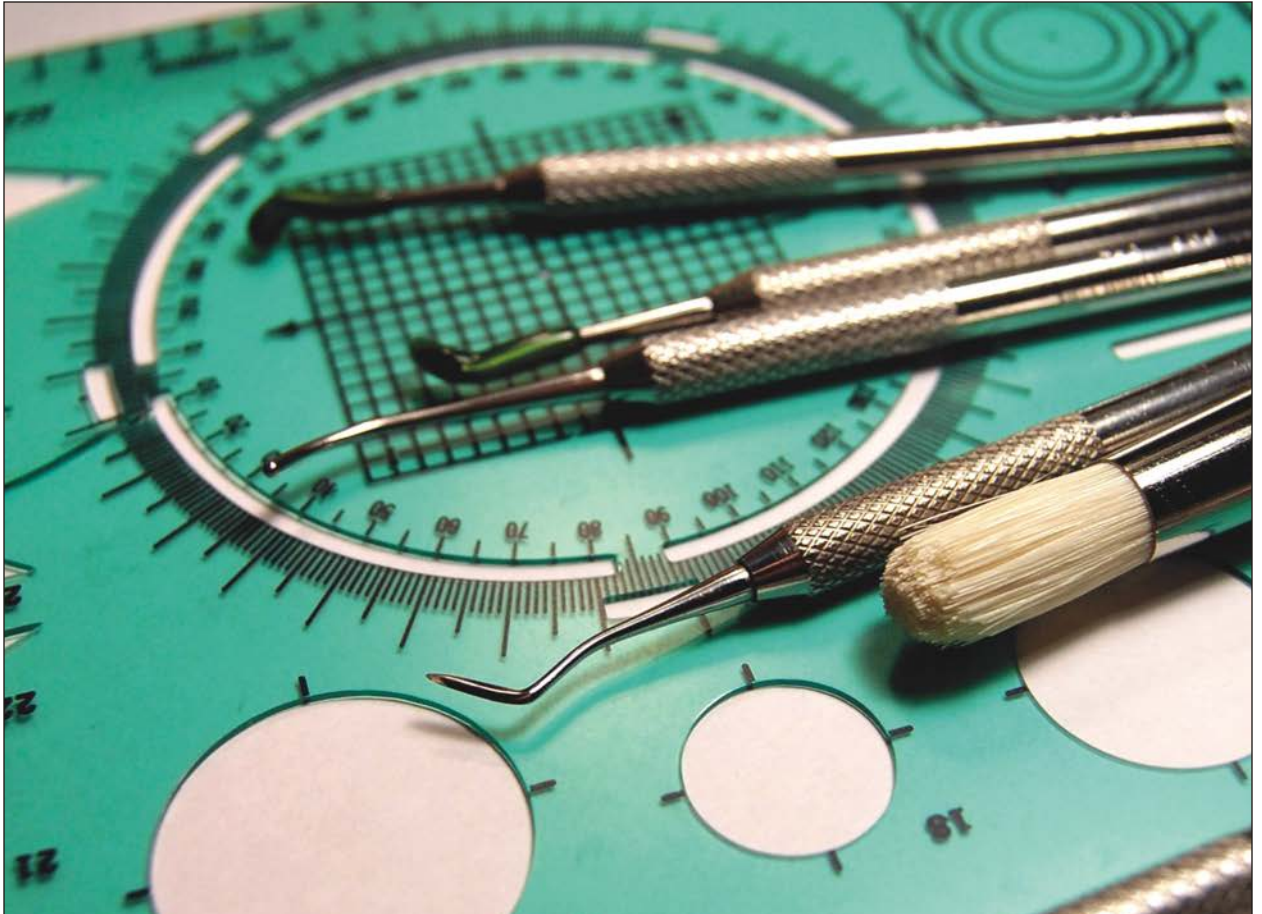




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Comparative Study on the Effectiveness of Acetaminophen and Diclofenac Pretreatment in the Relief of Acute Pain after Out-patient Surgery

