

Comparison of the Onset of Diclofenac Potassium Sachet(Voltfast) and Enteric-Coated Diclofenac Potassium(Cataflam) in Treatment of Pain Following Tooth Extraction

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الخلاصة

الأهداف: إن الهدف من هذه الدراسة هي مقارنة العقارين المسؤولين عن تسكين الآلام (فولط فاست و الكاتافلام) بعد قلع الأسنان. **المواد وطرائق العمل:** تم علاج مئة وخمسون مريضاً قسماً إلى مجموعتين كل مجموعة تحتوي على خمسة وسبعون مريضاً، تم إعطاء المجموعة الأولى عقار (الفولط فاست) والمجموعة الثانية عقار (الكاتافلام) بعد قلع الأسنان، وطلب من المريض إن يسجل متى تم تسكين الألم بعد زوال تأثير المخدر. **النتائج:** أظهرت النتائج إن كلا الدوائين قد لوحظ تأثيرهما الإيجابي في تسكين الألم ولكن بالمقارنة بينهما لوحظ بان (الفولط فاست) هو أسرع بكثير في تسكين الألم من (الكاتافلام). **الاستنتاجات:** إن الفولتارين الذي يعطى بالفم له تأثير إيجابي ملحوظ في تسكين الألم وهو يستخدم في حالات تسكين الآلام المتوسطة والشديدة خاصة بعد العمليات، في النهاية نستطيع ان نقول بان (الفولط فاست) هو أكثر سيطرة على الألم من ناحية سرعة التسكين إذا ما قارناه مع (الكاتافلام).

ABSTRACT

Aims: This study was undertaken to compare the analgesic onset of voltfast and diclofenac potassium in patients after extraction of teeth. **Materials and methods:** One hundred fifty patients were enrolled in this study and randomly divided into two groups. Group 1 received sachets of oral diclofenac potassium (Voltfast) and group 2 received enteric coated of diclofenac sodium (Cataflam) after extraction of teeth. The patients reported their pain relief in a questionnaire after the tooth extraction. The patient was instructed to take the drug as prescribed as the effect of local anesthesia begin to wear off and pain start. To evaluate the onset of the two drugs, the patients were asked to report if they had any problem using the drug. **Results:** seventy five patients received voltfast and cataflam seventy five patients received for relief of pain. The pain relief in both groups was efficient with statistically significant difference between the two groups. **Conclusions:** Oral diclofenac is an effective treatment for moderate to severe postoperative pain. Significantly more participants experienced a faster onset of pain relief with voltfast than with cataflam. **Key words:** Voltfast, Cataflam, Tooth extraction, Diclofenac potassium and Pain.

Al-juma`a DA, Comparison of the Onset of Diclofenac Potassium Sachet(Voltfast) and Enteric-Coated Diclofenac Potassium(Cataflam) in Treatment of Pain Following Tooth Extraction. *Al-Rafidain Dent J.* 2015; 15(1): 369-373.

Received: 13/5/2013

Sent to Referees: 16/5/2013

Accepted for Publication: 17/7/2013

INTRODUCTION

Pain is a complex experience consisting of a specific sensation and the reactions evoked by that sensation. Conventional analgesics either interrupt ascending nociceptive impulses or depress their interpretation within the central nervous system (CNS). A variety of analgesics have proven efficacy for managing chronic pain.⁽¹⁾

Pain of teeth, mouth, face or head usually has a local cause, often the sequelae of dental caries (odontogenic pain). However, psychogenic, neurological and vascular conditions, and conditions where pain is referred from elsewhere, may be responsible.⁽²⁾ Postextraction pain is a pathological sequel of normal healing of a wound due to alveolitis sicca dolorosa is a complication which appears after tooth extraction

which result in the occurrence of intensive pain.⁽³⁾ Pain is a common complaint often occurring with inflammatory processes after a tooth extraction⁽⁴⁾. Non-steroidal anti-inflammatory drugs (NSAIDs) are used in treatment of pain including tooth pains for many years. Even though they are effective in relief of pain, they may have adverse reactions.⁽⁵⁾

