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RESEARCH ARTICLE

ADVERSE EFFECTS OF DICLOFENAC SODIUM ON KIDNEYS IN ADULT VOLUNTEERS

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Abstract

The use of diclofenac sodium is a major concern in terms of renal function, patients were not given attention despite the clinical importance. This study aims to evaluate the prescribed doses (50mg/day) of diclofenac sodium by doctors for patients in the orthopedic unit.

This study was conducted on 36 volunteers, male and female, who were randomly selected from the orthopedic out-patient department and were divided into two groups (two treatments). The first group (18 volunteers) received diclofenac sodium 50 mg and the second group did not receive any medicine (control). The age of volunteers in this study ranged between 20 years to 59 years, both male and female, from September 2020 to September 2021.

The main indicators to detect toxic effects of diclofenac sodium on kidney function were urea, uric acid, and creatinine. The urea level in this study was 27mg/dL in the first group and 25mg/dL in the control. Uric acid was 4.12mg/dL in the first treatment and 4.04mg/dL in control and Creatinine level was 0.55mg/dL and control treatment was 0.48mg/dL .All these values collected from the study are within the normal range and cause no pathological or renal disorder.

Keywords: Diclofenac sodium, Toxicity, Renal function, Yemen.

Introduction:

Non-steroidal anti-inflammatory drugs (NSAIDs) are medicines that are widely used to relieve pain, reduce inflammation and maintain normal temperature [1]. They are often used to relieve symptoms of headache, sprains and strains, cold and flu, arthritis and other courses of long term pain [2]. Although NSAIDs are commonly used, they are not suitable for everyone and may lead to dangerous side effects. [3] The real concept is that diclofenac sodium may lead to renal problems if the person takes over dose; [4] it may lead to hypertensive, peptic ulcer and vomiting blood .If the drug is administrated in normal dose(100-150 mg)/day) there is no any toxicity [5]. Currently, diclofenac sodium is considered one of the oftenly used non-steroidal anti-inflammatory drugs. (NSAIDs). [6].

The Kidney is the largest organ for the adverse effects of Diclofenac sodium [7]. Dicl0fenac sodium (DS) its action inhibits cyclooxygenase enzyme so affecting prostaglandin synthesis. This compound participates in different physiological process of the kidney as glomerular filtration, tubular transfer and rennin release. [8].This study was directed to evaluate the toxic effect of diclofenac sodium on kidney function.

Methods:

This study was conducted during September 2020 to September 2021, the study was carried out on thirty six volunteers male and female patients were randmally selected, from orthopedic out-patient department and divided into two groups (two treatment). The first treatment received diclfenac sodium 50 mg for 30 days and the second treatment did not received any medicine (control). The age of volunteers in this study ranged between 20 years to 59 years, male and female patients, each treatment contained 18 volunteers. Volunteers selected for this study were free of any renal, hepatic, heart, hypertension and any gastrointestinal diseases or even obesity or taking NSAIDs.

Ethical consideration:

Ethical approved is obtained from the research ethics committee of the Faculty of Medicine and Health Sciences, University of Aden, Yemen.

Before initiating the study, any data are obtained from patients in both experimental and control were informed about the aim of the study.

The data collection and research procedures in this study are not likely to cause any physical or emotional harm on the population under study.

Parameters to be measured for diclfenac sodium effect:

RENAL FUNCTION TEST:

Urea	20-40 mg/dL
Uric acid	2.2-7 mg/dL
Creatinine	0.4-1.8 mg/Ll

Results:

Assessment of diclofenac sodium, which was introduced to 18 male and female volunteers, with age ranging between 20 years to 59years and were free from any previous diseases such as hypertension, diabetes and renal diseases. This study was divided into two groups,

1. Control group volunteers not received diclofenac sodium.
2. First group volunteers received diclofenac sodium(50mg) for 30 days.

Main indicators to diagnose the toxic effect of diclofenac sodium were, Urea, Uric acid and Creatinine for renal function test. The urea level in the serum is a main criteria to diagnose any kidney impairment due to rise in Urea level. The normal value of the urea in the serum is usually20-40mg/dL). The results in this study showed low level of the urea (27mg/dL)in the treatment group and (25mg/dL)in the control. No significant differences were detected at (P≤0.05) level between the two treatments. Therefore, the urea level was within the normal range.

