Comparative Evaluation of Ketorolac and Diclofenac for Pain Relief in Acute Lumbar Disc Prolapse

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Abstract

The study aimed to study the efficacy and safety of ketorolac tromethamine compared to diclofenac sodium in patients with acute lumbar disc prolapse.

Thirty three patients were included as subjects in the study, 17 of them received ketorolac 15 mg intramuscularly (IM) and 16 received 75 mg diclofenac IM. Analgesic efficacy was assessed using the visual analogue scale (VAS) 1, 3 and 6 hours after drug injection and side effects by enquiry and reporting whenever it occurred.

Ketorolac showed equi-analgesic effect as diclofenac at 1 3 and 6 hours post-injection and was as safe as diclofenac in the mentioned doses.

In conclusion: Ketorolac, as doe's diclofenac, appeared to be a safe, effective drug in the treatment of pain in cases of acute lumbar disc prolapse.

Further studies for more assessment of this drug in higher doses and longer durations and its use in other acute musculoskeletal conditions are recommended. We also suggest further investigations regarding the commonly used pain scales like VAS to highlight the influence of psychological or other social conditions in our community that may affect the expression of these pain scales.

الخلاصة

على الرغم من توفر العديد من طرق معالجة تدلي القرص القطني إلا أن معالجة هذه الحالة لا تزال تمثل مشكلة جدية و أن كثير من الباحثين لا يزالون يسعون الى اثبات فعالية مختلف العقاقير الجديدة والتقنيات لدعم خطوط المعالجة المتوفرة.

ان هدف هذه الدراسة هو دراسة نجاعة ومأمونيّة عقار (ketorolac) بالمقارنة مع عقار (diclofenac sodium) في مرضى تدليّ القرص القطني الحاد.

تضمنت الدراسة (٣٣) مريضا؛ تم اعطاء ١٧ منهم ١٥ ملغم من عقار (ketorolac) و١٦ مريضا أعطوا ٧٥ملغم من عقار (diclofenac sodium) عن طريق الحقن بالعضل. تم تقييم نجاعة التسكين باستعمال سلّم المضائهات الابصاري في ١ و ٣ و ٦ ساعات بعد حقن العقار كما تم تقييم الاعراض الجانبية بالاستفسار عنها وتسجيلها في حال حدوثها.

أظهر عقار (ketorolac) تأثير مسكّن مساوي لعقار (diclofenac sodium) في الساعات ١ و ٣و ٦ التي تلت الحقن كم كان مأمون بدرجة مماثلة. نستنتج مما تقدم أن عقار (ketorolac) كما هو الحال في عقار (diclofenac sodium) فأنه أمين وفعال في معالجة الالم في حالات تدليّ القرص القطني الحاد. كما نوصي باجراء دراسات اكثر وباستعمال جرع اعلى ولفترات اطول لغرض تققيم هذا العقار ولدارسة استخداماته في امراض الجهاز العضلي الهيكلي. كما نقترح اجراء استقصاءات اخرى تخص سلالم الالم الشائعة الاستخدام مثل سلّم المضائهات الابصاري لتوضيح تأثير الضروف النفسية والاجتماعية في مجتمعنا والتي تؤثر في التعبير عن الالم في سلالم الالم هذه.

Introduction

Low back pain due to lumbar disc prolapse is the major cause of morbidity throughout the world affecting mainly the young adults. Lifetime incidence of low back pain is 50-70% with incidence of sciatica more than 40%[1]. In spite of the availability of many modalities, the management of lumbar disc prolapse (LDP) is still a challenging issue and many authors are still trying to prove the efficacy of different new drugs and techniques to support their lines of management of this condition. Ketorolac tromethamine often provide effective pain relief in several conditions, and having prolonged analgesic activity[2], has neither sedative nor anxiolytic properties[3]. It has been used successfully to replace opiods in some situations. And it was found that pain relief was achieved with ketorolac earlier than diclofenac with equianalgesic effect to tramadol in patients undergoing minor surgical operations[4]. In addition to that ketorolac was found to has more analgesic effect than diclofenac for post-operative pain relief[5] and was significantly more effective than pethidine in reducing pain in renal colic[6]. With this background we designed this study to investigate the analgesic efficacy and safety of ketorolac compared to ,the widely used, diclofenac for pain relief in patients with acute lumbar disc prolapse, aiming to prove or disprove its value as one of the drugs of choice to treat this condition.

