5	8.3±28.9

Table 4: The overall distribution of dosage of the 12 patients of each group during the 10-day observation period

Dose (mg)	MCT Group	Control Group
Not needed	52.5%	10.7%
100	33.3%	23.7%
200	12.5%	28.7%
300	1.7%	25.4%
400	0.0%	11.5%

Table 5: Distribution of dose of tramadol in the 2 groups during the 10-day observation period.

Days and Group		0	100	200	300	400
1	Control	0	0	3	7	4
	MCT	7	4	1	0	0
2	Control	0	0	0	9	3
	MCT	1	8	2	1	0
3	Control	0	0	4	6	2
	MCT	8	3	1	0	0
4	Control	0	0	7	4	1
	MCT	2	3	6	1	0
5	Control	0	1	7	0	4
	MCT	0	8	4	0	0
6	Control	0	4	6	2	0
	MCT	5	6	1	0	0
7	Control	1	5	4	2	0
	MCT	9	3	0	0	0
8	Control	2	6	3	1	0
	MCT	11	1	0	0	0
9	Control	5	6	1	0	0
	MCT	9	3	0	0	0
10	Control	5	7	0	0	0
	MCT	11	1	0	0	0

Table 6: Grade of wound healing

Grade	Control	MCT
1	8.3%	50.0%
2	66.7%	41.7%
3	25.0%	8.3%

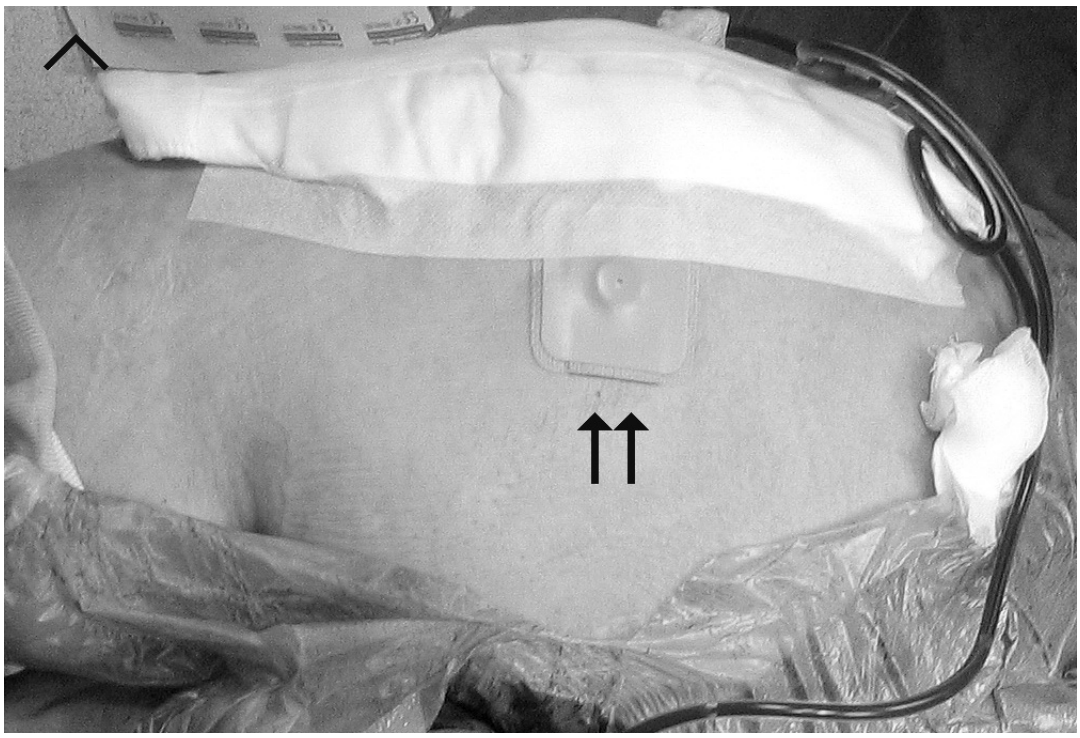

Figure 1: Microcurrent adhesive skin patch in situ (arrows) during postoperative dressing, the other patch is applied on opposite side of the knee at the level of the patella.