The analgesic drug of choice must not affect the patient's consciousness or disturbs his (her) normal activity.⁽⁶⁾ So, there was a need to evaluate the efficacy and safety of NSAIDs extensively.⁽⁷⁾ Cox-2 inhibitors were widely promoted as alternatives to both opioids and NSAIDs, mainly due to their less side effects.^(8,9,10)

The dentist is routinely faced with the situation of tooth extraction and subsequent

tissue trauma. Other studies reported the incidence of post-extraction pain, the incidence of analgesic administration following dental extraction and the reported efficacy of analgesics, in order to enable the practitioner to assess the need to manage post-extraction pain.⁽¹¹⁾

Diclofenac is a non steroidal anti-inflammatory drug (NSAID) that shows preferential inhibition of the cyclooxygenase-2 and COX1 (COX-2/1) enzyme, use for treatment of mild-moderate pain and also other mechanisms go beyond COX inhibition, affecting a broad range of pain and inflammatory mediators and intracellular pathways.^(12,13) The normal formulations of diclofenac (monolithic acid-resistant coated dragée or tablet) may result in retention of the drug in the stomach for hours or even days, which may cause retarded absorption and delayed plasma peak concentrations⁽¹⁴⁾. Moreover, diclofenac has been shown to undergo considerable first-pass metabolism, limiting its oral bioavailability (50–60%)^(15,16). To provide rapid pain relief, diclofenac potassium was launched as an immediate-release tablet.^(17,18,19) In contrast to delayed release preparations of the sodium salt, diclofenac-K is formulated to dissolve under the acid conditions of the stomach^(21,22).

Diclofenac is a non-steroidal anti-inflammatory drug largely used, mainly to relief pain of various origin. Diclofenac is present on the market as free acid, as sodium salt and as potassium salt. The potassium form has shown a prompter absorption rate and a faster onset of analgesic activity than the acid form and sodium salt (Increased absorption rate of diclofenac from fast acting formulations containing its potassium salt).

The average time to peak plasma concentration with the tablets was 53.10 min. the highly soluble potassium salt of diclofenac was rapidly absorbed, especially in its sachet formulation, and thus appears to be an invaluable analgesic agent that is particularly useful for quick pain relief⁽¹⁹⁾.

MATERIALS AND METHODS

One hundred fifty adult healthy patients attending in my clinic was enrolled for this study of both genders and ages (20-50years) in a private clinic and were divided randomly into two groups of seventy five patients each (male and female), the first group was given diclofenac potassium (volfast sachet 50mg, Novartis. Switzerland) and the second group was given diclofenac potassium (cataflam 50mg, Novartis. Switzerland) postoperative extraction (after the of local anesthesia begin to wear off and pain started).

Closed aseptic technique with forceps only was used as a method of extraction. One cartridge of anesthesia (lidocaine 2% E-80, Colombia S.A., epinephrine 1:80.000) separation of gingiva all around the tooth by surgical blade no.15 was performed to avoid any trauma on gingiva. After complete extraction gauze over the extracted socket was placed for 30 minutes. Postoperative instructions included a soft diet and avoiding mouth rinse on the same day postoperatively. 24h postoperatively mixed salt/water mouth rinse, three time daily for one week and the patient was followed-up for three days.

Medical prescription of analgesic only was given and to be used on (initial daily dosage is 50-150mg) without any antibiotic.

Table (1): Case sheet for patients

Name الاسم	Sex الجنس	Age العمر	Phone number رقم التلفون
Time for pain relief (volt fast)min.		Time for pain relief (cataflam)min.	
Unwanted effects			
<ul style="list-style-type: none"> • Skin rash • Respiratory depression • Bleeding • Cardiovascular problems • Gastrointestinal problems • Others 			

RESULTS

In this study the patient was given of oral sachets of diclofenac potassium (voltfast) in one group and oral enteric coated of diclofenac sodium (cataflam) in another group and asked to report the onset and any unwanted effects

of drugs. There is no any problem except bad taste and few cases(about 8) report nausea in voltfast. Statistical analysis used SSPS to show mean, standard deviation at P-value 5% and the results are explained in the Tables(2,3)