Aim of the Study

The study aimed to study the efficacy and safety of ketorolac tromethamine compared to diclofenac sodium in patients with acute lumbar disc prolapse.

Patients and Methods

Thirty three patients were included in this prospective study (n=33), not surfing from chronic illness with a normal liver and kidney function. 21 male and 12 female, their age range was 19-43 years, all were attendants of Dijlah rehabilitation hospital for the period 10th of January to the 30th of july 2006. All patients were diagnosed clinically to have lumbar disc prolapse by consultant rheumatologist and the diagnoses were confirmed by magnetic resonance imaging (MRI) studies. Patients with negative MRI, advanced lumbar spondylosis or other lumbar skeletal abnormalities were excluded from the study. Informed written consent was taken from all participants prior to study.The study participants (n=33) were divided into two groups ketorolac group(n=17) and diclofenac group (n=16). Ketorolac group received 15 mg ketorolac tromethamine IM and diclofenac group received 75mg diclofenac sodium IM at admission to our consultation department.Analgesic effect of both drugs was assessed by visual analogue scale (VAS) at 1,3 and 6 hours post-injection of either drugs, and side effects by enquiring about adverse reactions like nausea, vomiting , mouth dryness, injection site pain, heartburn and edema…etc, and its reporting whenever it occurs. Visual analogue scale (7,8): in this pain assessment method, a 10 cm scale ranged from 0-10 was shown and explained to all patients. 0 represents “no pain at all” while 10 represents the worst pain “as bad as could possibly imagine”. Patients were asked to mark the point of the scale where the pain lies as they feel it, this correspond to the numerical index of the severity of pain.Statistical analysis was done as mean ± standard deviation (SD) (or range). One way analysis of variance, students-t- test, chi-square test and Ducuns multiple range test were used as appropriate. A value of $P < 0.05$ was considered statically significant.

Results

A total of 33 patients were enrolled as subjects in this study, they were 21 male and

12 female. The age range was 19-43 years. Seventeen patients were placed in ketorolac and 16 in diclofenac groups. The age range of ketorolac group was 20-43 years and of diclofenac group 19-41 years.VAS scores of all patients in different times post-injection are shown in table 1. One way analysis of variance of VAS scores at pre-treatment , 1, 3 and 6 hours post_injection of both drugs reveals a significant relation (p=0.013 for ketorolac and 0.001 for diclofenac) proving the effective analgesic effect of both of them. At first hour, mean VAS score ± SD was recorded as 3.88 ± 1.69 and 4.75 ± 1.57 in the ketorolac-treated and diclofenac-treated groups respectively. At 3 hours mean VAS score ± SD was recorded as 3.35 ± 1. 90 for ketorolac group and 3.68 ± 1.53 for diclofenac group, while at 6 hours it was 3.29 ± 1.79 for kterolac and 3.56 ± 1.45 for diclofenac group, The difference between the 2 groups was statistically Non- significant pointing to an equi-analgesic effect of the 2 drugs (p=0.15).Four of 17 patients (23.5%) of ketorolac group experienced some sort of adverse effect compared to 3 of 16 patients (18.75%) of diclofenac group (table 2).One patient of ketorolac (5.88%) and one of diclofenac (6.25%) groups experienced dry mouth. One patient of ketorolac group (5.88%) experienced nausea in contrast to none of diclofenac group. While none of the two groups developed vomiting.No patient in ketorolac group complained of heartburn in contrast to 1 (6.25%) of diclofenac group. Mild edema occurred in 1 and injection site pain in another one (5.88%) of ketorolac group compared to none of the patients of the diclofenac group.Headache was a complaint in only one (6.25%) patients of diclofenac group with no such complaint in the ketorolac group.Statistical analysis of the two drugs regarding the occurrence of side effects reveals statistically Non-significant differences (p<0.05).