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ABSTRACT

The aim of this study is to evaluate and quantify the pain relief after minor surgery when certain analgesics are used before surgery. Double blind study was conducted on 300 outpatient surgery patients who were allocated into two groups. Before surgery, 100 mg of acetaminophen was given to one group and 75 mg of diclofenac to the other one. The pain level after surgery was measured and recorded in both groups by a ruler 10 cm using the Visual Analog Scale (VAS) method at intervals of 30 min, 1, 2 and 4 h after surgery. Also for the patients with VAS more than 7, it was recommended to administer IM 50-100 mg tramadol ampoule. Mean VAS in acetaminophen group was 5.28 ± 1.17 , 5.17 ± 1.04 , 4.47 ± 1.05 , 3.97 ± 1.09 while, in diclofenac group was 5.09 ± 1.10 , 5.10 ± 1.02 , 4.27 ± 1.05 and 3.73 ± 1.07 at 0.5, 1, 2 and 4 h after surgery, respectively. In fact there was no significant difference in pain level after surgery between acetaminophen and diclofenac groups ($p > 0.05$). Moreover, there was no significant difference in the effectiveness of pain relief induced by administering tramadol calmativ ampoule along with acetaminophen and diclofenac groups ($p > 0.05$). Acetaminophen results in as effective pain relief as diclofenac with or without tramadol calmativ. Due to minimal side effects of acetaminophen when compared to other analgesics, like diclofenac, it is recommended to use acetaminophen for safe and efficient pain relief after outpatients surgeries.

Key words: Acetaminophen, post surgical pain, diclofenac, non-steroidal analgesics

INTRODUCTION

Pain is an unpleasant feeling in response to acute tissue injury that induces releasing painful material like histamine, serotonin and substance (Ronald and Miller, 2005). All patients under small- or large- scale surgery, or confined and outpatient surgery need to reduce/relieve pain before, during and after surgery (Santeularia *et al.*, 2009). Lack of enough and efficient treatment of pain is one of the most important factors in long hospitalization after outpatient surgery (White, 2000).

Years ago, narcotics have been used as strong analgesics as they have been used in relieving severe acute or chronic pain. However, high dose of narcotics leads to many side effects to take place such as respiratory depression, apnea, nausea, vomiting, itching and physical and mental dependence which sometimes result in longer admission and late discharge of patients from

hospitals. Moreover, the use of high dose of bullous or continuous infusion of some narcotics, such as alfentanil, increases pain because of the fast absorption and tolerance (Guignard *et al.*, 2000).

Therefore, most of anesthetists believe that narcotic analgesics can be used in outpatient surgery only as adjuvant therapy to help relieve pain before or after surgery. Thus, sometimes, low dose narcotics along with other analgesic medicines such as Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) were being increasingly used (Eriksson *et al.*, 1996).

Many studies reported that a single dose of oral NSAIDS treatment can somehow be effective for pain relief in average to severe pain surgery (Barden *et al.*, 2004a, b; Collins *et al.*, 2000). Furthermore, many other studies, in different parts of the world, found that using, particularly, single oral dose of acetaminophen in surgery of medium to severe pain can lead to a very effective pain relief and these studies also found that acetaminophen caused fewer side effects than many other analgesics (Smith *et al.*, 2001; Moore *et al.*, 1997, 2000; Barden *et al.*, 2004a).

Pain measurement is usually difficult because pain is qualitative and subjective rather than quantitative and objective variable. Moreover, pain is different under many conditions such as individual morals, culture, age, sex and the nature of surgery performed. Nevertheless, Visual Analog Scale (VAS) is considered one of the best methods for pain measurement and has been used as a pain evaluating indicator. In this method, pain is measured by using a scale rated from zero to ten. Zero indicates no pain while ten indicates maximum pain experienced in patient's life. By this scale, individuals' subjective perception of pain can be ranked in numbers (Ronald and Miller, 2005).

In regard to the significance of the anesthesia/analgesia science in surgery, this study aimed at determining and comparing the effectiveness of 100 mg oral acetaminophen and 75 mg of oral diclofenac, as a pre-treatment, in decreasing acute pain experienced after outpatient surgery.