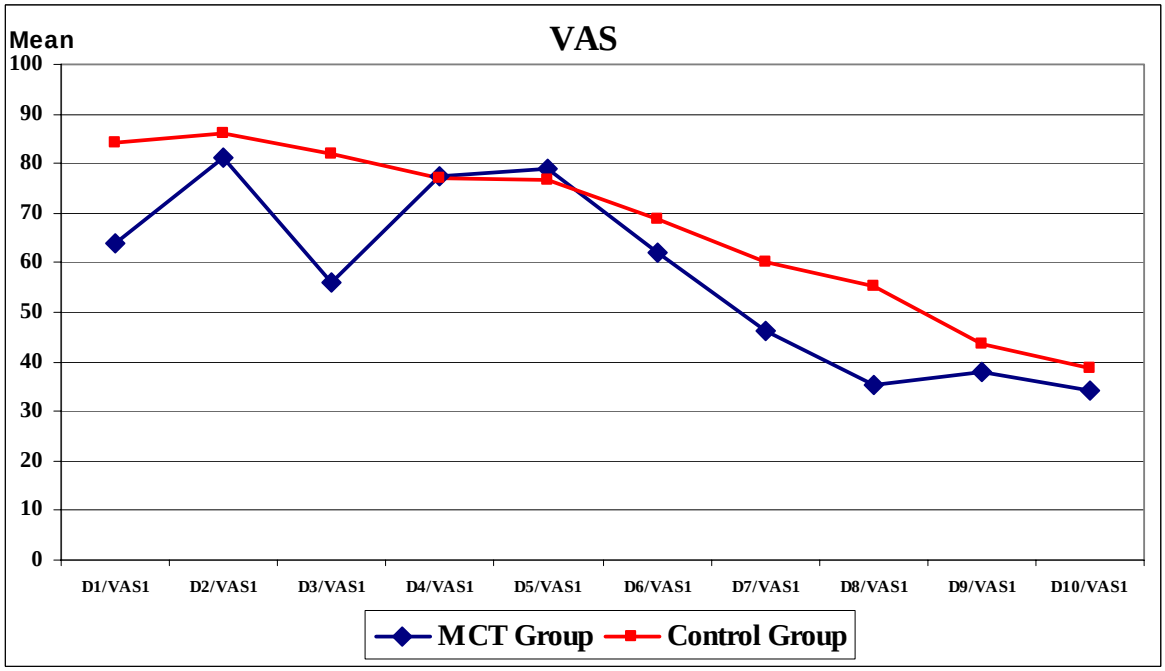

Figure 2: Change in Visual Analog Score in the 2 groups during the 10-day observation period

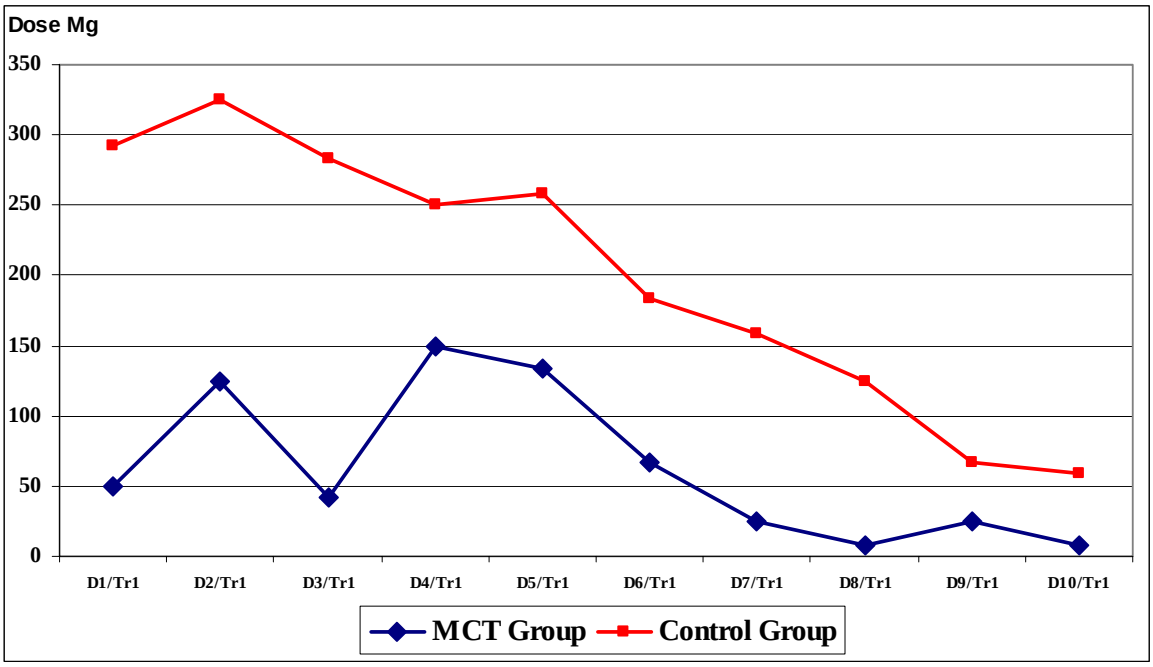

Figure 3: Average daily dose of tramadol needed by patients in the 2 groups during the 10-day observation period