Discussion

In this prospective study we have tried to evaluate the effectiveness of single dose, 15mg IM, ketorolac tromethamine in the management of pain of patients with acute lumbar disc prolapse and to compare it with the older, widely used drug, diclofenac sodium.Ketorolac tromethamine is a non-steroidal anti-inflammatory drug (NSAID) that is newer than diclofenac and it yields promising results in many previous studies as a pain killer. It has been shown to be an effective analgesic in treating patients with acute musculoskeletal pain in the emergency department[9]. Some authors have concluded that it may be comparable to pethidine[10] and morphine[11] as a pain-killer in some situations, others proved its superior analgesia over pethidine[6] and others noted equi-analgesic but faster onset of action of analgesia than diclofenac[4]. Our results proved a statistically significant analgesic effect of both ketorolac tromethamine and diclofenac sodium, and showed their certain effectiveness as pain killers in cases of acute lumbar disc prolapse, the analgesic effect of ketorolac was similar to that of diclofenac throughout the period of the study (1, 3 and 6 hours).Visual analogue scale (VAS) is a valid, reliable and appropriate instrument for quantifying pain[12] and can be used separately to assess pain severity[13]. In our study, the value of pretreatment VAS (5.17±1.91for ketorolac and 5.56±1.54 for diclofenac) was higher than many other studies, which is not a limitation to the test, as it is a subjective one and may depends largely upon some personal, psychological or social backgrounds that may affect the pain expression or description by the patients in different communities. However, our patients showed statistically significant regression of pain post-injection with both of the drugs.The analgesia evoked by ketorolac and diclofenac did not differ when compared in the 1, 3 and 6 hours pertaining to a similar profile over

the 1st 6 hours after their injection.Nausea occurred in our series in 5.88% and dry mouth in 5.88% also, while vomiting and abdominal pain did not occur at all, this observation is similar to that of Burhan Uddin et al[14]. Mild edema occurred in one patient, this side effect was reported in many previous reports and was transitory and attributed to fluid and water retention of ketorolac as a common side effect of NSAIDs[15]. Tarkkila and Saarnivaara[16] reported nausea to occur in 47%, injection site pain in 16%, vomiting in 26% and abdominal pain in 11%. All percentages are higher than the studded ones and this finding may be explained by the higher dose of ketorolac used in their study.

However, the side effects profile for both ketorolac and diclofenac in our study showed statistically insignificant differences.

Conclusions

Considering all the above observations we have concluded that ketorolac is an effective analgesic agent in acute lumbar disc prolapse and it can be added to the group of NSAIDs that have proved an efficacy in this situation, in addition to that it seems as safe as diclofenac for use in such dose and regimen.

Recommendations

We recommend further studies on ketorolac in higher doses and longer durations to assess its efficacy in lumbar disc prolapse and in other acute rheumatic diseases. Further studies considering the factors affecting the expression of pain by VAS (or any other pain scale) in the Iraqi community is recommended also.

Table 1. Assessment of pain in the two groups by VAS

Time	Ketorolac group (n=17)(mean±SD)	Diclofenac group (n=16)(mean±SD)
Pretreatment	5.17±1.91	5.56±1.54
1 hour	3.88±1.69	4.75±1.57
3 hours	3.35±1.90	3.68±1.53
6 hours	3.29±1.79	3.56±1.45

From the table data there are no significant difference. (p=0.15)

Table 2. Side effects in the two groups

Side effects	Ketorolac group(n=17)	Diclofenac group(n=16)
Dry mouth	1	1
Nausea	1	0
Vomiting	0	0
Heartburn	0	1
Mild edema	1	0
Injection site pain	1	0
Headache	0	1

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