MATERIALS AND METHODS

The population of the study: This study was conducted as double blind experiment. Three hundreds patients of age ranged 14 to 44 years and mean body weight 50 kg were involved in this study in the period from 2008 to 2009. They were referred to Mobasher hospital of Hamadan and underwent orthopedic outpatient surgeries. Patients were evaluated by, at first, an emergency physician to decide their need for hospitalization and treatment. Patients were then confined to bed and were supervised at emergency section. The patients were then prepared for operation after obtaining written consent for doing surgery. The exclusion criteria of patients were that they have no previous history of sensitivity to acetaminophen or diclofenac, no current medical illness or chronic illness, particularly, digestive diseases, no other drugs, particularly, NSAIDs are taken and no history of psychological disturbance which might affect patients' perception of pain. The human subjects in this study were dealt with full care and in harmony with the biomedical research committee of ethics.

Surgery pretreatment of analgesia and anesthesia: Under the supervision of a surgery specialist of orthopedics, 150 patients were administered 1000 mg of acetaminophen (Barden *et al.*, 2004a) while the other 150 patients were administered 75 mg of diclofenac tablets (Barden *et al.*, 2004b) with half cup of water 40-60 min before induction of anesthesia. Afterwards, 8 mg Dexamethazone and 10 mg metoclopramide were given for all patients just before doing the surgery in the operation room. Moreover, patients received 1 µg fentanyl per kg of weight before anesthesia which is a short-term narcotics for inducing pain relief during surgical operation (Eriksson *et al.*, 1996). Induction of anesthesia was done with 5-7 mg kg⁻¹ of thiopental and

if necessary, for continuing the anesthesia, vaporization anesthesia was also used (Ronald and Miller, 2005).

Visual analog scale assessment of pain: After surgery, it was not possible to measure pain in terms of VAS within the first 15 min after the operation because all patients still did not recover yet. The post-operational pain was measured in terms of VAS (0 to 10) at intervals of 0.5, 1, 2 and 4 h after the operation. In order to conduct a double blind study, VAS was evaluated blindly by two members of research team who knew nothing on the pre-surgery treatment and VAS was then averaged. Attentive to proposed form and also based on moral considerations, patients with severe pain (VAS>7) must receive 25 mg pethidine; due to unavailability of pethidine at that time, 50-100 mg tramadol were used (Hyllested *et al.*, 2002).

Statistical analysis: Data was analyzed by SPSS software using student t-test and chi-square (χ^2) statistical tests.

RESULTS

The demographic data of the involved patients was not different between the studied groups ($p>0.05$) (Table 1). Therefore, both acetaminophen and diclofenac groups were proved to be reliably comparable with each other. The overall mean index measurement of pain (VAS) in the period from 30 min to 4 h after surgery showed insignificant difference between the two groups of acetaminophen and diclofenac ($p>0.05$) (Table 2). It was also confirmed that the mean VAS for each time interval, 0.5, 1, 2 and 3 h, was not significantly different from the VAS value of the corresponding time interval in the other group ($p>0.05$). Table 2 indicate that both tested analgesics exerted an equivocal pain relief and their efficiency was highly comparable. Moreover, in each group, average VAS was not significantly different among the different intervals of measurement, namely, 0.5, 1, 2 and 3 h after the surgery ($p>0.05$) (Table 2) providing evidence that the analgesic effect of these drugs was evident as early as 30 min after surgery and the analgesic effect was of close efficiency of pain relief when compared to 3 h later. On the other hand, the administration of tramadol calmativ ampoule within the first 4 h after outpatient surgery for was for patients

Table 1: Demographic data of surgery outpatients

Results	Acetaminophen group	Diclofenac group	p-value
Males	106 (70.6%)	112 (74.7%)	0.430
Females	44 (29.33%)	38 (25.3%)	
Mean age (year)	36.09±14.53	35.75±1.087	0.822
Mean weight (kg)	69.92±8.71	68.51±7.50	0.135