Table (2): Statistical analysis of the samples in SSPS program

Drug name	N	Mean (minutes)	Std. Deviation	Std. Error Mean	T-test	df	Sig.
Voltfast	75	8.1467	3.478848	.40166	10.035	58	.000
Cataflam	75	25.1067	6.99918	.80820	10.035	35.889	.000

N: number of patients

Table (3): independent samples test

Time	N	Mean (minutes)	Std. Deviation
	-18792	148	.000

df: degree of freedom | T-test: calculated | P-value: significant value 5%

DISCUSSIONS

Treatments are usually administered post-operatively at moderate or severe pain intensities, thereby decreasing the dispersion of pain intensity measures by only including patients in need of analgesics. However, treatment have been administered after tooth extraction in order to study preemptive effects of analgesics⁽¹⁹⁾.

Voltfast and cataflam are a non-steroidal anti-inflammatory drugs(NSAID) and contain the potassium salt of diclofenac. In Voltfast and cataflam, the sodium ion of diclofenac has been replaced by a potassium ion. The active principle is thus the same as in voltaren. These preparation possesses analgesic, anti-inflammatory, and antipyretic properties, voltfast sachets have a rapid onset of action which makes them particularly suitable for the treatment of acute painful and inflammatory conditions^(21,22).

Diclofenac is rapidly and completely absorbed from diclofenac potassium sachets. The quantity of active substance absorbed is not diminished when the contents of the sachet are taken together with food⁽²²⁾.

The important findings of this study are that the time to achieve this peak onset is approximately one third (from median time of 25.1067 minutes for tablet to a median time of 8.1467minutes for the powder), because it is taken as a solution in which activation and release of active substance in fluid may be absorbed quickly and has quick onset – sometimes as quick as within 8.14 minutes. The 3 steps approach for treatment of acute pain developed by the World Health Organization (WHO) recommends; first-line therapy using

a NSAID, second-line therapy (with a weak opioid such as codeine) and third-line therapy(with a strong opioid such as morphine or fentanyl)⁽²³⁾. The NSAID diclofenac is produced using 2 distinct salt bases: potassium and sodium; thus, its chemical formula is [(2,6-dichlorophenyl) amine] benzene acetic acid monopotassium or monosodium salt, depending on the salt base being used.^(24,25) This study agree with Olson et al,1997(21) that there are differences between potassium based diclofenac which is soluble in water and formulated to release diclofenac in stomach, and sodium based diclofenac which is sparingly soluble in water and resists dissolution in low PH of gastric fluid, allowing for a rapid release of diclofenac in the higher PH fluid of the duodenum.

This study showed the rapid onset of diclofenac potassium (voltfast) due to potassium salt content which causes high absorption and lead to increased plasma concentration of drug. Diclofenac sodium takes up to 2hours to achieve maximum plasma concentration. This study agrees with Reiner V et al(2001)⁽¹⁸⁾, while the diclofenac sodium in enteric-coated form tablet takes more time for release of effective agent and take more time for relief of pain. Reiner V et al(2001)⁽¹⁸⁾ showed very fast absorption and onset with peak plasma concentration after 13.65 min. and the quick absorption rate was attributed to the special combination of the salt of diclofenac with dynamic buffering agent, namely bicarbonate.

The rate of absorption with the sachets proved to be very fast, reaching peak values at 10 min in seven subjects and at 15 min in the remaining subjects: mean time was 13.68

min, with concentrations at 5 min being 38% of Cmax.⁽¹⁹⁾

The technology combines the active drug with dispersing agents so that the active drug is rapidly distributed in the gastric juice to maximize absorption and further reduce the time to maximum drug concentration. The technology was based on the theory that rapid and consistent absorption would tend to accelerate pain relief.⁽²⁵⁾

CONCLUSIONS

The major advantage of diclofenac potassium is peak effect that achieved rapidly with minimal variability between patients, potentially speeding the time to patient pain relief. Voltfast sachet provided a very rapid onset of analgesic activity. The rapid absorption of NSAID may positively affect the time of onset of inflammatory pain compared with the commercially available NSAID.

Many institutions have created restrictive formularies to reduce health care cost, however, it is important to consider costs in the context of treatment goals, including costs beyond the acquisition of a specific agent and incremental value. Rapid pain relief is not just an issue for quality of life, but patient in pain may be more likely to seek other health services.

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