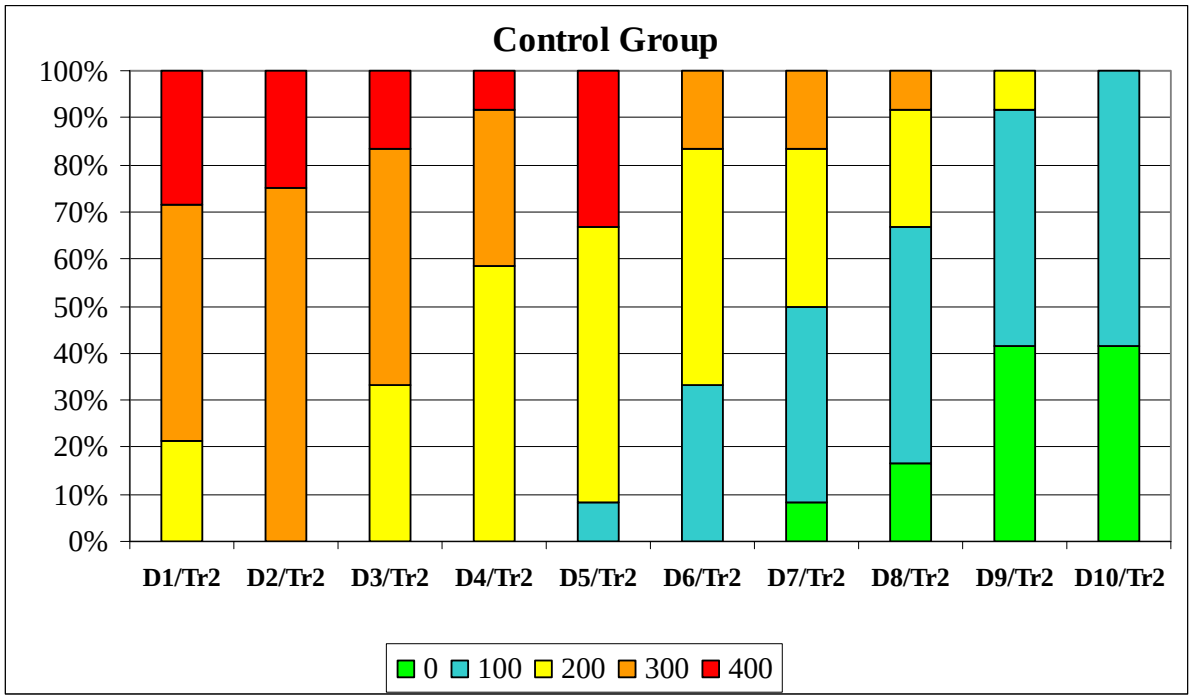

Figure 4: Frequency of different daily doses of tramadol needed after Total Knee Arthroplasty (TKA) for patients in control group during the 10-day observation period