Table 2: The mean index pain (VAS) assessment of the involved patients at different intervals after the outpatient surgery

	VAS		

	Acetaminophen group	Diclofenac group	
Time (h)	----- (Mean±SD) -----		p-value
0.5	5.28±1.17	5.09±1.10	0.140
1	5.17±1.04	5.10±1.02	0.576
2	4.47±1.05	4.27±1.05	0.100
3	3.97±1.09	3.73±1.07	0.540
Overall mean VAS (0.5-3 h)	4.72±1.08	5.54±1.06	0.420

experienced VAS value >7 . Similarly, it was shown that there was no significant difference in the overall mean VAS between acetaminophen group, 5.67 ± 2.2 and diclofenac group, 6.33 ± 2.4 ($p > 0.5$).

DISCUSSION

The current study is the first study evaluating the use of acetaminophen and diclofenac on a huge number of patients undergo surgery. Moreover, this study compared these drugs together on adult patients where most previous studies were exerted on children patients. The current study indicated that the average VAS was not significantly different in both groups of diclofenac and acetaminophen. This finding confirms the results of other studies on the effect of pain relief of acetaminophen compared to NSAIDS. A study performed in Singapore on children who had miringotomy surgery showed that acetaminophen and diclofenac can reduce post surgical pain in the same extent (Romsing *et al.*, 2000). Nevertheless, unlike the current study, the used dose in Singapore was much less, 15 mg kg^{-1} and it seems that this dose is effective in children. The current study showed that the average VAS in all periods of pain measurement, 0.5, 1, 2 and 4 h after the operation, were not different between diclofenac and acetaminophen patients and moreover, average VAS was not different with time in both groups of study. These findings confirm that the efficiency of pain relief after surgical operation is the same by both acetaminophen and diclofenac drugs at the used dose which was supported by Romsing *et al.* (2000) study. Furthermore, it was shown that the post operational pain relief of diclofenac and acetaminophen drugs was efficient as early as 30 min after the surgery which gives clues that these drugs exert prompt and potent analgesic effect at acceptable doses.

In a conclusion of a huge review article in 2002 on the pain relief effect of acetaminophen compared with NSAIDS, it was shown that acetaminophen is a suitable and effective analgesic medicine and due to its less side effects compared to NSAIDS, it can be used in major and orthopedic surgeries. Moreover, they indicated that acetaminophen can be useful in creating a good pain relief when compound with NSAIDS (Hyllsted *et al.*, 2002). This agrees with the results of current study.

The findings of the current study also showed that the dose of using teramadol calmative, 50-100 mg, along with acetaminophen and diclofenac after the operation is found to be recommended in cases of pain score more than 7. However, in the two groups of comparison, namely acetaminophen and diclofenac groups, the use of teramadol calmative resulted in unremarkable differences in pain relief indexed by VAS system. Many studies were done on the effect of acetaminophen and NSAIDS separately on the dose of narcotics, in general and teramadol calmative, in particular, after the operation. Leontev *et al.* (2005) study explained that using 1 g of acetaminophen in major orthopedic surgery can reduce effectively the use of narcotics. Moreover, Joshia *et al.* (2004) reported in their study that 100 mg of diclofenac, 1000 mg of acetaminophen and 60 mg of codeine were recommended in 119 patients during a period of 15, 30 min, 1 and 2 h after tooth surgery. Hence, these findings collectively revealed that the use of narcotics has been greatly reduced when a proper use of other analgesics, particularly acetaminophen was pursued which in turn solidify the basis of the findings of the current study.

CONCLUSION

Taken together, the findings of the current study showed that rate of pain relief created by using acetaminophen and diclofenac after surgical operation is not different from each other. So attentive to less side effects of acetaminophen than NSAIDS, it is recommended to use acetaminophen for inducing prompt, safe and efficient pain relief in post outpatient surgery. Furthermore, acetaminophen can be considered a golden choice for reducing the concomitant use of narcotics as pain relievers.

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