Table (1): Statistical analysis of the urea level in the serum of volunteers of the study groups in comparison with the level in the sera of the control group

UREA							
Group	No.	Mean	±SD	±SE	T-value	P-value	Significance
Control	18	25	4.81	2.15			
Treatment	18	27	4.12	1.55	0.464	0.652	

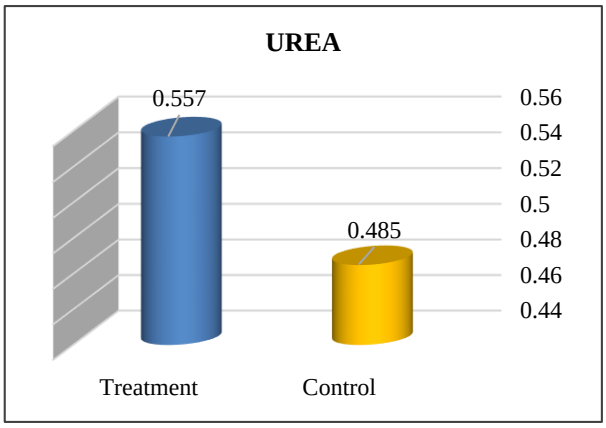

Fig. (1): The urea in the study groups compared to the control group.

Uric acid is another major component considered to determine the kidney function and /or any toxical effects of drugs used by patients. Normal value of Uric acid reported previously in this study range between 2.2-7 mg/dL. In this study, volunteers used diclofenac sodium showed a higher increase in uric acid, but still within the normal range and statistically, there was no significant differences (P≤0.05) in uric acid level between the treatment and control.

Table (2): Statistical analysis of the uric acid level in the serum of volunteers of the study groups in comparison with the level in the sera of the control group

URIC ACID							
Group	No.	Mean	±SD	±SE	T-value	P-value	Significance
Control	18	4.04	0.433	0.193			
Treatment	18	4.12	0.531	0.531	0.306	0.766	

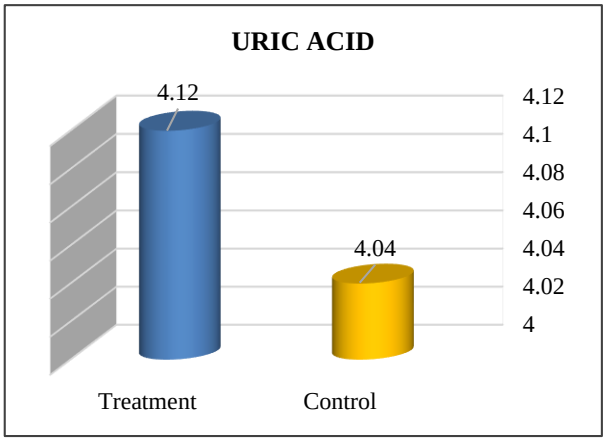

Fig. (2): The uric acid in the study groups compared to the control group.

Creatinine is another important key factor to diagnose kidney function, and nepherological disorder in case of high level of creatinine in serum.

Normal value of creatinine range between 0.4-1.8 mg/dL. In this study ,volunteers took diclofenac sodium for 30 days .The creatinine level was 0.557mg/dL and control treatment was 0.485mg/dL.These value are within the

range of normal value(0.4-1.4mg/dL).Therefore the drug used in this study does not cause any kidney harm.

Table (3): Statistical analysis of the creatinine level in the serum of volunteers of the study groups in comparison with the level in the sera of the control group

CREATININE							
Group	No.	Mean	±SD	±SE	T-value	P-value	Significance
Control	18	0.485	0.241	0.091			
Treatment	18	0.557	0.222	0.084	-1.413	0.188	

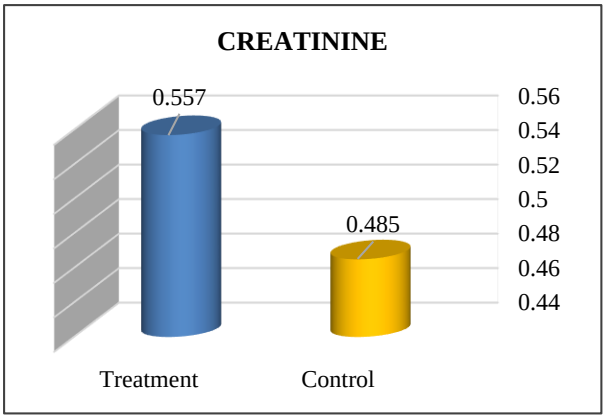

Fig. (3): The creatinine in the study groups compared to the control group

Discussion:

Non-steroidal anti-inflammatory drugs alter renal functions through their effects on renal prostaglandins leading to reversible renal ischemia [9]. Although NSAIDs are related to hypertension, salt and water retention, oedema and hyperkalemia are highly in frequent but they remain a concern in patients who are at risk and can develop acute renal failure as reported by [2].This supported our findings, since all patients in this study were healthy and have not developed any renal problem.

NSAIDs deteriorate kidney function to some extent [10]. Finding of this study commensurate that there were not any abnormality range in patients who took the drugs, most tests were with in normal range. Diclofenac sodium usually inhibits cyclo-oxygenase enzyme and so affects prostaglandins synthesis .This compound participates in different physiological processes of the kidney as glomerular filtration, tubular transport and rennin release [8]. Our results is in consistent because the dose is as recommended under normal range [11] ,Creainine and urea level are used as markers of kidney function due to chemical stresses ,but the test for creatinine is more sensitive than urea [12, 13].

Therefore, the results obtained herein revealed that diclofenac sodium administration of 50 mg/day for one month had no significant alteration in renal function determinants, urea and creatinine. The use of diclofenac sodium with in prescribed dose by doctors is safe and may not cause any nepherological disorders.

Conclusion:

Application of overdose of Diclofenac Sodium may lead to serious impairment of kidneys function and this study show that 50 mg/day of diclofenac sodium in normal dose or below normal (dose-dependent) there is no dangerous adverse or side effects on kidney.

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مقالة بحثية

التأثيرات الضارة للديكلوفيناك صوديوم على الكلى في المتطوعين البالغين

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المُلخّص

هدفت هذه الدراسة تحديد سموم وثاتيرات مادة الديكوفيناك صوديوم (فولتارين)على وظائف الكلى حسب الجرعات المعتمدة من شركات الأدوية.

أجريت هذه الدراسة على عينه قوامها 36 متطوع بالغ ذكور وإناث اختيرت عشوائيا من العيادات الخارجية للعظام لمستشفى الجمهورية وبابل والنقيب حيث كانوا لايعانون من أي إمراض مزمنة ,حيث قسموا إلى مجموعتين ألمجموعه الأولى 18 متطوع وقد اخذوا جميعهم 50 ملغ من ديكلوفيناك الصوديوم لمدة 30 يوم والمجموعة الضابطة لم تأخذ الديكلوفيناك صوديوم فقط اخذوا نيوربيون فيتامين حيث كانت أعمارهم تتراوح مابين 20-59 سنه وكانت الفترة التي أجريت فيها الدراسة مابين سبتمبر 2020-سبتمبر 2021 ميلادية وتم تحليل النتائج باستخدام البرنامج الإحصائي.(SPSS 22)

حيث كانت أهم المؤشرات ألمختبريه لتقيم ثاثيرات السمية للديكلوفيناك صوديوم على وظائف الكلى هي اليوريا واليوريك أسيد والكريتينين. فقد أظهرت معدل اليوريا للمجموعة الأولى 27 ملغ وللمجموعة الضابطة 25 ملغ واليوريك أسيد 4.12 ملغ للمجموعة الأولى و 4.48 للمجموعة الضابطة والكريتينين 0.55 ملغ للمجموعة الأولى 0.48 ملغ للمجموعة الضابطة أي في المستوى الطبيعي. لم تحدث أي تأثير على وظائف الكلى ولم تظهر أي مضاعفات أو اختلالات كلوية.

إن استخدام مادة الديكلوفيناك صوديوم حسب وصفة الأطباء وحسب الجرعات المقررة من شركات الأدوية المعترف بها لم تسبب أي مضاعفات في وظائف الكلى.

الكلمات المفتاحية: دكلوفيناك الصوديوم، السمية الكلوية، ظائف الكلى، اليمن.

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