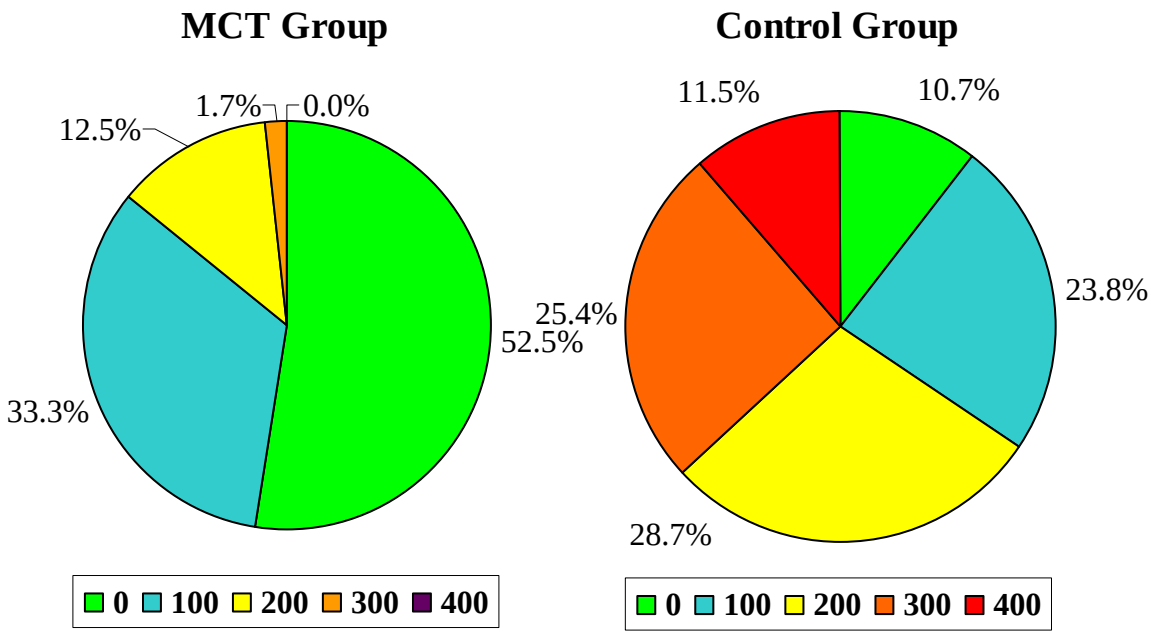

Figure 5: Frequency of different doses of Tramadol needed after Total Knee Arthroplasty (TKA) for patients who received MCT and control group during the 10-day observation period

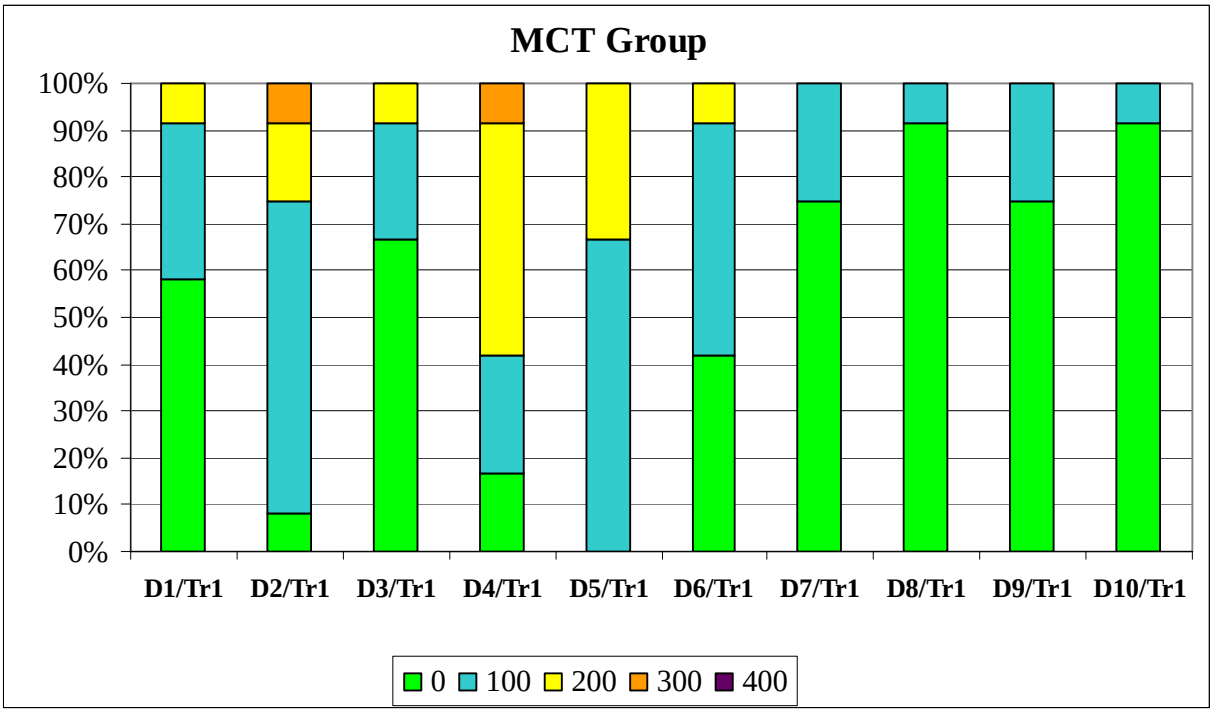

Figure 6: Frequency of different doses of tramadol needed after Total Knee Arthroplasty (TKA) for patients who received MCT and control group during the 10-day observation period

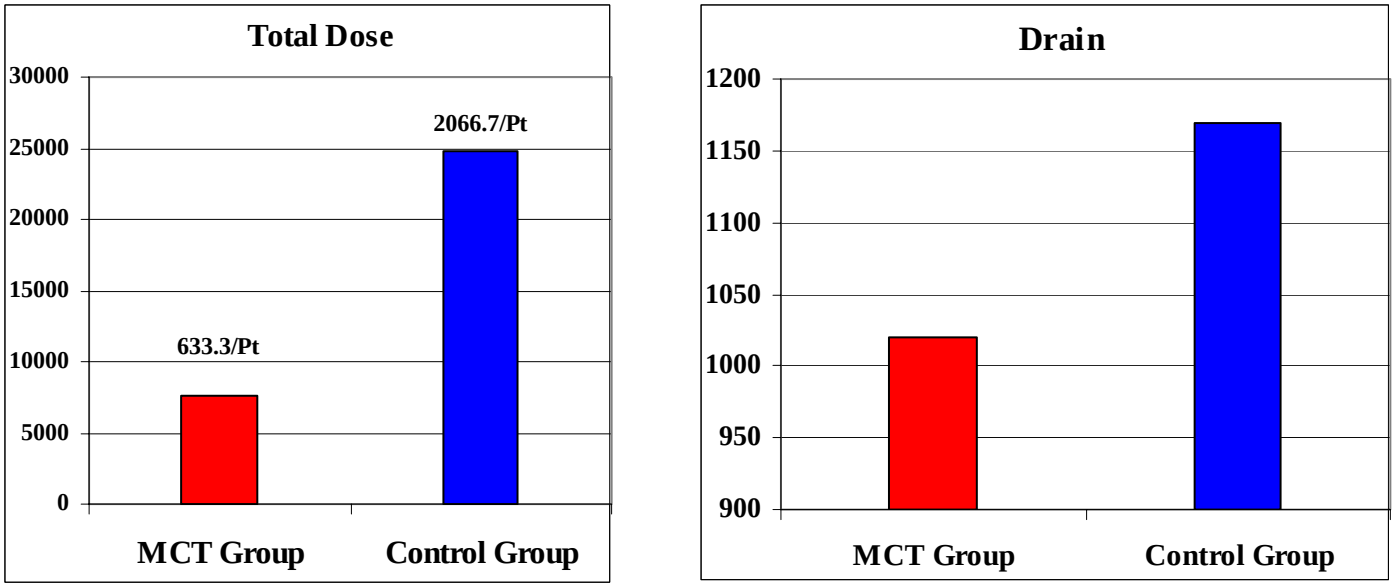

Figure 7: Total dose of tramadol needed during the study period and drain volume in each group

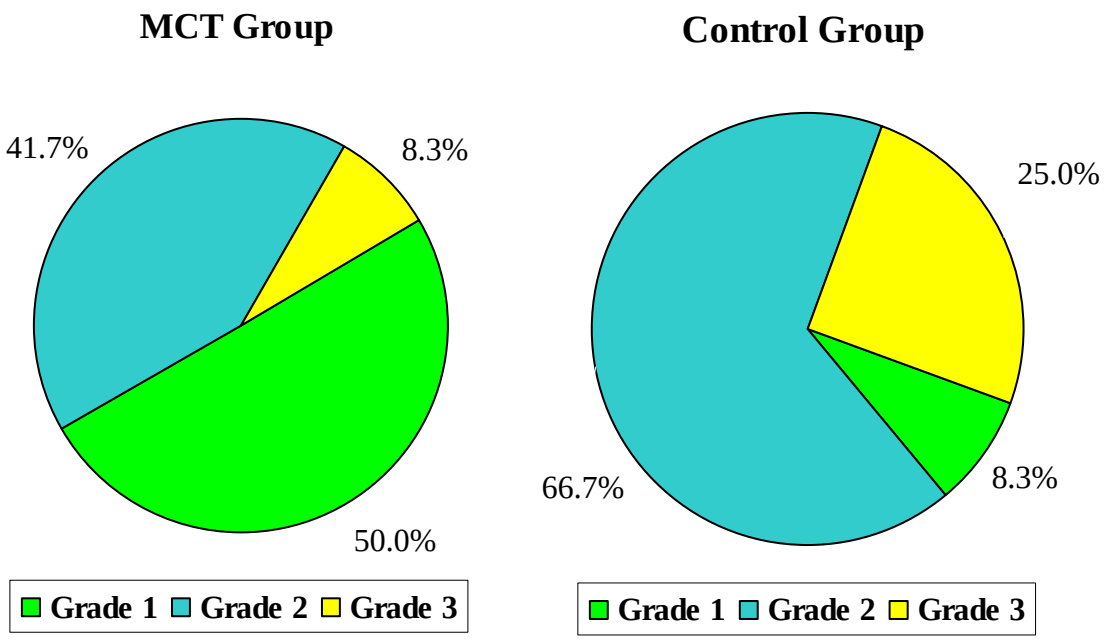

Figure 8: Distribution of grades of wound healing after Total Knee Arthroplasty (TKA) among MCT and control groups